



EQA/PT SCHEMES FOR MOLECULAR INFECTIOUS DISEASE TESTING

2025 CATALOGUE

Version number CAT2025/01

EQA FOR MOLECULAR INFECTIOUS DISEASE TESTING

QCMD (Quality Control for Molecular Diagnostics) is an independent External Quality Assessment (EQA) / Proficiency Testing (PT) provider specialising in molecular testing of a wide range of infectious diseases.

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AN INTRODUCTION TO THE QCMD EQA SCHEMES

The aim of QCMD's External Quality Assessment (EQA) schemes is to help monitor and improve laboratory quality by assessing a laboratory's use of molecular testing for infectious diseases. The EQA schemes are both educational and regulatory in application and support continuous quality improvement, as well as assist laboratory accreditation / certification to ISO15189 or equivalent.

Who can participate?

The EQA schemes are provided global either directly from QCMD or through one of many QCMD approved QA collaborators and distributors. To register or find out more go to www.QCMD.org

The EQA scheme format

All individual QCMD EQA schemes have their own design specifications which are agreed by the QCMD scientific experts / advisors for each scheme. The distribution frequencies (number of challenges per year) within an EQA scheme often vary in different countries due to regional regulatory requirements. As a result, QCMD offers a range of options from a single challenge per year to a 4 challenge EQA format per year depending on the EQA scheme.

Participants can select which EQA format is best for their laboratory and regulatory requirements. This is a new paragraph from the line above. Can you add a space between as per below.

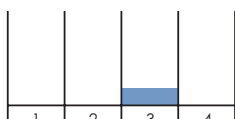
For more details on the format of each of the EQA schemes see the individual EQA specifications within the catalogue or visit the QCMD website.

For example, the HIVRNA, HBV, and HCV BBV viral load EQA schemes are provided with the option of either 1, 2 or 4 challenges per year.

1 CHALLENGE

Catalogue No.
QAV994108_1

Panel Members:
8 per Challenge



2 CHALLENGES

Catalogue No.
QAV994108_2

Panel Members:
4 per Challenge



4 CHALLENGES

Catalogue No.
QAV994108_4

Panel Members:
4 per Challenge



Distribution and Testing Period(s)

An Introduction to the QCMD EQA Schemes

EQA Distribution schedule

The EQA schemes are distributed at set dates throughout the year. An outline of the distribution schedule is provided in appendix I and further details regarding the annual distribution schedule are provided on registration through the QCMD website (www.qcmd.org). On receipt of the EQA panel the laboratory has a defined period of time to test the panel and return their results to QCMD through the secure web-based portal. An outline of the testing periods is also provided within appendix I.

QCMD EQA Reports & feedback

After close of the EQA results return phase, Laboratories receive an individual report for the EQA challenge / scheme they have participated in. This provides an overview of their performance in relation to their method / technology type peer group and where appropriate the overall consensus from all participants within the EQA scheme.

On completion of the EQA scheme, a supplementary report may be provided (depending on the EQA scheme).

The supplementary report includes any relevant additional information regarding the recent EQA scheme, and where appropriate any Scientific Expert commentary / feedback on the overall EQA scheme results. Where required, National EQA providers or country specific EQA groups are also provided with an additional country specific EQA report.

Further information

For further details register on line and visit your profile area, download the QCMD participant manual at www.QCMD.org

BENEFITS



EXTENSIVE PROGRAMME OFFERING

Boasting the largest selection of molecular EQA programmes for infectious disease testing, you are sure to find what you're looking for.



FREQUENCY

Choose between one, two and four challenges* per year to suit your laboratory requirements. Reports are available within 2 weeks of the submission deadline (up to 4 weeks for the drug resistance / sequence based schemes), ensuring any corrective actions can be taken quickly.



HIGH QUALITY MATERIAL

The availability of whole pathogen samples in clinically relevant matrices mimics the performance of patient samples and ensures samples can be used to effectively monitor the performance of the entire testing process.



INTERNATIONAL ACCREDITATION

Where appropriate the EQA schemes are accredited to ISO 17043 highlighting the superior quality and organisation of the QCMD scheme.



ONLINE EQA MANAGEMENT SYSTEM

IT EQA Management System (ITEMS) provides an online tool to easily manage all EQA activities from scheme registration to submission of results and provision of EQA reports.



HIGH LEVEL OF PARTICIPATION

With over 15,000 participant registrations in more than 120 countries, peer groups are maximised, increasing statistical validity.



COMPREHENSIVE REPORTS

Individual reports are provided with each EQA challenge. In line with the requirements of ISO 17043, they provide the laboratories with their results and performance assessment in relation to their EQA assessment group (peer review group).

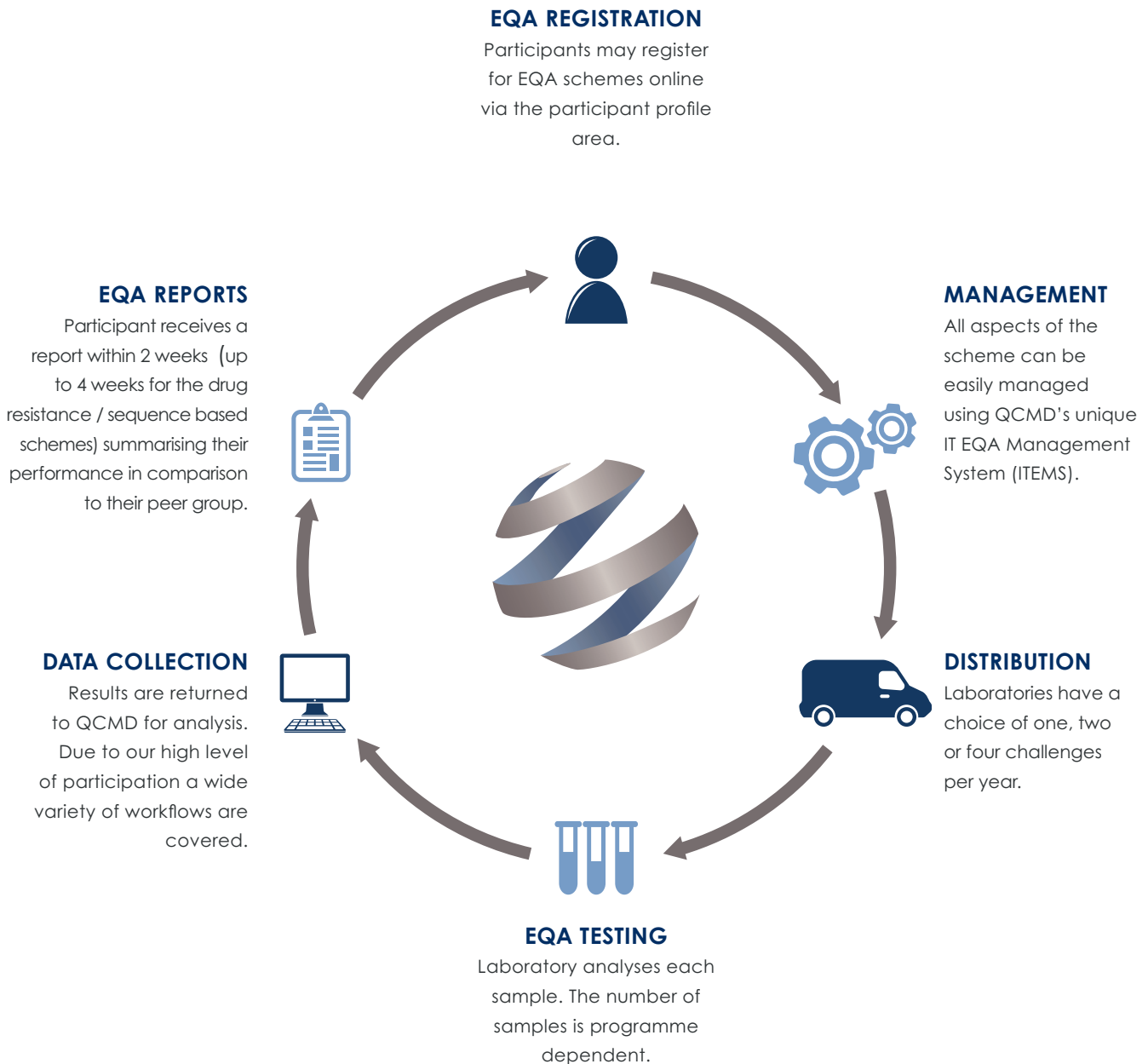
Supplementary reports which include scientific expert commentary may be provided at the end of the EQA cycle if appropriate.

*programme dependent

HOW IT WORKS

The QCMD catalogue is extensive with more than 100 EQA/PT schemes and pilot studies covering over 300 target organisms.

The following diagram provides an overview of the schemes operation.



EQA GROUPS

BLOODBORNE VIRUS

The Bloodborne Virus (BBV) group of QCMD External Quality Assessment (EQA) schemes consists of pathogens that are detected from the blood. This includes human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) B19 virus (B19) and more recently hepatitis A virus (HAV), hepatitis E virus (HEV) and hepatitis D virus (HDV).

To compliment the detection and viral load determination schemes above a range of genotyping and drug resistance BBV EQA schemes are available.

For the drug resistance BBV EQA schemes different current resistance markers are included and emphasis is placed on the determination and interpretation of these resistance markers.

| | Page Number | | Page Number |
|-----------------------|-------------|-----------------------------------|-------------|
| B19 virus | 15 | Hepatitis C virus | 25 |
| BBV Dried Blood Spots | 65 | Hepatitis D virus | 26 |
| HBV Drug Resistance | 21 | Hepatitis E virus | 26 |
| HBV Genotyping | 22 | HIV-1 (DNA) | 28 |
| HCV Drug Resistance | 23 | HIV-1 (RNA) | 28 |
| HCV Genotyping | 24 | HIV-1 Drug Resistance | 29 |
| Hepatitis A virus | 24 | HIV-1 Drug Resistance (Integrase) | 29 |
| Hepatitis B virus | 25 | HIV-2 | 30 |

CENTRAL NERVOUS SYSTEM

Infections of the Central Nervous System (CNS) can occur indirectly via the blood following damage to the blood brain barrier or directly through intraneuronal routes. Encephalitis and meningitis are important CNS infections which can have viral, bacterial or parasitic origins.

Viral encephalitis can occur as a result of acute infection or as the consequence of latent infection. Common viral causes include herpes simplex virus (HSV), specific enteroviruses (EV), JC and BK virus, as well as Varicella-Zoster virus (VZV). Bacterial infections within the CNS such as meningitis can be a result of direct infection of the brain or may be due to underlying diseases which can lead to secondary CNS infection. Parasites such as *Toxoplasma gondii* can also cause CNS infections particularly in immunocompromised individuals.

In recent years significant advances have been made in understanding CNS pathogenesis with the development of molecular technologies for the diagnosis and monitoring of disease, the introduction of effective treatment therapies and, in some cases, the development of vaccines (e.g. Japanese encephalitis & rabies). The range of QCMD EQA schemes within this area focus on pathogens known to play a significant clinical role in CNS infection. The general aim of this group of EQA schemes is to assess the laboratories' ability in the detection and determination of the selected pathogen. Where appropriate pathogen load estimation is also evaluated.

| | Page Number | | Page Number |
|---|-------------|--------------------------------------|-------------|
| Arthropod-borne viruses | 56 | Herpes simplex virus 1 & 2 | 27 |
| BK virus | 16 | Herpes simplex virus Drug Resistance | 27 |
| Borrelia burgdorferi spp. (Lyme Disease) | 43 | JC virus | 35 |
| Central nervous system CNS I (Viral Meningitis and Encephalitis) | 57 | Measles / Mumps | 35 |
| Central nervous system CNS II (Non-Viral Meningitis and Encephalitis) | 57 | Parechovirus | 37 |
| Chikungunya virus | 16 | <i>Toxoplasma gondii</i> | 55 |
| Dengue virus | 19 | Varicella-Zoster virus | 40 |
| Enterovirus | 19 | West Nile virus | 40 |
| Enterovirus typing | 20 | Zika virus | 41 |

CONGENITAL INFECTIONS

The term congenital infection is used to describe those infections transmitted from mother to child either during pregnancy (Transplacental infection) or immediately after childbirth. They can be caused by viruses, bacteria and on occasion parasites. The ability of a particular pathogen to cross the placenta and infect the foetus /embryo is dependent on many factors including the mother's immune status. Primary infections during pregnancy can result in spontaneous abortion or major developmental disorders if undetected and left untreated.

