

# Rapid and Accurate Detection of Whooping Cough in Clinical Samples

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## Background

Despite a high vaccination coverage in the EU, whooping cough is not only present in Europe, but is dramatically on the rise in the post-pandemic era. Several countries reported outbreaks or increasing numbers in 2023/24<sup>1,2</sup>:

-  Infection cases 4-fold higher in 2023 (compared to 2022)
-  Infection cases 7-fold higher in 2023 (compared to 2022)
-  553 cases in January 2024 (2023 858 per annum; 7-fold)
-  6.261 cases reported in the first 3 month in 2024

The main cause of whooping cough is *Bordetella pertussis* (Bpt), however, *Bordetella parapertussis* (Bpa) and *Bordetella holmesii* (Bho) can also cause infection. Therefore, rapid and accurate diagnostic tools are still necessary for their detection in clinical specimen. The Vivalytic instrument is a new PCR platform using either multiplex RT PCR or microarray for detection of nucleic acids from microbes. The easy-to use cartridge system can be applied in the micro lab or as point-of-care test (POCT).

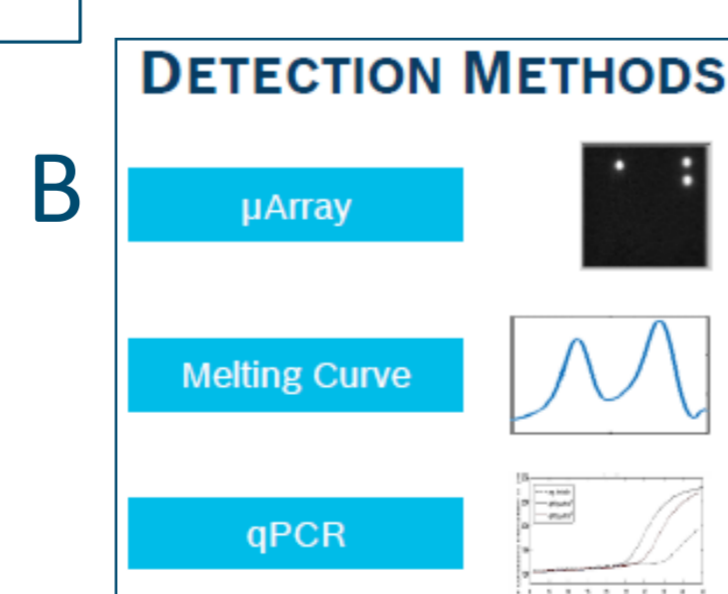
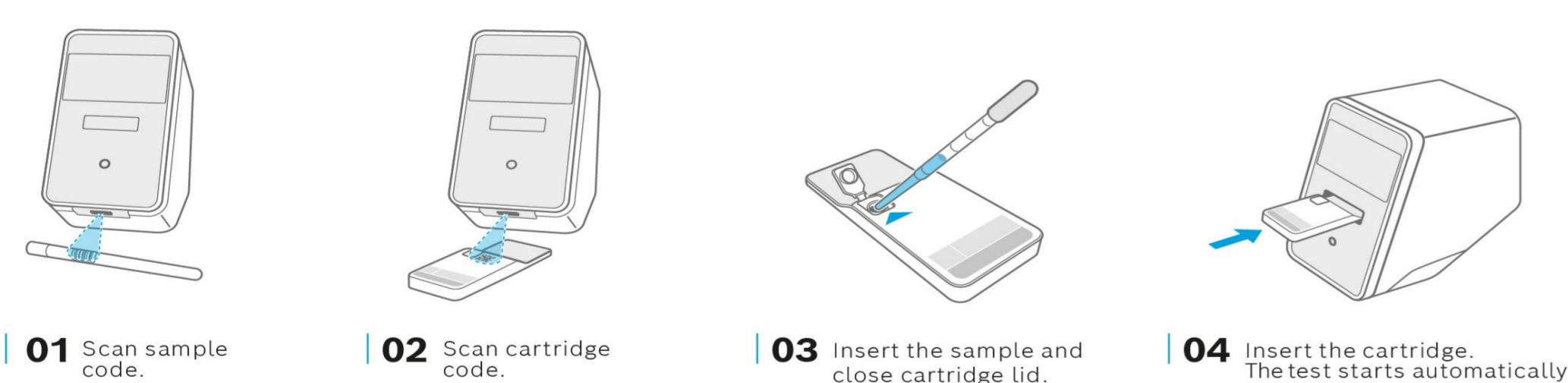
## Methods

411 nasopharyngeal specimens (all in Copan eNAT™ swabs) collected from symptomatic patients in Croatia were tested in our lab. All 411 samples were pre-characterized with the reference test.