In recent years the diagnosis of congenital infections has been significantly improved by the ability to obtain clinical samples such as blood through chorionic villus sampling. In addition, the application of molecular technologies has helped significantly in the diagnosis, monitoring, and treatment rationale. CMV Dried Blood Spots is one of the EQAs provided in this disease group.

| | Page Number | | Page Number |
|-----------------------------------|-------------|---------------------------|-------------|
| Chagas | 66 | <i>Toxoplasma gondii</i> | 55 |
| Cytomegalovirus Dried Blood Spots | 18 | Cytomegalovirus Non-Blood | 67 |

DRUG RESISTANCE

The ability of microorganisms to adapt and develop resistance to antimicrobials is natural and an evolutionary trait they have been employing for thousands of years. Hence there are many examples of drug resistant strains in viral, bacterial and parasitic diseases. However, it is well recognised that the over prescription of antimicrobials within clinical practice and their overuse in domestic products has helped to accelerate drug resistance and led to the emergence of multidrug resistance.

QCMD has established a range of Drug Resistance EQA schemes covering a variety of pathogen types. The primary aims of these schemes are to assess the laboratory in their ability to detect and determine the presence of drug resistance at the molecular level. In addition, some of the schemes also cover drug resistance interpretation.

| | Page Number | | Page Number |
|--|-------------|--|-------------|
| CMV Drug Resistance | 17 | HIV-1 Drug Resistance | 29 |
| Extended Spectrum β -lactamase and Carbapenemase | 46 | HIV-1 Drug Resistance (Integrase) | 29 |
| HBV Drug Resistance | 21 | Methicillin Resistant <i>Staphylococcus aureus</i> | 49 |
| HCV Drug Resistance | 23 | <i>Mycobacterium tuberculosis</i> Drug Resistance | 50 |
| Herpes simplex virus Drug Resistance | 27 | Vancomycin Resistant Enterococci | 52 |

EXOTIC/EMERGING DISEASES

A complex relationship exists between pathogen genetics, host and the environment. As a result, predicting the future emergence of exotic diseases is difficult. However, globalisation coupled with rapid increases in human populations over the last 50 years has played an important role. Local environmental changes such as deforestation due to urbanisation bring humans into closer contact with potential new pathogen vectors. These factors disturb the subtle balance between pathogen, host and the environment and create the opportunity for the emergence of new disease pathogens or the re-emergence of existing pathogens. These diseases can be caused by newly identified pathogens, pathogen strains such as SARS or the mutation of existing strains such as Influenza virus. In addition, the spread of known pathogens (e.g. West Nile virus & dengue virus) into new geographical areas leading to new potential endemics account for a large number of exotic / emerging diseases. The EQAs within this group focus on those emerging diseases that are frequently being identified within progressive geographic regions.

| | Page Number | | Page Number |
|-------------------------|-------------|--------------------|-------------|
| Arthropod-borne viruses | 56 | MERS coronavirus | 36 |
| Babesia | 64 | Poxviruses | 72 |
| Chagas | 66 | Respiratory I Plus | 59 |
| Chikungunya virus | 16 | SARS-CoV-2 | 39 |
| Dengue virus | 19 | West Nile virus | 40 |
| Francisella tularensis | 68 | Yellow fever virus | 41 |
| Malaria | 71 | Zika Virus | 41 |

GASTROINTESTINAL DISEASES

Gastroenteritis can be caused by a wide variety of bacteria, viruses and parasites. It is often associated with severe inflammation of the gastrointestinal tract involving both the stomach and small intestine. This results in acute diarrhoea and vomiting.

Diagnosis is primarily based on clinical symptoms but laboratory diagnosis on the etiological cause is often needed in order to support patient care. In recent years molecular diagnostic techniques such as real-time PCR have also been introduced for the laboratory diagnosis of gastroenteritis, including the ability to simultaneously screen for a wide range of enteric pathogens using multiplex assays. As a result, molecular diagnostic techniques are increasingly being used in the routine laboratory setting for detection, determination and surveillance of a wide range of enteric pathogens.

The general aim of this group of EQA schemes is to allow laboratories to assess their ability in the use of molecular diagnostic tests for a range of viral, bacterial and parasitic enteric pathogens.

| | Page Number | | Page Number |
|--------------------------------|-------------|---------------------------|-------------|
| Adenovirus | 15 | Helicobacter pylori | 47 |
| Bacterial Gastroenteritis | 56 | Norovirus | 36 |
| Clostridium difficile | 45 | Parasitic Gastroenteritis | 58 |
| Diarrheagenic Escherichia coli | 46 | Viral Gastroenteritis | 63 |

IMMUNOCOMPROMISED ASSOCIATED DISEASES

The treatment and management of patients with compromised immune systems has seen important developments in recent years with, for example, the introduction of novel multi-drug treatment regimes. As a result, the healthcare and management of immunocompromised patients has greatly improved. However, pathogen infection or viral reactivation remain significant contributors to morbidity and mortality in these patients.

A number of opportunistic parasitic, fungal and viral pathogens are of concern in the management of immunocompromised patients due to both acute infection and reactivation of latent virus in the immunocompromised host.

Advances in molecular diagnostics have allowed accurate pathogen assessment and quantitative monitoring, particularly of viral activity over time, which allows early and accurate pre-emptive intervention and management of antiviral drug therapy.

The range of QCMD EQA schemes within this area focus on pathogens known to play a significant clinical role in the management of immunocompromised patients. The general aim of this group of EQA schemes is to assess the ability of laboratories in the detection of the selected pathogen and where appropriate quantitative estimation is also evaluated.

| | Page Number | | Page Number |
|-----------------------------|-------------|---|-------------|
| <i>Aspergillus spp.</i> | 53 | Epstein-Barr virus | 20 |
| Babesia | 64 | Epstein-Barr virus Whole Blood | 21 |
| BK virus | 16 | Human cytomegalovirus | 30 |
| <i>Candida auris</i> | 65 | Human herpes virus 6 | 31 |
| <i>Candida spp.</i> | 53 | JC virus | 35 |
| Chagas | 66 | <i>Pneumocystis jirovecii</i> pneumonia (PCP) | 54 |
| CMV Drug Resistance | 17 | Torque teno virus | 39 |
| CMV Non-Blood | 67 | <i>Toxoplasma gondii</i> | 55 |
| Cytomegalovirus Whole Blood | 18 | Transplantation (viral) | 62 |

MULTIPLE PATHOGEN/SYNDROMIC

Multiplex based molecular diagnostic tests offer the ability for the detection of a wide range of pathogens within a single diagnostic test.

Syndromic approaches to test respiratory, gastroenteritis and meningitis infections allows clinicians to identify the cause of infection from a wide range of pathogens often in a near patient, point of impact setting where rapid diagnosis aids faster clinical decision making and patient treatment. These technologies are generally used as a screening approach where identification of pathogens allow improved patient management at initial point of contact.

QCMD have introduced multi-pathogen/syndromic schemes to address this growing need in the clinical setting. A range of schemes cover respiratory infections, transplant associated infections, central nervous system infections, sexually transmitted infections and gastroenteritis infections caused by a range of aetiologies.

| | Page Number | | Page Number |
|---|-------------|------------------------------------|-------------|
| Arthropod-borne viruses | 56 | Respiratory I plus | 59 |
| Bacterial Gastroenteritis | 56 | Respiratory II | 60 |
| Central Nervous System I (Viral Meningitis and Encephalitis) | 57 | Respiratory III | 60 |
| Central Nervous System II (Non-Viral Meningitis and Encephalitis) | 57 | Sepsis | 61 |
| <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i> | 44 | Sexually Transmitted Infections I | 61 |
| MALDI-TOF | 58 | Sexually Transmitted Infections II | 62 |
| Parasitic Gastroenteritis | 58 | Transplantation (viral) | 62 |
| Respiratory I | 59 | Viral Gastroenteritis | 63 |

RESPIRATORY DISEASES

Respiratory tract infections (RTIs) are common conditions, experienced by most adults and children each year. They can affect both the upper and lower respiratory tract and range from the common cold to viral and bacterial pneumonia. For the young, the elderly and the immune compromised, RTIs can be a significant health threat if not managed effectively.

RTIs can be caused by a large number of bacterial, viral and fungal pathogens which have nearly indistinguishable physiological symptoms. This can increase the chances of undiagnosed or misdiagnosed infections leading to patients either not receiving critical medications, or receiving unnecessary antibiotics. The advance of molecular diagnostic techniques has improved our ability to rapidly determine the causative agents of RTIs and has the potential to improve patient management, control of nosocomial transmission and promote targeted therapy.

The Respiratory EQA schemes cover 17 of the major viral, bacterial and fungal causes of RTIs, focusing on the pathogen load and allowing assessment of the laboratories ability to accurately identify the species of interest at clinically relevant levels.

| | Page Number | | Page Number |
|---------------------------------|-------------|--|-------------|
| Adenovirus | 15 | <i>Mycobacterium tuberculosis</i> | 49 |
| Atypical mycobacterium | 42 | <i>Mycobacterium tuberculosis</i> Drug Resistance | 50 |
| <i>Bordetella pertussis</i> | 43 | <i>Mycoplasma pneumoniae</i> | 51 |
| <i>Chlamydia psittaci</i> | 44 | Parainfluenza virus | 37 |
| <i>Chlamydophila pneumoniae</i> | 45 | <i>Pneumocystis jirovecii</i> pneumonia (PCP) | 54 |
| Coronavirus | 17 | Respiratory I | 59 |
| Group A Streptococcus | 69 | Respiratory I plus | 59 |
| Human metapneumovirus | 31 | Respiratory II | 60 |
| Influenza A & B virus | 34 | Respiratory III | 60 |
| Influenza Typing | 34 | Respiratory syncytial virus | 38 |
| <i>Legionella spp.</i> | 48 | Rhinovirus | 38 |
| Measles / Mumps | 35 | SARS-CoV-2 | 39 |
| MERS coronavirus | 36 | | |

SEXUALLY TRANSMITTED INFECTIONS

Sexually transmitted infections (STIs) remain a major public health concern throughout the world with some infections reaching epidemic proportions in sexually active groups. As a result, a number of WHO and UN global strategies have been initiated in an attempt to control the spread of STIs.

STIs are the main preventable cause of infertility, particularly in women. However, some STIs remain asymptomatic before leading to serious reproductive complications and congenital infections, therefore appropriate diagnosis and treatment is essential.

Molecular diagnostic assays allow the accurate assessment of STIs in patients that present with similar symptoms or asymptomatic persons from at risk groups allowing early and accurate intervention and treatment.

The range of QCMD EQA schemes within this area focus on pathogens known to be the most common cause of STIs. The general aim of this group of EQA schemes is to assess the ability of laboratories in the detection of the selected pathogen.

| | Page Number | | Page Number |
|---|-------------|------------------------------------|-------------|
| <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> | 44 | <i>Mycoplasma Genitalium</i> | 61 |
| Herpes simplex virus 1 & 2 | 27 | Sexually Transmitted Infections I | 61 |
| Herpes simplex virus Drug Resistance | 27 | Sexually Transmitted Infections II | 62 |
| Human Papillomavirus (PreservCyt) | 32 | Syphilis | 51 |
| Human Papillomavirus (SurePath) | 33 | <i>Trichomonas vaginalis</i> | 55 |

TRANSPLANT ASSOCIATED DISEASES

Advances in transplant medicine, including the development of immunosuppressive agents, has greatly improved the prospects of transplant recipients. However, pathogen infection and in particular viral reactivation remain significant contributors to transplant patient morbidity and mortality.

A number of viruses are of particular concern, these include: human herpes virus 6 (HHV6), human cytomegalovirus (CMV) and Epstein-Barr virus (EBV) along with human adenovirus (ADV), JC virus (JCV) and BK virus (BKV). Other opportunistic infections such as the parasite *Toxoplasma gondii* are also relevant. Advances in molecular diagnostics have allowed accurate pathogen assessment prior to transplant and accurate quantitative monitoring, particularly of viral activity over time, after the transplant has been performed. This in turn allows early and accurate pre-emptive intervention and antiviral drug therapy.

The range of QCMD EQA schemes within this area focus on those pathogens known to play a significant clinical role in transplant medicine. The general aim of this group of EQA schemes is to assess the ability of laboratories in the detection of the selected pathogen and where appropriate quantitative estimation is also evaluated.

| | Page Number | | Page Number |
|--------------------------------|-------------|--------------------------|-------------|
| Adenovirus | 15 | Human cytomegalovirus | 30 |
| BK virus | 16 | Human herpes virus 6 | 31 |
| CMV Drug Resistance | 17 | JC virus | 35 |
| Cytomegalovirus Non-Blood | 67 | Torque teno virus | 39 |
| Cytomegalovirus Whole Blood | 18 | <i>Toxoplasma gondii</i> | 55 |
| Epstein-Barr virus | 20 | Transplantation (viral) | 62 |
| Epstein-Barr virus Whole Blood | 21 | | |

EQA GROUPS

TYPING

Advances in the treatment and management of patient infection have seen important developments in recent years. In particular the introduction of novel antiviral drug therapies has improved the medium and long-term prospects of infected patients. However, the development of drug resistant pathogens is an increasing complication and remains a significant factor in the treatment of these patient groups.

The use of genotyping and sequencing technologies has allowed accurate pathogen assessment and monitoring of patient samples over time. This allows early and accurate determination of pathogen status. Which in turn allows pre-emptive intervention and management of antiviral drug therapy.

The range of QCMD EQA schemes within this area focus on pathogens known to play a significant clinical role in the management of infection. The general aim of this group of EQA schemes is to assess the ability of laboratories in the genetic determination of the selected pathogen and where appropriate the specific mutation points within the target gene.

| | Page Number | | Page Number |
|-----------------------------|-------------|---|-------------|
| Bacterial 16S Ribosomal RNA | 42 | Herpes simplex virus Drug Resistance | 27 |
| CMV Drug Resistance | 17 | HIV-1 Drug Resistance | 29 |
| Enterovirus Typing | 20 | HIV-1 Drug Resistance (Integrase) | 29 |
| HBV Drug Resistance | 21 | Influenza Typing | 34 |
| HBV Genotyping | 22 | MALDI-TOF | 58 |
| HCV Drug Resistance | 23 | Methicillin Resistant <i>Staphylococcus aureus</i> Typing (epidemiology and outbreak studies) | 48 |
| HCV Genotyping | 24 | | |

OTHER

QCMD are continuously expanding our range of EQA schemes, some of which are outside the defined EQA groups listed above

| | Page Number | | Page Number |
|-----------------------|-------------|------------------------|-------------|
| Dermatophytosis | 54 | Joint Infection | 70 |
| Group B Streptococcus | 47 | Viral Metagenomics NGS | 72 |

VIRAL EQA

ADENOVIRUS

ADVDNA25 - QAV054133

To assess the proficiency of laboratories in the detection and quantitation of adenovirus.

To assess the proficiency of laboratories in the detection of different adenovirus serotypes including currently circulating serotypes of interest.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV054133_1 | QAV054133_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium and/or Plasma | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Condition | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

B19 VIRUS

B19DNA25 - QAV034116

To assess the proficiency of laboratories in detection and quantitation of B19 virus.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV034116_1 | QAV034116_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 8 | 4 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Clinical material | |
| Matrix Panel Format | Plasma | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.2 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

BK VIRUS

BKDNA25 - QAV144166

To assess the proficiency of laboratories molecular assays in detecting various types and concentrations of BK virus (BKV). To assess the proficiency of laboratories in the reliable quantitation of BKV viral load.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV144166_1 | QAV144166_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium and/or Plasma and/or Urine | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

CHIKUNGUNYA VIRUS

CHIKV25 - QAV154175

To assess the laboratory's ability to detect chikungunya virus using their routine molecular diagnostic platform and procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV154175_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CMV DRUG RESISTANCE

CMVDR25-QAV144169

To assess the laboratories' ability to detect CMV drug resistance mutations in kinase UL97, polymerase UL54 gene and the UL56 that forms part of the terminase, using sequencing techniques.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV144169_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma and/or Physiological Buffer |
| Panel Member Target Range | various mutations - kinase (UL97) and polymerase (UL54) genes |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Sequence Analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Condition | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CORONAVIRUS

CVRNA25 - QAV064137

To assess the proficiency of laboratories in the detection of coronavirus. To assess the proficiency of laboratories in the detection of different coronavirus genotypes.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV064137_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering Clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CYTOMEGALOVIRUS DRIED BLOOD SPOTS

CMVDBS25 - QAV064127

To assess the performance of laboratories in the detection of clinically relevant levels of human cytomegalovirus (CMV) from dried blood spots.

| Feature | Available format(s) |
|-------------------------------|---------------------|
| Catalogue Number | QAV064127_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |

| Specifications | |
|--|--|
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Dried Blood Spots |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 2x50µl |
| Panel Sample Pre-treatment Requirement | DNA extraction from dried blood spot |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CYTOMEGALOVIRUS WHOLE BLOOD

CMVWB25 - QAV124150

To evaluate the ability of laboratories in the detection of CMV from whole blood samples. To assess the precision of molecular assays at clinically relevant viral loads.

| Feature | Available format(s) | |
|-------------------------------|---------------------|-------------|
| Catalogue Number | QAV124150_1 | QAV124150_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |

| Specifications | |
|--|---|
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Qualitative & Quantitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-30°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

DENGUE VIRUS

DENVRNA25 - QAV114148

To assess the proficiency of laboratories in the detection of dengue virus. To assess the proficiency of laboratories in distinguishing dengue virus from other flaviviruses.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV114148_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

ENTEROVIRUS

EVRNA25 - QAV984104

To assess the ability of laboratories molecular assays to detect different types and concentrations of enterovirus (EV). To review the performance of laboratories quantitative EV molecular assays.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV984104_1 | QAV984104_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured virus and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative. Quantitative for information purposes only | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

ENTEROVIRUS TYPING

EVTP25 - QAV164185

To assess laboratories ability to correctly identify specific enterovirus types using their routine molecular method and procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV164185_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering Clinical range |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

EPSTEIN-BARR VIRUS

EBVDNA25 - QAV024121

To assess the proficiency of laboratories in the detection and quantitation of Epstein-Barr virus (EBV).

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV024121_1 | QAV024121_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium and/or Plasma | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

EPSTEIN-BARR VIRUS WHOLE BLOOD

EBVWB25 - QAV134161

To assess the proficiency of laboratories in the detection and quantitation of Epstein-Barr virus (EBV) in whole blood samples.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV134161_1 | QAV134161_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Whole Blood | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-30°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

HBV DRUG RESISTANCE

HBVDR25 - QAV124160

To assess the performance of laboratories in the detection of drug resistance mutations in the hepatitis B virus (HBV) DNA polymerase gene using sequencing techniques and/or LiPA technology.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV124160_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Various mutations – DNA polymerase |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Sequence Analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HBV GENOTYPING

HBVGT25 - QAV064118

To assess the proficiency of laboratories in the correct genotyping of hepatitis B virus (HBV) using molecular methods.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV064118_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Clinical material |
| Genotypic Variant | Various HBV genotypes |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.2 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HCV DRUG RESISTANCE

HCVDR25 - QAV134167

The QCMD HCV Drug Resistance (HCVDR) scheme has to-date been based around resistance to the first-generation Direct Acting Antiviral (DAA) NS3 protease inhibitors, boceprevir and telaprevir, which became widely available circa 2011. However the “previr” family of drugs are only effective against HCV genotype 1 infections limiting the scope of the HCVDR scheme to single genotype, single gene target. First generation DAAs were supplemented in 2014 with the release of the first “buvir” NS5b inhibitors for use against genotype 1 followed by the release of the first NS5a inhibitor “asvir” family of drugs in 2015, which are effective against both genotype 1 and 3 infections.

All three drug families are now in routine use and are included in both the WHO list of essential medicines and the national guidelines of several countries for treatment of HCV. Based on this the HCVDR scheme has been updated to reflect the current clinical environment with regards to drug resistance testing.

The aim of the HCVDR EQA is to assess the performance of laboratories in the detection of drug resistance mutations in the hepatitis C virus (HCV) genotypes 1 and 3 (NS3 and NS5 regions) using sequencing techniques.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV134167_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Various mutations – NS3 and NS5a regions |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Sequence Analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HCV GENOTYPING

HCVGT25 - QAV034117

To assess the proficiency of laboratories in the correct genotyping of hepatitis C virus (HCV) using molecular methods.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV034117_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Clinical material |
| Genotypic Variant | Various HCV genotypes and subtypes |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Covering clinical range |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HEPATITIS A VIRUS

HAVRNA25 - QAV124156

To evaluate the ability of laboratories in the molecular detection of hepatitis A virus (HAV) in terms of sensitivity and specificity.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV124156_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.2 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HEPATITIS B VIRUS

HBVDNA25 - QAV994110

To assess the proficiency of laboratories in the detection and quantitation of hepatitis B virus (HBV). To assess the proficiency of laboratories is the detection and quantitation of different HBV genotypes.

| Feature | Available format(s) | | |
|--|---|-------------|-----------------|
| Catalogue Number | QAV994110_1 | QAV994110_2 | QAV994110_4 |
| Total Number of Challenges | 1 | 2 | 4 |
| Number of Panel Members | 8 | 4 | 4 |
| Distribution / Testing Period | Q3 | Q1 & Q3 | Q1, Q2, Q3 & Q4 |
| Specifications | | | |
| Sample NA Target Source | Cultured virus and/or Clinical material | | |
| Matrix Panel Format | Plasma | | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | | |
| Panel Member Target Range | Covering clinical range | | |
| Panel Member Sample Volume | 1.2 ml | | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU | | |
| Panel Analysis type | Qualitative & Quantitative | | |
| Panel Testing | Evaluated by various molecular methodologies | | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | | |

HEPATITIS C VIRUS

HCVRNA25 - QAV994112

To assess the proficiency of laboratories in the detection and quantitation of hepatitis C virus (HCV) RNA. To assess the proficiency of laboratories in the detection and quantitation of different HCV genotypes.

| Feature | Available format(s) | | |
|--|---|-------------|-----------------|
| Catalogue Number | QAV994112_1 | QAV994112_2 | QAV994112_4 |
| Total Number of Challenges | 1 | 2 | 4 |
| Number of Panel Members | 8 | 4 | 4 |
| Distribution / Testing Period | Q3 | Q1 & Q3 | Q1, Q2, Q3 & Q4 |
| Specifications | | | |
| Sample NA Target Source | Clinical material | | |
| Matrix Panel Format | Plasma | | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | | |
| Panel Member Target Range | Covering clinical range | | |
| Panel Member Sample Volume | 1.2 ml | | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU | | |
| Panel Analysis type | Qualitative & Quantitative | | |
| Panel Testing | Evaluated by various molecular methodologies | | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | | |

HEPATITIS D VIRUS

HDV25 - QAV144170

To evaluate laboratories in the detection of HDV within the routine clinical setting.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV144170_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted |
| Panel Member Target Range | Covering clinical range |
| Panel Analysis type | Qualitative & Quantitative |
| Panel Member Sample Volume | 1.2 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HEPATITIS E VIRUS

HEVRNA25 - QAV124157

To evaluate the ability of laboratories in the detection and quantification of hepatitis E virus (HEV).