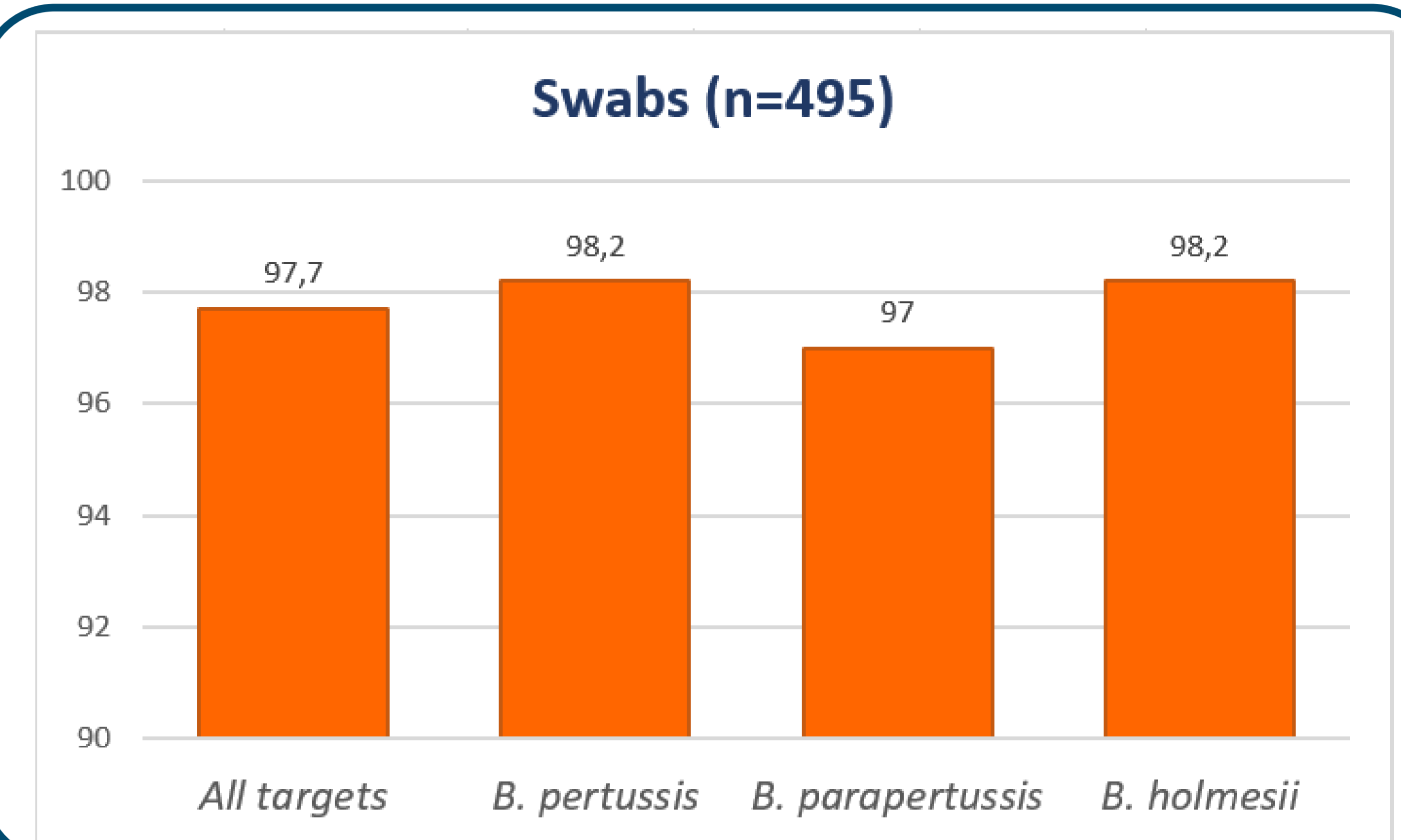
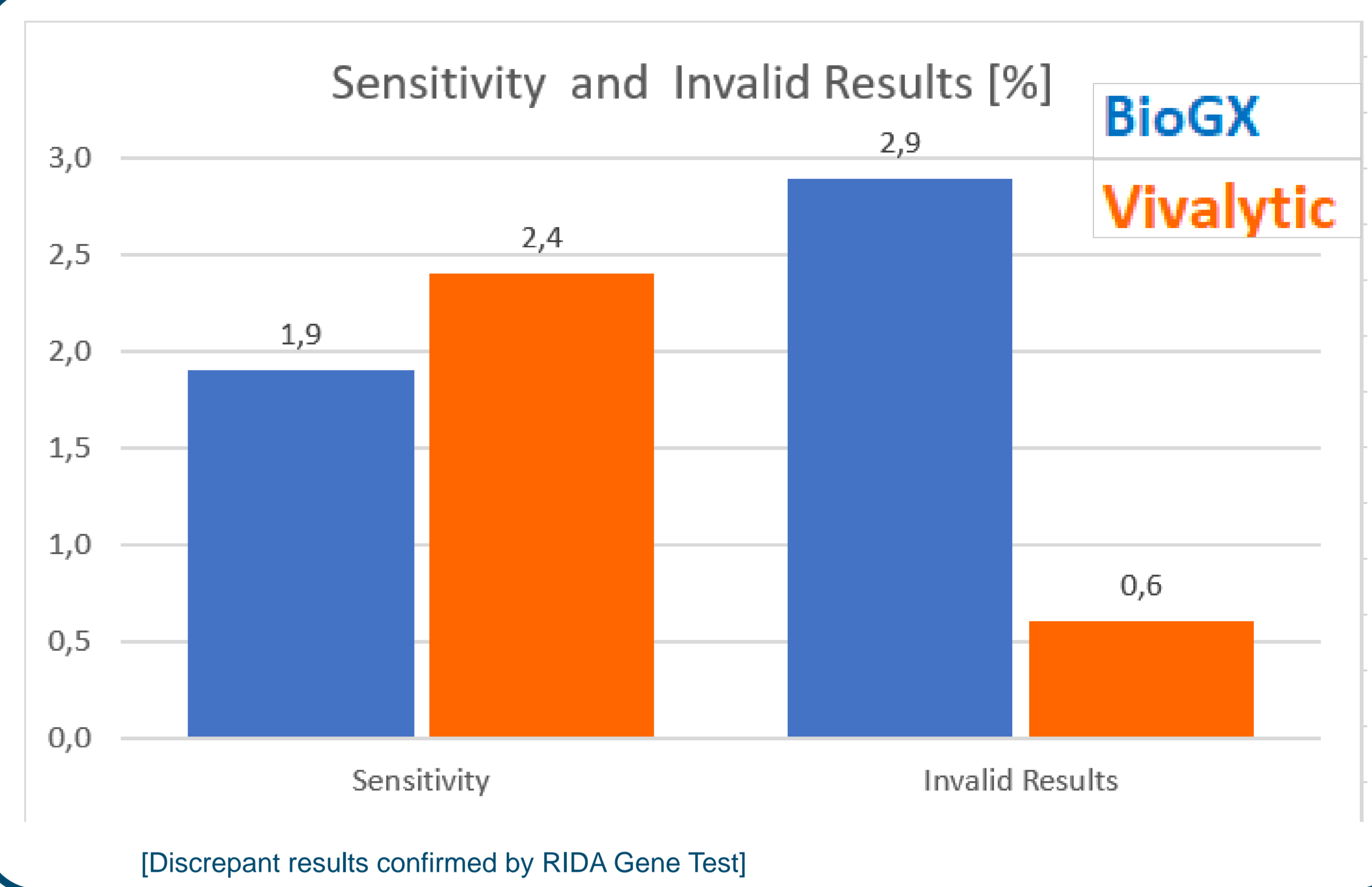
In addition, we received 11 positive samples from a hospital in Split (Croatia).