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV124157_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Covering Clinical range |
| Panel Member Sample Volume | 0.6 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately, Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Qualitative & Quantitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HERPES SIMPLEX VIRUS 1 & 2

HSVDNA25 - QAV994105

To assess the ability of laboratories molecular assays to detect different types and concentrations of herpes simplex virus (HSV).To review the performance of laboratories quantitative HSV molecular assays.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV994105_1 | QAV994105_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured virus and/or Clinical material | |
| Matrix Panel Format | Transport medium and/or synthetic CSF | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative. Quantitative for information purposes only | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

HERPES SIMPLEX VIRUS DRUG RESISTANCE

HSVDR25 - QAV164184

To assess the performance of laboratories in the detection of drug resistance mutations in the herpes simplex virus thymidine kinase (UL23) and DNA polymerase (UL30) genes using sequencing techniques.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV164184_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Various mutations - Thymidine Kinase (UL23) and DNA polymerase (UL30) |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Sequence Analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HIV-1 (DNA)

HIVDNA25 - QAV034114

To assess the proficiency of laboratories in the detection of human immunodeficiency virus type 1 (HIV-1) pro-viral DNA.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV034114_1 | QAV034114_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 8 | 4 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured proviral cells | |
| Matrix Panel Format | Physiological Buffer | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 0.2 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative. Quantitative for information purposes only | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

HIV-1 (RNA)

HIVRNA25 - QAV994108

To assess the proficiency of laboratories in detection and quantitation of human immunodeficiency virus (HIV) RNA. To assess the proficiency of laboratories in detection and quantitation of different HIV genotypes.

| Feature | Available format(s) | | |
|--|---|-------------|-----------------|
| Catalogue Number | QAV994108_1 | QAV994108_2 | QAV994108_4 |
| Total Number of Challenges | 1 | 2 | 4 |
| Number of Panel Members | 8 | 4 | 4 |
| Distribution / Testing Period | Q3 | Q1 & Q3 | Q1, Q2, Q3 & Q4 |
| Specifications | | | |
| Sample NA Target Source | Cultured virus and/or Clinical material | | |
| Matrix Panel Format | Plasma | | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | | |
| Panel Member Target Range | Covering clinical range | | |
| Panel Member Sample Volume | 1.2 ml | | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU | | |
| Panel Analysis type | Qualitative & Quantitative | | |
| Panel Testing | Evaluated by various molecular methodologies | | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | | |

HIV-1 DRUG RESISTANCE

HIVDR25 - QAV024131

To assess the performance of laboratories in the detection of drug resistance mutations in the HIV-1 protease and reverse transcriptase genes.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV024131_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Various mutations - reverse transcriptase (RT) and protease (PR) genes |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Sequence Analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HIV-1 DRUG RESISTANCE (INTEGRASE)

HIVDRint25 - QAV114146

To assess the performance of laboratories in the detection of drug resistance mutations in the HIV-1 integrase gene using sequencing techniques.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV114146_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma |
| Panel Member Target Range | Various mutations - integrase (INT) gene |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Sequence Analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HIV-2

HIV2_25 - QAV204212

To assess the proficiency of laboratories in the detection and quantitation of human immunodeficiency virus type2 (HIV-2).

| Feature | Available format(s) |
|--|--|
| Catalogue Number | QAV204212_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured material and/or Clinical material |
| Matrix Panel Format | Plasma |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.2ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly. |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HUMAN CYTOMEGALOVIRUS

CMVDNA25 - QAV014120

To assess the proficiency of laboratories in the detection and quantitation of human cytomegalovirus (CMV)

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV014120_1 | QAV014120_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Plasma | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

HUMAN HERPES VIRUS 6

HHV6DNA25 - QAV084119

To assess the proficiency of laboratories' molecular assays in the detection of various types of human herpes virus 6 (HHV6). To assess the proficiency of laboratories in the reliable quantitation of HHV6 viral load.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV084119_1 | QAV084119_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Genotypic Variant | Subtypes A and B | |
| Matrix Panel Format | Transport Medium and/or Plasma | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

HUMAN METAPNEUMOVIRUS

MPV25 - QAV054135

To assess the sensitivity and specificity of laboratories in the detection of human metapneumovirus (MPV). To assess the ability of laboratories in the detection of different human MPV types.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV054135_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HUMAN PAPILLOMAVIRUS (PRESERVCYT)

HPVPRES25 - QAV094130

Human Papillomavirus (HPV) infection has been detected in over 95% of cervical cancers. The second most common cancer detected in females worldwide. The detection of HPV infection is an important part of the triage, with cytomorphological examination in the early detection of cervical cancer in scrapings. For effective triage, quantitative detection and accurate HPV-typing at clinically relevant levels is essential. The introduction of nucleic acid amplification technologies (NAT) and nucleic acid hybridisation assays has led to the development of sensitive, type specific diagnostic tests that can rapidly identify HPV infection. As a result, these tests are now of great practical and clinical relevance. The aim of the EQA is to assess the proficiency of laboratories in the detection of different high risk Human Papillomavirus types within a PreservCyt matrix.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV094130_1 | QAV094130_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 12 | 6 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Clinical material and/or cell lines containing HPV | |
| Matrix Panel Format | Transport Medium (PreservCyt) | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 4.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | 15-30°C / Liquid Ambient | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

HUMAN PAPILLOMAVIRUS (SUREPATH)

HPVSURE25 - QAV184204

Human Papillomavirus (HPV) infection has been detected in over 95% of cervical cancers, the second most common cancer detected in females worldwide. The detection of HPV infections is an important part of the triage with cytomorphological examination in the early detection of cervical cancer in scrapings. For effective triage, quantitative detection and accurate HPV- typing at clinically relevant levels is essential. The introduction of nucleic acid amplification technologies (NAT) and nucleic acid hybridisation assays has led to the development of sensitive, type specific diagnostic tests that can rapidly identify HPV infection. As a result, these tests are now of great practical and clinical relevance.

To assess the proficiency of laboratories in the detection of different high risk Human Papillomavirus types within a SurePath™ matrix.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV184204_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 12 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Clinical material and/or cell lines containing HPV |
| Matrix Panel Format | Transport Medium (SurePath) |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

INFLUENZA A & B VIRUS

INFRNA25 - QAV054134

To assess the proficiency of laboratories in detection of influenza virus RNA.

To assess the proficiency of laboratories in distinguishing influenza virus A and B.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV054134_1 | QAV054134_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

INFLUENZA TYPING

INFTP25 - QAV064138

To assess the proficiency of laboratories in the detection of different influenza virus types, subtypes and lineages To assess the proficiency of laboratories in the typing and subtyping/lineage determination of influenza viruses.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV064138_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

JC VIRUS

JCDNA25 - QAV074106

To assess the proficiency of laboratories molecular assays in detecting various types and concentrations of JC virus (JCV). To assess the proficiency of laboratories in the reliable quantitation of JCV viral load.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV074106_1 | QAV074106_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium and/or Plasma | |
| Units of Measurement | The primary unit is IU/ml however other units will be accepted | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

MEASLES / MUMPS

MM25 - QAV144171

To assess the proficiency of laboratories in the detection of mumps and/or measles using routine molecular methods.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV144171_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

MERS CORONAVIRUS

MERS25 - QAV154181

To assess the proficiency of laboratories molecular technologies for the detection and determination of MERS-CoV from other coronaviruses.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV154181_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering Clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

NOROVIRUS

NVRNA25 - QAV084139

To assess the specificity and sensitivity of laboratories in the detection of norovirus. To assess the ability of the laboratories to detect different norovirus genogroups.

| Feature | Available format(s) | |
|--|--|-------------|
| Catalogue Number | QAV084139_1 | QAV084139_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium and/or Physiological Buffer and/or Synthetic Faecal Matrix | |
| Panel Member Sample Volume | 1.0 ml VTM, 0.1 ml Buffer | |
| Panel Sample Pre-treatment Requirement | NA samples are ready for analysis. Pre-treatment may be needed for SFM. Follow manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

PARAINFLUENZA VIRUS

PINFRNA25 - QAV064136

To assess the proficiency of laboratories in the detection of parainfluenza virus.

To assess the proficiency of laboratories in the detection of different parainfluenza virus types.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV064136_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering Clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

PARECHOVIRUS

PEVRNA25 - QAV114145

To assess the ability of laboratories molecular assays to detect different types and concentrations of parechovirus.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV114145_1 | QAV114145_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured virus and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

RESPIRATORY SYNCYTIAL VIRUS

RSV25 - QAV054142

To assess the specificity and sensitivity of laboratories in the detection of respiratory syncytial virus (RSV) by NAT. To assess the ability of laboratories in the detection of different RSV types by NAT.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV054142_1 | QAV054142_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

RHINOVIRUS

RVRNA25 - QAV064143

To assess the proficiency of laboratories in the detection of rhinovirus.
To assess the proficiency of laboratories in the detection of different rhinovirus genotypes

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV064143_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

SARS-COV-2

SCV2_25 - QAV204215

To assess the proficiency of laboratories in the detection of the new variant SARS-CoV-2 coronavirus including variants of concern (VOC). To assess the proficiency of laboratories in the differentiation of different coronavirus genotypes.

| Feature | Available format(s) | | | |
|--|---|--------------|--------------|--------------|
| Catalogue Number | QAV204215_1A | QAV204215_1B | QAV204215_1C | QAV204215_1D |
| Total Number of Challenges | 1 | 1 | 1 | 1 |
| Number of Panel Members | 5 | 5 | 5 | 5 |
| Distribution / Testing Period | Q1 | Q2 | Q3 | Q4 |
| Specifications | | | | |
| Sample NA Target Source | Cultured and/or Clinical material | | | |
| Matrix Panel Format | Transport Medium | | | |
| Panel Member Target Range | Covering clinical range | | | |
| Panel Member Sample Volume | 1.0 ml | | | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | | | |
| Panel Analysis type | Qualitative | | | |
| Panel Testing | Evaluated by various molecular methodologies | | | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | | | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | | | |

TORQUE TENO VIRUS

TTV25 - QAV184203

The aim of the Torque Teno Virus (TTV) EQA is to assess laboratories ability to detect TTV using routine molecular diagnostic platform and procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV184203_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 6 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required follow test manufacturers IFU |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

VARICELLA-ZOSTER VIRUS

VZVDNA25 - QAV034103

To assess the ability of laboratories molecular assays to detect different concentrations of Varicella-Zoster virus (VZV). To review the performance of laboratories quantitative VZV molecular assays.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV034103_1 | QAV034103_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured virus and/or Clinical material | |
| Matrix Panel Format | Transport medium and/or synthetic CSF | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative. Quantitative for information purposes only | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

WEST NILE VIRUS

WNVRNA25 - QAV104141

To assess the proficiency of laboratories in the detection of West Nile virus.
To determine the proficiency of laboratories in distinguishing West Nile virus from other flaviviruses.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV104141_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

YELLOW FEVER VIRUS

YFV25 - QAV194207

To assess the proficiency of laboratories in the detection of yellow fever virus.

To determine the proficiency of laboratories in distinguishing yellow fever virus from other flaviviruses.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV194207_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

ZIKA VIRUS

ZIKA25 - QAV164186

To assess the proficiency of laboratories in the detection of Zika virus and determine the proficiency of laboratories in distinguishing Zika virus from other flaviviruses.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV164186_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL EQA

ATYPICAL MYCOBACTERIUM

NTM25 - QAB194208

To assess the proficiency of laboratories to detect atypical mycobacterium or non-tuberculous mycobacteria (NTM).

| Feature | Available format(s) |
|--|--|
| Catalogue Number | QAB194208_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium and/or Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Pre-treatment not generally required - follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Liquid Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL 16S RIBOSOMAL RNA

B16SrRNA25 - QAB164183

To assess the proficiency of laboratories to detect, identify and interpret which bacterial species are provided within each panel member using their routine 16S rRNA molecular diagnostic procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB164183_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Physiological Buffer |
| Panel Member Target Range | Covering Clinical range |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BORDETELLA PERTUSSIS

BPDNA25 - QAB094132

To assess the proficiency of laboratories in the detection of *Bordetella pertussis*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB094132_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BORRELIA BURGDORFERI SPP. (LYME DISEASE)

BbDNA25 - QAB114147

To assess the qualitative detection of *B. burgdorferi* sensu lato genospecies complex at different concentrations.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB114147_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Microbiological Medium and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CHLAMYDIA PSITTACI

CPS25 - QAB134165

To assess the laboratories ability in the molecular detection of *Chlamydia psittaci*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB134165_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE

CTNG25 - QAB174191

To assess proficiency of laboratories in the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using molecular technologies.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAB174191_1 | QAB174191_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured bacteria and/or Clinical material | |
| Matrix Panel Format | Urine and/or Physiological Buffer and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 4.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

CHLAMYDOPHILA PNEUMONIAE

CP25 - QAB084107

To assess the proficiency of laboratories in the correct detection of *Chlamydomphila pneumoniae*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB084107_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Bronchoalveolar Lavage (BAL) and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CLOSTRIDIUM DIFFICILE

CDDNA25 - QAB084125

A terminology update in the Clostridium field has introduced a name change from *Clostridium difficile* to *Clostridioides difficile* this has been adopted by the European Study Group for *Clostridium difficile*. Please note that QCMD will however continue to refer to this scheme and associated pathogens as *Clostridium difficile* at this time.

To assess the proficiency of laboratories in the molecular detection of *Clostridium difficile*.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAB084125_1 | QAB084125_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Microbiological Medium and/or Synthetic Faecal Matrix | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for SFM. Follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

DIARRHEAGENIC ESCHERICHIA COLI

E.COLI25 - QAB154179

To assess laboratories ability to detect diarrheagenic *E. coli* strains using their routine molecular diagnostic platform and procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB154179_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Synthetic Faecal Matrix and/or Physiological Buffer and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for SFM. Follow test manufacturers IFU |
| Panel Analysis type | Molecular Typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

EXTENDED SPECTRUM β -LACTAMASE AND CARBAPENEMASE

ESBL25 - QAB134162

To assess the laboratories ability to detect β -lactamase and carbapenemase coding genes in a clinical setting using their routine molecular diagnostic procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB134162_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Genotypic Variant | Various drug resistance strains |
| Matrix Panel Format | Physiological Buffer |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL EQA

GROUP B STREPTOCOCCUS

GBS25 - QAB174200

To assess the laboratories ability in the qualitative detection of group B Streptococcus using their routine molecular diagnostic procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB174200_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q4 |
| Specifications | |
| Sample NA Target Source | Cultured material and/or Clinical material |
| Matrix Panel Format | Plasma and/or Synthetic CSF and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

HELICOBACTER PYLORI

H.PYLORI25 - QAB164190

To assess the laboratories ability in the qualitative detection of *H. pylori* and where appropriate, the identification of *H. pylori* antibiotic resistance status using their routine molecular diagnostic procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB164190_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Synthetic Faecal Matrix and/or Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for the SFM. Follow test manufacturers IFU |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL EQA

LEGIONELLA SPP.

LPDNA25 - QAB044122

To assess proficiency of laboratories in the detection of *Legionella* species.

| Feature | Available format(s) |
|--|--|
| Catalogue Number | QAB044122_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q1 |
| Specifications | |
| Sample NA Target Source | Cultured bacteria and/or Clinical material |
| Matrix Panel Format | Bronchoalveolar lavage (BAL) and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU. |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS TYPING (EPIDEMIOLOGY AND OUTBREAK STUDIES)



MRSATP25 - QAB074128

To assess the proficiency of laboratories in the molecular typing for outbreak analysis of Methicillin Resistant *Staphylococcus aureus*.

This EQA scheme is suitable for all molecular methods for typing *Staphylococcus aureus* strains including SPA typing and whole genome sequence analysis, where the type and/or the relationship between isolates can be determined.

| Feature | Available format(s) |
|--|--|
| Catalogue Number | QAB074128_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Microbiological Medium and/or Transport Medium |
| Panel Member Target Range | Genetic variants of <i>Staphylococcus aureus</i> |
| Panel Member Sample Volume | 0.2 ml |
| Panel Sample Pre-treatment Requirement | Culture followed by standard NA extraction |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various methodologies |
| Storage / Shipment Conditions | 2-8°C / Liquid Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL EQA

METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS

MRSADNA25 - QAB064124

To assess the performance of laboratories in the detection of Methicillin Resistant *Staphylococcus aureus*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB064124_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Microbiological Medium and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Liquid Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

MYCOBACTERIUM TUBERCULOSIS

MTBDNA25 - QAB014129

To assess the proficiency of laboratories in the molecular detection of *Mycobacterium tuberculosis* complex.

| Feature | Available format(s) | |
|--|--|-------------|
| Catalogue Number | QAB014129_1 | QAB014129_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Sputum and/or Synthetic Sputum and/or Synthetic CSF | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Pre-treatment may be required for the sputum samples – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | 2-8°C / Liquid Ambient | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

MYCOBACTERIUM TUBERCULOSIS DRUG RESISTANCE

MTBDR25 - QAB194209

To assess the proficiency of laboratories to detect and differentiate MTB drug resistance strains using their routine molecular diagnostic procedures.

| Feature | Available format(s) |
|--|--|
| Catalogue Number | QAB194209_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Genotypic Variant | Various drug resistance strains |
| Matrix Panel Format | Sputum and/or Synthetic Sputum and/or Synthetic CSF |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Pre-treatment may be required for the sputum samples – follow test manufacturers IFU |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Liquid Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

MYCOPLASMA GENITALIUM

MG25 - QAB184205

To assess the performance of laboratories in the detection of *Mycoplasma genitalium*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB184205_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured material and/or Clinical material |
| Matrix Panel Format | Transport medium and/or Urine and/or Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 4.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL EQA

MYCOPLASMA PNEUMONIAE

MP25 - QAB174192

To assess the proficiency of laboratories in the correct detection of *Mycoplasma pneumoniae*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB174192_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q2 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Bronchoalveolar Lavage (BAL) and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

SYPHILIS

SYPH25 - QAB154180

To assess laboratories ability to detect *Treponema pallidum* using their routine molecular diagnostic platform and procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB154180_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Urine and/or Physiological Buffer and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL EQA

VANCOMYCIN RESISTANT ENTEROCOCCI

VRE25 - QAB134163

This EQA will focus on the laboratories ability to detect and determine different VRE in clinically relevant sample types using molecular techniques.

| Feature | Available format(s) |
|-------------------------------|---------------------|
| Catalogue Number | QAB134163_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |

| Specifications | |
|--|---|
| Sample NA Target Source | Cultured and/or Clinical material |
| Genotypic Variant | Various drug resistance strains |
| Matrix Panel Format | Microbiological Medium and/or Transport Medium |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Molecular typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

FUNGAL EQA

ASPERGILLUS SPP.

ASPDNA25 - QAF104140

To assess the qualitative detection of *Aspergillus* species at different concentrations.

| Feature | Available format(s) |
|--|--|
| Catalogue Number | QAF104140_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma and/or Physiological Buffer and/or Panel Member Sample Volume |
| Panel Member Target Range | Covering Clinical Range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Analysis type | Qualitative, Quantative for information purposes only |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for Panel Member Sample Volume. Follow test manufacturers IFU |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

CANDIDA SPP.

CANDNA25 - QAF124151

To evaluate the ability of laboratories to use molecular techniques for detection of *Candida* species.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAF124151_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Plasma and/or Physiological Buffer |
| Panel Member Target Range | Covering clinical and analytical range |
| Sputum | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

DERMATOPHYTOSIS

DERMA25 - QAF164187

To assess laboratories ability to detect dermatophytes using their routine molecular diagnostic platform and procedures.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAF164187_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

PNEUMOCYSTIS JIROVECII PNEUMONIA (PCP)

PCPDNA25 - QAF114144

To assess laboratories ability in the molecular detection of *Pneumocystis jirovecii*.

To assess the sensitivity of molecular assays in routine clinical use for the detection of *P. jirovecii*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAF114144_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Clinical material |
| Matrix Panel Format | Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis Type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

PARASITIC EQA

TRICHOMONAS VAGINALIS

TV25 - QAP184202

To assess the performance of laboratories in the detection of *Trichomonas vaginalis*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAP184202_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 8 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport medium, Urine and/or Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 4.0 ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

TOXOPLASMA GONDII

TGDNA25 - QAP044123

To assess the qualitative detection of *Toxoplasma gondii* at different concentrations.

| Feature | Available format(s) | |
|--|--|-------------|
| Catalogue Number | QAP044123_1 | QAP044123_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Amniotic Fluid and/or Plasma | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | Lyophilised | |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

MPP EQA

ARTHROPOD-BORNE VIRUSES

ARBO25 - QAM194206

The Arthropod-borne virus EQA will focus on the molecular detection and determination of different arthropod-borne viruses (including viruses from Flavi-, Toga-, Bunya-, and/or Reoviridae families). The panel is designed to represent various clinical scenarios (fever, haemorrhagic symptoms and/or neurological illness) and may include medically important arboviruses such as tick-borne encephalitis viruses, sandfly fever viruses, Japanese encephalitis viruses, Rift Valley fever viruses, Usutu virus, Murray Valley encephalitis virus, or St. Louis encephalitis virus. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAM194206_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-Treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis Type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C /Lyophilised Ambient |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

BACTERIAL GASTROENTERITIS

GASTROB25 - QAB124153

Different species of pathogenic bacteria are known to cause gastroenteritis. The panel members of this EQA will resemble clinical samples and may include current clinically relevant strains of *Salmonella*, *Shigella*, *Yersinia*, *E.coli* 0157, *C. difficile* or *Campylobacter* species. The aim of the Bacterial Gastroenteritis EQA is to assess laboratories ability to detect a range of bacterial pathogens known to cause gastroenteritis using their routine molecular diagnostic platform and procedures.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAB124153_1 | QAB124153_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Synthetic Faecal Matrix and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for SFM. Follow test manufacturers IFU | |
| Panel Analysis type | Qualitative. | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

CENTRAL NERVOUS SYSTEM I (VIRAL MENINGITIS AND ENCEPHALITIS)

CNSI25 - QAV174195

The central nervous system I (viral meningitis and encephalitis) EQA scheme will focus on the molecular detection and determination of various enterovirus, parechovirus, herpes simplex virus 1/2, Varicella-Zoster virus and JC virus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV174195_1 | QAV174195_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured material and/or Clinical material | |
| Matrix Panel Format | Synthetic CSF and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative. Quantitative for information purposes only | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

CENTRAL NERVOUS SYSTEM II (NON-VIRAL MENINGITIS AND ENCEPHALITIS)

CNSII25 - QAM174196

The central nervous system II (non-viral meningitis and encephalitis) EQA scheme will focus on the molecular detection and determination of various *Listeria* spp, *Neisseria meningitidis*, *Streptococcus pneumoniae*, *Streptococcus agalactiae*, *Escherichia coli* K1, *Cryptococcus* spp., *Aspergillus* spp. or *Haemophilus influenzae* strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAM174196_1 | QAM174196_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured material and/or Clinical material | |
| Matrix Panel Format | Synthetic CSF and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative. Quantitative for information purposes only | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

MALDI-TOF

MALDI25 - QAB124155

The primary aim of this EQA is to evaluate the ability of laboratories in the detection and determination of different clinically relevant isolates using MALDI-TOF and other similar mass spectrometry based technologies in the routine microbiology laboratory.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB124155_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Microbiological Medium and/or Transport Medium |
| Panel Member Target Range | Clinically relevant range of microorganisms for detection & determination |
| Panel Member Sample Volume | 0.5 ml |
| Panel Sample Pre-treatment Requirement | Culture followed by standard MALDI protocol |
| Panel Analysis type | Typing |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

PARASITIC GASTROENTERITIS

GASTROP25 - QAP124154

Parasites are a frequent cause of gastroenteritis and are a growing risk in this age of global travel. The panel members of this EQA will resemble clinical samples and may include current clinically relevant strains of *Giardia*, *Cryptosporidium*, *Dientamoeba*, *Blastocystis* and *Entamoeba*. The aim of the Parasitic Gastroenteritis EQA is to assess laboratories' ability to detect a range of parasitic pathogens known to cause gastroenteritis using their routine molecular diagnostic platform and procedures.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAP124154_1 | QAP124154_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured material and/or Clinical material | |
| Matrix Panel Format | Synthetic Faecal Matrix and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for SFM. Follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

RESPIRATORY I

RESPI25 - QAV164188

The Respiratory I EQA will focus on the molecular detection and determination of various influenza A & B and respiratory syncytial virus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAB164188_1 | QAV164188_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering Clinical Range | |
| Panel Member Sample Volume | 1.0ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis Type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

RESPIRATORY I PLUS

RESPIplus25 - QAM204216

The Respiratory I Plus EQA will focus on the molecular detection and determination of various influenza A & B, respiratory syncytial virus strains and SARS-Cov-2. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|--------------|
| Catalogue Number | QAM204216_1A | QAM204216_1B |
| Total Number of Challenges | 1 | 1 |
| Number of Panel Members | 10 | 10 |
| Distribution / Testing Period | Q2 | Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering Clinical Range | |
| Panel Member Sample Volume | 1.0ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis Type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