To accurately validate the new Vivalytic Bordetella assay (Bosch Healthcare Solutions, Waiblingen, Germany) we used 150 spiked samples: 50 samples of each virulent species *Bordetella pertussis* (Bpt), *B. parapertussis* (Bpa) and *B. holmesii* (Bho) were spiked with 3 different inocula, low, medium and high (20/50/200 10e3 copies/mL). All 561 samples were compared to the Bordetella Speciation Plus Toxin-OSR (BioGX, Amsterdam/NL) as reference test, which also covers all three virulent Bordetella species. To achieve comparable results both tests were performed within 72 hours. Discrepant results were tested with a third party test: RIDA Gene Bordetella.

### Workflow



**Fig. 1:**  
Vivalytic® instrument (A)  
Detection methods:  $\mu$  Array, Melting curve analysis and qPCR (B)  
Cartridge with reservoirs and microfluidic system (C)  
[The study was supported by BHCS by providing Vivalytic® cartridges]



## Results

In the 411 Croatian samples we detected 10 Bordetella positive specimens with Vivalytic (2,4%) and 8 with BioGX assay (1,9%).

The Vivalytic Bordetella cartridge showed a very high concordance to the reference test 97.7%. The positive percent agreement (PPA) was 97.9%. As the positivity rate of the specimen set was rather low, we received additional positive samples (n=11) from a hospital in Split (Croatia). All swabs gave positive results for Bordetella pertussis in the Vivalytic, 100% PPA. Within the 150 spiked samples the PPA was >98% for all tests and >95% for the challenging low inocula samples. Time-to result was only 45min for the Vivalytic test compared to 150min for the comparator assay. The rate of invalid results of the Vivalytic assay was very low 0,6%.

## Conclusion

The Vivalytic Bordetella cartridge demonstrated excellent concordance with a sensitive reference test and delivered accurate and rapid results. The assay is suitable for hospital labs and for outpatients' settings due to its easy use and short time-to report.

Easy-to use PCR systems with rapid results are suitable also for smaller hospitals and outpatient department. Early identification of infected patients will help to intercept transmission of the current re-emerging whooping cough epidemics.

Ref:  
1) ECDC Weekly Communicable Disease Threats Report, Week 51/2023  
2) Smout E., et al.; BMJ 2024; 385:q736, epub 02 April 2024