RESPIRATORY II

RESPII25 - QAV164189

The Respiratory II EQA will focus on the molecular detection and determination of human metapneumovirus, respiratory adenoviruses, rhinoviruses, coronaviruses, enterovirus and parainfluenza viruses. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV164189_1 | QAV164189_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

RESPIRATORY III

RESPIII25 - QAM174193

The Respiratory III EQA will focus on the molecular detection and determination of various *Bordetella pertussis*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, *Streptococcus pneumoniae* or *Haemophilus influenzae* strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and to report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAM174193_1 | QAM174193_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q3 | Q1 & Q3 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

SEPSIS

SEPSIS25 - QAB164178

This EQA scheme consists of a range of pathogens associated with sepsis such as *Staphylococcus spp.*, *Escherichia coli*, *Enterococcus spp.*, *Streptococcus spp.*, *Klebsiella spp.*, *Pseudomonas spp.*, and *Candida spp.*, *Pseudomonas* and *Candida spp.* The participating laboratory will be required to use their current molecular diagnostic processes and procedures for the detection and identification of microorganisms within blood or plasma based matrices.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB164178_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood and/or Plasma and/or Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |
| Accreditation/Regulatory Status | Accredited to ISO17043 |

SEXUALLY TRANSMITTED INFECTIONS I

STI_I25 - QAB154177

The aim of the Sexually Transmitted Infection (STI) EQA is to assess the laboratories' ability to detect a range of sexual transmitted infections known to cause disease using their routine molecular diagnostic platform and procedures. The panel members will resemble clinical samples and may include current clinically relevant strains of *Mycoplasma genitalium*, *Mycoplasma hominis*, *Trichomonas vaginalis*, *Ureaplasma urealyticum* and *Gardnerella vaginalis*.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAB154177_1 | QAB154177_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Urine and/or Physiological Buffer and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 4.0ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

SEXUALLY TRANSMITTED INFECTIONS II

STI_II25 - QAM174201

The sexually transmitted infection II EQA will focus on the molecular detection and determination of various *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum*, and herpes simplex virus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and to report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAM174201_1 | QAM174201_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Urine and/or Physiological Buffer and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 4.0ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

TRANSPLANTATION (VIRAL)

TRANS25 - QAM174198

The viral transplant EQA scheme will focus on the molecular detection and determination of various cytomegalovirus, Epstein-Barr virus, human herpes virus 6, BK virus, B19 virus and adenovirus strains. The panel is designed to represent various clinical scenarios. Participating laboratories will be expected to test each panel using their appropriate molecular methods and to report their individual test results to QCMD.

| Feature | Available format(s) | |
|--|---|--|
| Catalogue Number | QAM174198_1 | |
| Total Number of Challenges | 1 | |
| Number of Panel Members | 10 | |
| Distribution / Testing Period | Q2 | |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Plasma and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU | |
| Panel Analysis type | Qualitative & Quantitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

VIRAL GASTROENTERITIS

GASTROV25 - QAV124152

Viruses are a major cause of gastroenteritis outbreaks. It has been estimated that at least 50% of foodborne gastroenteritis cases are caused by noroviruses. Approximately another 20% of cases, and the majority of severe cases in children, are due to rotavirus. Other clinically significant viral enteropathogens include adenovirus, particularly types 40 and 41, and astroviruses. The aim of the Viral Gastroenteritis EQA is to assess laboratories ability to detect a range of viral pathogens known to cause gastroenteritis using their routine molecular diagnostic platform and procedures. The panel members will resemble clinical samples and may include current clinically relevant strains of norovirus, rotavirus, astrovirus, sapovirus and adenovirus.

| Feature | Available format(s) | |
|--|---|-------------|
| Catalogue Number | QAV124152_1 | QAV124152_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured material and/or Clinical material | |
| Matrix Panel Format | Synthetic Faecal Matrix and/or Transport Medium | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0ml | |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment may be required for SFM. Follow test manufacturers IFU | |
| Panel Analysis type | Qualitative | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |
| Accreditation/Regulatory Status | Accredited to ISO17043 | |

EQA PILOT STUDIES

BABESIA

BABESIA25 - QAP214219

Pathogens of the genus *Babesia* (Family: Babesiidae, Order: Piroplasmida) are important blood parasites in mammals and less frequently in birds. Of the more than 100 known tick-borne species, only a few have been identified as causing human infections. Of zoonotic importance are parasites of bovine babesiosis (*Babesia divergens* and *B. divergens*-like forms), rodent babesiosis (*B. microti*) and a few other *Babesia* species like *B. venatorum* in wild deer. During a blood meal, hard-bodied ticks (e.g. *Ixodes ricinus*) inoculate sporozoites with their saliva, which, like plasmodia, enter human erythrocytes and undergo asexual reproduction.

In Europe, *B. divergens* is the main pathogen of human babesiosis. Infections have been reported in various European countries. In the United States, *B. microti* is the agent most frequently identified. Other cases have been reported from Africa, Mexico, Japan, Taiwan and India (*B. microti* or unidentified *Babesia*).

The diagnosis of an acute infection is confirmed through identification of *Babesia* on microscopic examination or detection of *Babesia* nucleic acid. Nucleic acid testing (NAT) correlates better with active infection and more effectively identifies low-level infections than other laboratory tests, making them important for donor screening and donation testing to reduce the risk of transfusion-transmitted babesiosis.

The pilot EQA scheme will assess the proficiency of laboratories in the correct detection and identification of *Babesia* species causing human babesiosis.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAP214219_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |

BBV DRIED BLOOD SPOT

BBVDBS25 - QAM254228

Dried blood spot testing for blood borne virus diagnosis is typically used to support screening in settings where plasma or serum sampling and cold storage is challenging.

The pilot EQA scheme will assess the performance of laboratories in the detection of hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV) from dried blood spots.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAP214217_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |

CANDIDA AURIS

CANAUR25 - QAF254229

Candida auris (*C. auris*) is an emerging fungal pathogen associated with nosocomial infections. It is considered a serious global health threat due to its multi-drug resistance and difficulty of identification using standard methods which can misidentify *C. auris* as other phenotypically related *Candida* species. *C. auris* spreads easily in healthcare settings where some patients can develop severe and even life-threatening symptoms especially in immunocompromised patients. Early and correct identification of patients colonised with *C. auris* is critical in containing its spread.

The pilot EQA scheme will assess laboratories ability in the molecular detection and identification of *Candida auris*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAP214217_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |

CHAGAS

CHAGAS25 - QAP214217

Trypanosoma cruzi is the causative agent of Chagas disease or American trypanosomiasis. *T. cruzi* is primarily transmitted by triatomine bugs, known as "kissing bugs"; other transmission routes such as transplacental, blood transfusion, organ transplantation and contaminated food are known.

Since parasite detection is difficult during both the acute and the latent phase of infection, antibody detection plays a crucial role in laboratory diagnostics. Serologic testing is also the method for blood donor screening. Compared to conventional blood smears techniques, molecular tools such as PCR offer improved sensitivity for detection of acute and early congenital disease and are considered the test of choice in these settings. Also, PCR is maybe useful for monitoring reactivation in immunosuppressed patients or parasitological response to treatment.

The pilot EQA scheme will assess the proficiency of laboratories in the correct detection of *Trypanosoma cruzi* causing Chagas disease.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAP214217_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |

CYTOMEGALOVIRUS NON-BLOOD



CMVNB25 - QAV254230

Cytomegalovirus (CMV) is a betaherpes virus with a high prevalence (40-80%) in populations throughout the developed world. CMV is normally a latent lifelong infection that is completely asymptomatic in those infected with the virus.

The situation in persons with compromised immune systems such as transplant recipients is much more serious, with CMV recognised as one of the most important viral pathogens causing high rates of mortality and morbidity in these groups. It is also a highly prevalent congenital infectious agent throughout the developed world. The clinical consequences of infection may be present at birth or manifest themselves during childhood.

While blood samples are tested routinely and used for diagnosis and monitoring purposes, a range of other non-blood specimens are also extremely useful as they are non-invasive and usual have increased viral load, these samples include urine and salivary swab.

The introduction of nucleic acid amplification technologies (NAT) has led to the development of sensitive diagnostic tests that can rapidly confirm or exclude CMV infection. As a result, these tests are now of great practical and clinical relevance.

The aim of the EQA scheme is to assess the performance of molecular based assays on non-blood specimen types, which includes urine, swab and amniotic fluid.

| Feature | Available format(s) | |
|--|--|-------------|
| Catalogue Number | QAV254230_1 | QAV254230_2 |
| Total Number of Challenges | 1 | 2 |
| Number of Panel Members | 10 | 5 |
| Distribution / Testing Period | Q4 | Q2 & Q4 |
| Specifications | | |
| Sample NA Target Source | Cultured and/or Clinical material | |
| Matrix Panel Format | Transport Medium and/or Urine and/or Amniotic Fluid | |
| Panel Member Target Range | Covering clinical range | |
| Panel Member Sample Volume | 1.0 ml | |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly. | |
| Panel Analysis type | Qualitative. | |
| Panel Testing | Evaluated by various molecular methodologies | |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice | |

FRANCISELLA TULARENSIS

FRATUL25 - QAB214220

Tularemia is a severe zoonotic disease and is caused by the bacteria *Francisella tularensis*. Transmission is typically through the skin or mucous membranes. For example, infection can occur when improperly cooked meat (typically rabbit) is eaten or from contaminated water is drunk, inhalation or through arthropod bites. Reservoirs of *Francisella tularensis* include lagomorphs, rodents and blood-sucking arthropods.

Laboratory confirmation of tularemia consists in detecting the bacteria in a biological sample or a specific antibody response. Molecular methods (i.e. PCR) are rapid and can allow identification of the subspecies and obviate the need for cultivation. Serological methods are routinely used for diagnosis and are considered highly specific despite cross-reactions with *Brucella*, *Yersinia*, *Proteus*, *Legionella* and *Mycoplasma* species may occur.

The pilot EQA scheme will assess the proficiency of laboratories on the detection of *Francisella tularensis*.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB214220_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium and/or Physiological Buffer |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |

GROUP A STREPTOCOCCUS

GAS25 - QAB234226

Group A Streptococcus (GAS) is one of the most common causes of bacterial infections of the throat and skin. GAS or *Streptococcus pyogenes* is also the cause of 'Scarlet fever' which most commonly affects children between 5 and 15 years old. Early antibiotic treatment has been shown to be effective in reducing both the transmission and severity of disease therefore rapid diagnosis is key. The SARS-CoV-2 pandemic resulted in an influx of near patient / PoC molecular testing platforms, with GAS added to the test menu of several commercial instruments for use within a non-laboratory, point of impact test setting or in a 'statim' or 'out of hours' capacity within the central laboratory. We have therefore introduced a pilot EQA to assess the performance of molecular GAS testing, allowing test sites to assess the performance of their assays.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAB234226_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |

JOINT INFECTON

JOINT25 - QAM244227

Bone and Joint infection diagnosis can be challenging as the symptoms are similar to other common conditions such as gout and rheumatoid arthritis. Culturing can require up to two weeks due to the potentially fastidious nature of the pathogens associated with this type of infection. Average sensitivity rates of approximately 72% have been recorded and this can be further reduced where antibiotics have been administered.

The aim of the joint infection pilot study is to assess the ability of laboratories to detect a range of Gram positive, Gram negative and fungal pathogens alongside common resistance markers using their routine molecular diagnostic platforms and procedures. The panel members will resemble clinical samples and will include current clinically relevant strains.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAM244227_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-treatment Requirement | Thaw and test immediately. Pre-treatment not generally required – follow test manufacturers IFU |
| Panel Analysis type | Qualitative. |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |

MALARIA

MALARIA25 - QAP214218

Malaria is a life threatening, mosquito borne, infectious disease in humans. The causative agents of malaria are a number protozoan species of the genus Plasmodium.

There are five Plasmodium species that commonly cause disease in humans. *Plasmodium falciparum* is the causative agent for most cases of malaria (malaria tropica) and is found across Africa. *P. falciparum* and malaria tropica are the most severe form and account for the majority of malaria fatalities worldwide. *Plasmodium vivax* (malaria tertiana) is the second most prevalent species and is found mostly in Latin America and Asia, whereas *Plasmodium ovalae sensu lato*, which is also a causative agent of malaria tertiana, is mainly restricted to West African regions. *Plasmodium malariae* (malaria quartan) is found worldwide but at a relatively low incidence. *Plasmodium knowlesi* was identified as the causative agent of localised outbreaks in Malaysia and has since been reported in nearly all Southeast Asian countries.

In Europe, malaria is mainly a travel medicine issue. In patients with a fever of unknown cause and a stay in an area where malaria is endemic, acute malaria must be excluded. The diagnosis of malaria is based on microscopic, serological or molecular detection of Plasmodium species. Although microscopy is still the most routinely used method for diagnosis by clinical laboratories, molecular testing has become increasingly popular.

The pilot EQA scheme will assess the proficiency of laboratories in the correct detection of *Plasmodium* species.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAP214218_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Whole Blood |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | Lyophilised |
| Panel Sample Pre-treatment Requirement | Reconstitution of lyophilised material |
| Panel Analysis type | Qualitative. Quantitative for information purposes only |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | 2-8°C / Lyophilised Ambient |

POXVIRUSES

POX25 - QAV224225

Due to the global outbreak of monkeypox and increasing demand for laboratory preparedness, we have introduced a pilot EQA scheme for poxviruses that will include inactivated monkeypox virus and other orthopoxviruses (Cowpox, and Vaccinia). This will offer laboratories, that have recently set up generic orthopoxvirus or specific monkeypox virus molecular diagnostics, the opportunity to assess the performance of their assays.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV224225_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 10 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured and/or Clinical material |
| Matrix Panel Format | Transport Medium |
| Panel Member Target Range | Covering clinical range |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-Treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis Type | Qualitative |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |

VIRAL METAGENOMICS NGS

NGSMETA_25 - QAV204213

Viral metagenomics has been proposed as an unbiased method with unique clinical opportunities to identify the composition of clinical specimens without introduction of selection bias due to processing methods. The techniques used in these protocols are however complex and analysis methods require standardisation. This EQA pilot study aims to assess performance of existing metagenomics protocols as currently implemented by participating laboratories. Samples will be provided which will mimic cerebrospinal fluid samples containing known viral pathogens including enterovirus, herpes simplex virus and influenza virus.

Performance will be assessed based on the qualitative identification of viruses present in the samples, at the family, genus, species and subtype levels.

| Feature | Available format(s) |
|--|---|
| Catalogue Number | QAV204213_1 |
| Total Number of Challenges | 1 |
| Number of Panel Members | 5 |
| Distribution / Testing Period | Q3 |
| Specifications | |
| Sample NA Target Source | Cultured material |
| Matrix Panel Format | Synthetic CSF + human cell lines |
| Panel Member Sample Volume | 1.0ml |
| Panel Sample Pre-Treatment Requirement | Ready for analysis. Treat as clinical samples and analyse accordingly |
| Panel Analysis Type | Sequence analysis |
| Panel Testing | Evaluated by various molecular methodologies |
| Storage / Shipment Conditions | <-20°C / Frozen on Dry-ice |

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| TARGET PATHOGEN | | | | | | | PAGE NUMBER |
|---|------------------|-------------------|-----------------------------|--------------------------------------|---------------------|----------------------------|--------------------------------|
| SCHEME CODE | CATALOGUE NUMBER | NO. OF CHALLENGES | PANEL MEMBERS PER CHALLENGE | DISTRIBUTION DATE(S)/ TESTING PERIOD | SHIPPING CONDITIONS | ANALYSIS TYPE | SCHEME TYPE |
| Adenovirus | | | | | | | Page 15 |
| ADVDNA25 | QAV054133_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV054133_2 | 2 | 5 | Q2, Q4 | | | |
| Arthropod-borne viruses | | | | | | | Page 56 |
| ARBO25 | QAM194206_1 | 1 | 10 | Q3 | Ambient | Qualitative | Multi-Pathogen / Syndromic EQA |
| Aspergillus spp. | | | | | | | Page 53 |
| ASPDNA25 | QAF104140_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Fungal EQA |
| Atypical mycobacterium | | | | | | | Page 42 |
| NTM25 | QAB194208_1 | 1 | 10 | Q1 | Ambient | Qualitative | Bacterial EQA |
| B19 virus | | | | | | | Page 15 |
| B19DNA25 | QAV034116_1 | 1 | 8 | Q3 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV034116_2 | 2 | 4 | Q1, Q3 | | | |
| Babesia | | | | | | | Page 64 |
| BABESIA25 | QAP214219_1 | 1 | 10 | Q3 | Ambient | Qualitative | Pilot Study |
| Bacterial 16S Ribosomal RNA | | | | | | | Page 42 |
| B16SrRNA25 | QAB164183_1 | 1 | 8 | Q3 | Dry-ice | Typing | Bacterial EQA |
| Bacterial Gastroenteritis | | | | | | | Page 56 |
| GastroB25 | QAB124153_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAB124153_2 | 2 | 5 | Q2, Q4 | | | |
| BBV Dried Blood Spot | | | | | | | Page 65 |
| BBVDBS25 | QAM254228 | 1 | 10 | Q3 | Ambient | Qualitative | Pilot Study |
| BK virus (BKV) | | | | | | | Page 16 |
| BKDNA25 | QAV144166_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV144166_2 | 2 | 5 | Q2, Q4 | | | |
| Bordetella pertussis | | | | | | | Page 43 |
| BPDNA25 | QAB094132_1 | 1 | 10 | Q2 | Dry-ice | Qualitative | Bacterial EQA |
| Borrelia burgdorferi spp. (Lyme Disease) | | | | | | | Page 43 |
| BbDNA25 | QAB114147_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Bacterial EQA |
| Candida auris | | | | | | | Page 65 |
| CANAUR25 | QAF254229_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Pilot Study |

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|--|------------------|-------------------|-----------------------------|--------------------------------------|---------------------|------------------------------|--------------------------------|
| SCHEME CODE | CATALOGUE NUMBER | NO. OF CHALLENGES | PANEL MEMBERS PER CHALLENGE | DISTRIBUTION DATE(S)/ TESTING PERIOD | SHIPPING CONDITIONS | ANALYSIS TYPE | SCHEME TYPE |
| Candida spp. | | | | | | | Page 53 |
| CANDNA25 | QAF124151_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Fungal EQA |
| Central Nervous System I (viral Meningitis and Encephalitis) | | | | | | | Page 57 |
| CNSI25 | QAV174195_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAV174195_2 | 2 | 5 | Q2, Q4 | | | |
| Central Nervous System II (Non-viral Meningitis and Encephalitis) | | | | | | | Page 57 |
| CNSII25 | QAM174196_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAM174196_2 | 2 | 5 | Q2, Q4 | | | |
| Chagas | | | | | | | Page 66 |
| CHAGAS25 | QAP214217_1 | 1 | 10 | Q3 | Ambient | Qualitative | Pilot Study |
| Chikungunya virus (CHIKV) | | | | | | | Page 16 |
| CHIKV25 | QAV154175_1 | 1 | 10 | Q3 | Ambient | Qualitative | Viral EQA |
| Chlamydia psittaci | | | | | | | Page 44 |
| CPS25 | QAB134165_1 | 1 | 8 | Q2 | Dry-ice | Qualitative | Bacterial EQA |
| Chlamydia trachomatis and Neisseria gonorrhoeae | | | | | | | Page 44 |
| CTNg25 | QAB174191_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Bacterial EQA |
| | QAB174191_2 | 2 | 5 | Q1, Q3 | | | |
| Chlamydomonada pneumoniae | | | | | | | Page 45 |
| CP25 | QAB084107_1 | 1 | 5 | Q2 | Dry-ice | Qualitative | Bacterial EQA |
| Clostridium difficile (CD) | | | | | | | Page 45 |
| CDDNA25 | QAB084125_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Bacterial EQA |
| | QAB084125_2 | 2 | 5 | Q2, Q4 | | | |
| Coronavirus (CoV) | | | | | | | Page 17 |
| CVRNA25 | QAV064137_1 | 1 | 10 | Q2 | Dry-ice | Qualitative | Viral EQA |
| Cytomegalovirus (CMV) Dried Blood Spots | | | | | | | Page 18 |
| CMVDBS25 | QAV064127_1 | 1 | 8 | Q3 | Ambient | Qualitative | Viral EQA |
| Cytomegalovirus (CMV) Drug Resistance | | | | | | | Page 17 |
| CMVDR25 | QAV144169_1 | 1 | 5 | Q2 | Dry-ice | Drug Resistance / Sequencing | Viral EQA |
| Cytomegalovirus (CMV) | | | | | | | Page 30 |
| CMVDNA25 | QAV014120_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV014120_2 | 2 | 5 | Q2, Q4 | | | |

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| SCHEME CODE | CATALOGUE NUMBER | NO. OF CHALLENGES | PANEL MEMBERS PER CHALLENGE | DISTRIBUTION DATE(S)/ TESTING PERIOD | SHIPPING CONDITIONS | ANALYSIS TYPE | SCHEME TYPE |
| Cytomegalovirus (CMV) Non-Blood | | | | | | | Page 67 |
| CMVNB25 | QAV254230_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Pilot Study |
| | QAV254230_2 | 2 | 5 | Q2, Q4 | | | |
| Cytomegalovirus (CMV) Whole Blood | | | | | | | Page 18 |
| CMVWB25 | QAV124150_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV124150_2 | 2 | 5 | Q2, Q4 | | | |
| Dengue virus (DENV) | | | | | | | Page 19 |
| DENVRNA25 | QAV114148_1 | 1 | 10 | Q3 | Ambient | Qualitative | Viral EQA |
| Dermatophytosis | | | | | | | Page 54 |
| DERMA25 | QAF164187_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Fungal EQA |
| Diarheagenic <i>Escherichia coli</i> | | | | | | | Page 46 |
| E.COLI25 | QAB154179_1 | 1 | 8 | Q3 | Dry-ice | Typing | Bacterial EQA |
| Enterovirus (EV) | | | | | | | Page 19 |
| EVRNA25 | QAV984104_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Viral EQA |
| | QAV984104_2 | 2 | 5 | Q1, Q3 | | | |
| Enterovirus Typing (EV) | | | | | | | Page 20 |
| EVTP25 | QAV164185_1 | 1 | 8 | Q1 | Dry-ice | Typing | Viral EQA |
| Epstein-Barr virus (EBV) | | | | | | | Page 20 |
| EBVDNA25 | QAV024121_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV024121_2 | 2 | 5 | Q2, Q4 | | | |
| Epstein-Barr virus (EBV) Whole Blood | | | | | | | Page 21 |
| EBVWB25 | QAV134161_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV134161_2 | 2 | 5 | Q2, Q4 | | | |
| Extended Spectrum β-lactamase and Carbapenemase | | | | | | | Page 46 |
| ESBL25 | QAB134162_1 | 1 | 8 | Q3 | Dry-ice | Typing | Bacterial EQA |
| <i>Francisella tularensis</i> | | | | | | | Page 68 |
| FRATUL25 | QAB214220_1 | 1 | 10 | Q3 | Ambient | Qualitative | Pilot Study |
| Group A Streptococcus | | | | | | | Page 69 |
| GAS25 | QAB234226_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Pilot Study |
| Group B Streptococcus | | | | | | | Page 47 |
| GBS25 | QAB174200_1 | 1 | 8 | Q4 | Dry-ice | Qualitative | Bacterial EQA |

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| Helicobacter pylori | | | | | | | Page 47 |
| H.PYLORI25 | QAB164190_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Bacterial EQA |
| Hepatitis A virus (HAV) | | | | | | | Page 24 |
| HAVRNA25 | QAV124156_1 | 1 | 8 | Q1 | Dry-ice | Qualitative | Viral EQA |
| Hepatitis B virus (HBV) | | | | | | | Page 25 |
| HBVDNA25 | QAV994110_1 | 1 | 8 | Q3 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV994110_2 | 2 | 4 | Q1, Q3 | | | |
| | QAV994110_4 | 4 | 4 | Q1, Q2, Q3, Q4 | | | |
| Hepatitis B virus (HBV) Drug Resistance | | | | | | | Page 21 |
| HBVDR25 | QAV124160_1 | 1 | 5 | Q3 | Dry-ice | Drug Resistance / Sequencing | Viral EQA |
| Hepatitis B virus (HBV) Genotyping | | | | | | | Page 22 |
| HBVGT25 | QAV064118_1 | 1 | 8 | Q1 | Dry-ice | Typing | Viral EQA |
| Hepatitis C virus (HCV) | | | | | | | Page 25 |
| HCVRNA25 | QAV994112_1 | 1 | 8 | Q3 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV994112_2 | 2 | 4 | Q1, Q3 | | | |
| | QAV994112_4 | 4 | 4 | Q1, Q2, Q3, Q4 | | | |
| Hepatitis C virus (HCV) Drug Resistance | | | | | | | Page 23 |
| HCVDR25 | QAV134167_1 | 1 | 5 | Q3 | Dry-ice | Drug Resistance / Sequencing | Viral EQA |
| Hepatitis C virus (HCV) Genotyping | | | | | | | Page 24 |
| HCVGT25 | QAV034117_1 | 1 | 8 | Q1 | Dry-ice | Typing | Viral EQA |
| Hepatitis D virus (HDV) | | | | | | | Page 26 |
| HDV25 | QAV144170_1 | 1 | 8 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| Hepatitis E virus (HEV) | | | | | | | Page 26 |
| HEVRNA25 | QAV124157_1 | 1 | 8 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| Herpes simplex virus 1 & 2 (HSV) | | | | | | | Page 27 |
| HSVDNA25 | QAV994105_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Viral EQA |
| | QAV994105_2 | 2 | 5 | Q1, Q3 | | | |
| Herpes simplex virus Drug Resistance | | | | | | | Page 27 |
| HSVDR25 | QAV164184_1 | 1 | 5 | Q1 | Dry-ice | Drug Resistance / Sequencing | Viral EQA |

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| Human herpes virus 6 (HHV6) | | | | | | | Page 31 |
| HHV6DNA25 | QAV084119_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV084119_2 | 2 | 5 | Q2, Q4 | | | |
| Human Immunodeficiency virus type 1 (HIV-1) – DNA | | | | | | | Page 28 |
| HIVDNA25 | QAV034114_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Viral EQA |
| | QAV034114_2 | 2 | 4 | Q1, Q3 | | | |
| Human Immunodeficiency virus type 1 (HIV-1) – Drug Resistance | | | | | | | Page 29 |
| HIVDR25 | QAV024131_1 | 1 | 5 | Q4 | Dry-ice | Drug Resistance / Sequencing | Viral EQA |
| Human Immunodeficiency virus type 1 (HIV-1) – Drug Resistance (Integrase) | | | | | | | Page 29 |
| HIVDRint25 | QAV114146_1 | 1 | 5 | Q4 | Dry-ice | Drug Resistance / Sequencing | Viral EQA |
| Human Immunodeficiency virus type 1 (HIV-1) – RNA | | | | | | | Page 28 |
| HIVRNA25 | QAV994108_1 | 1 | 8 | Q3 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV994108_2 | 2 | 4 | Q1, Q3 | | | |
| | QAV994108_4 | 4 | 4 | Q1, Q2, Q3, Q4 | | | |
| HIV-2 | | | | | | | Page 30 |
| HIV2_25 | QAV204212_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Viral EQA |
| Human metapneumovirus (MPV) | | | | | | | Page 31 |
| MPV25 | QAV054135_1 | 1 | 8 | Q2 | Dry-ice | Qualitative | Viral EQA |
| Human Papillomavirus (HPV) – PreservCyt | | | | | | | Page 32 |
| HPVPRES25 | QAV094130_1 | 1 | 12 | Q3 | Ambient / Specialist | Qualitative | Viral EQA |
| | QAV094130_2 | 2 | 6 | Q1, Q3 | | | |
| Human Papillomavirus (Surepath) | | | | | | | Page 33 |
| HPVSURE25 | QAV184204_1 | 1 | 12 | Q3 | Ambient | Qualitative | Viral EQA |
| Influenza A & B virus (FLU) | | | | | | | Page 34 |
| INFRNA25 | QAV054134_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Viral EQA |
| | QAV054134_2 | 2 | 5 | Q2, Q4 | | | |
| Influenza Typing | | | | | | | Page 34 |
| INFTP25 | QAV064138_1 | 1 | 8 | Q4 | Dry-ice | Typing | Viral EQA |
| JC virus (JCV) | | | | | | | Page 35 |
| JCDNA25 | QAV074106_1 | 1 | 10 | Q4 | Dry-ice | Qualitative & Quantitative | Viral EQA |
| | QAV074106_2 | 2 | 5 | Q2, Q4 | | | |

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| Joint Infection | | | | | | | Page 70 |
| JOINT25 | QAM244227_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Pilot Study |
| Legionella spp. | | | | | | | Page 48 |
| LPDNA25 | QAB044122_1 | 1 | 10 | Q1 | Dry-ice | Qualitative | Bacterial EQA |
| Malaria | | | | | | | Page 71 |
| MALARIA25 | QAP214218_1 | 1 | 10 | Q3 | Ambient | Qualitative | Pilot Study |
| MALDI-TOF | | | | | | | Page 58 |
| MALDI25 | QAB124155_1 | 1 | 10 | Q3 | Dry-ice | Typing | Multi-Pathogen / Syndromic EQA |
| Measles / Mumps | | | | | | | Page 35 |
| MM25 | QAV144171_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Viral EQA |
| MERS coronavirus (MERS-CoV) | | | | | | | Page 36 |
| MERS25 | QAV154181_1 | 1 | 8 | Q2 | Dry-ice | Qualitative | Viral EQA |
| Methicillin Resistant Staphylococcus aureus (MRSA) | | | | | | | Page 49 |
| MRSADNA25 | QAB064124_1 | 1 | 10 | Q3 | Ambient | Qualitative | Bacterial EQA |
| Methicillin Resistant Staphylococcus aureus (MRSA) – Typing | | | | | | | Page 48 |
| MRSATP25 | QAB074128_1 | 1 | 8 | Q3 | Ambient | Typing | Bacterial EQA |
| Mycobacterium tuberculosis (MTB) | | | | | | | Page 49 |
| MTBDNA25 | QAB014129_1 | 1 | 10 | Q3 | Ambient | Qualitative | Bacterial EQA |
| | QAB014129_2 | 2 | 5 | Q1, Q3 | | | |
| Mycobacterium tuberculosis Drug Resistance | | | | | | | Page 50 |
| MTBDR25 | QAB194209_1 | 1 | 8 | Q3 | Ambient | Typing | Bacterial EQA |
| Mycoplasma genitalium | | | | | | | Page 50 |
| MG25 | QAB184205_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Bacterial EQA |
| Mycoplasma pneumoniae | | | | | | | Page 51 |
| MP25 | QAB174192_1 | 1 | 5 | Q2 | Dry-ice | Qualitative | Bacterial EQA |

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| Norovirus (NV) | | | | | | | Page 36 |
| NVRNA25 | QAV084139_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Viral EQA |
| | QAV084139_2 | 2 | 5 | Q2, Q4 | | | |
| Parainfluenza virus (PIV) | | | | | | | Page 37 |
| PINFRNA25 | QAV064136_1 | 1 | 10 | Q2 | Dry-ice | Qualitative | Viral EQA |
| Parasitic Gastroenteritis | | | | | | | Page 58 |
| GastroP25 | QAP124154_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAP124154_2 | 2 | 5 | Q2, Q4 | | | |
| Parechovirus (HPeV) | | | | | | | Page 37 |
| PeVRNA25 | QAV114145_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Viral EQA |
| | QAV114145_2 | 2 | 5 | Q1, Q3 | | | |
| Pneumocystis jirovecii pneumonia (PCP) | | | | | | | Page 54 |
| PCPDNA25 | QAF114144_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Fungal EQA |
| Poxviruses | | | | | | | Page 72 |
| POX25 | QAV224225_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Pilot Study |
| Respiratory I | | | | | | | Page 59 |
| RESPI25 | QAV164188_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAV164188_2 | 2 | 5 | Q1, Q3 | | | |
| Respiratory I Plus | | | | | | | Page 59 |
| RESPIplus25 | QAM204216_1A | 1 | 10 | Q2 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAM204216_1B | 1 | 10 | Q4 | | | |
| Respiratory II | | | | | | | Page 60 |
| RESPII25 | QAV164189_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAV164189_2 | 2 | 5 | Q1, Q3 | | | |
| Respiratory III | | | | | | | Page 60 |
| RESPIII25 | QAM174193_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAM174193_2 | 2 | 5 | Q1, Q3 | | | |
| Respiratory syncytial virus (RSV) | | | | | | | Page 38 |
| RSV25 | QAV054142_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Viral EQA |
| | QAV054142_2 | 2 | 5 | Q2, Q4 | | | |

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| Rhinovirus (RV) | | | | | | | Page 38 |
| RVRNA25 | QAV064143_1 | 1 | 10 | Q2 | Dry-ice | Qualitative | Viral EQA |
| SARS-CoV-2 | | | | | | | Page 39 |
| SCV2_25 | QAV204215_1A | 1 | 5 | Q1 | Dry-ice | Qualitative | Viral EQA |
| | QAV204215_1B | 1 | 5 | Q2 | | | |
| | QAV204215_1C | 1 | 5 | Q3 | | | |
| | QAV204215_1D | 1 | 5 | Q4 | | | |
| Sepsis | | | | | | | Page 61 |
| SEPSIS25 | QAB164178_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| Sexually Transmitted Infections I | | | | | | | Page 61 |
| STI_I25 | QAB154177_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAB154177_2 | 2 | 5 | Q2, Q4 | | | |
| Sexually Transmitted Infections II | | | | | | | Page 62 |
| STI_II25 | QAM174201_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAM174201_2 | 2 | 5 | Q2, Q4 | | | |
| Syphilis | | | | | | | Page 51 |
| SYPH25 | QAB154180_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Bacterial EQA |
| Torque teno virus (TTV) | | | | | | | Page 39 |
| TTV25 | QAV184203_1 | 1 | 6 | Q4 | Dry-ice | Qualitative | Viral EQA |
| Toxoplasma gondii | | | | | | | Page 55 |
| TGDNA25 | QAP044123_1 | 1 | 10 | Q3 | Ambient | Qualitative | Parasitic EQA |
| | QAP044123_2 | 2 | 5 | Q1, Q3 | | | |
| Transplantation (viral) | | | | | | | Page 62 |
| TRANS25 | QAM174198_1 | 1 | 10 | Q2 | Dry-ice | Qualitative & Quantitative | Multi-Pathogen / Syndromic EQA |
| Trichomonas vaginalis | | | | | | | Page 55 |
| TV25 | QAP184202_1 | 1 | 8 | Q3 | Dry-ice | Qualitative | Parasitic EQA |
| Vancomycin Resistant Enterococci (VRE) | | | | | | | Page 52 |
| VRE25 | QAB134163_1 | 1 | 10 | Q3 | Dry-ice | Typing | Bacterial EQA |

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| Varicella-Zoster virus (VZV) | | | | | | | Page 40 |
| VZVDNA25 | QAV034103_1 | 1 | 10 | Q3 | Dry-ice | Qualitative | Viral EQA |
| | QAV034103_2 | 2 | 5 | Q1, Q3 | | | |
| Viral Gastroenteritis | | | | | | | Page 63 |
| GastroV25 | QAV124152_1 | 1 | 10 | Q4 | Dry-ice | Qualitative | Multi-Pathogen / Syndromic EQA |
| | QAV124152_2 | 2 | 5 | Q2, Q4 | | | |
| Viral Metagenomics NGS | | | | | | | Page 72 |
| NGSmeta_25 | QAV204213_1 | 1 | 5 | Q3 | Dry-ice | Sequencing | Pilot Study |
| West Nile virus (WNV) | | | | | | | Page 40 |
| WNVRNA25 | QAV104141_1 | 1 | 10 | Q3 | Ambient | Qualitative | Viral EQA |
| Yellow Fever Virus | | | | | | | Page 41 |
| YFV25 | QAV194207_1 | 1 | 8 | Q3 | Ambient | Qualitative | Viral EQA |
| Zika Virus | | | | | | | Page 41 |
| ZIKA25 | QAV164186_1 | 1 | 10 | Q3 | Ambient | Qualitative | Viral EQA |



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