Multicentric evaluation of a point-of-care test for the diagnosis of whooping cough

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Introduction

The magnitude of the epidemic wave that struck France and Europe in 2024 clearly highlighted the need for a simple and fast molecular tool for the diagnosis of whooping cough. The main cause of whooping cough is *Bordetella pertussis*, although other *Bordetella* species can also cause infection. **We evaluated the performance of the automated qPCR Vivalytic Bordetella test (Bosch Healthcare Solutions GmbH, Germany) for the detection of *Bordetella* species outside its intended use, using additional sample types**. The Vivalytic platform, with its intuitive cartridge system, is designed for application in laboratories and point-of-care settings.

Materials and methods

- **57 positive samples**
  32 aspirates
  25 nasopharyngeal swabs (UTM medium)

- **Fresh and frozen samples at - 80°C**
  CHU Nantes,
  CHU Angers,
  Institut Pasteur Paris

Routine diagnostic methods

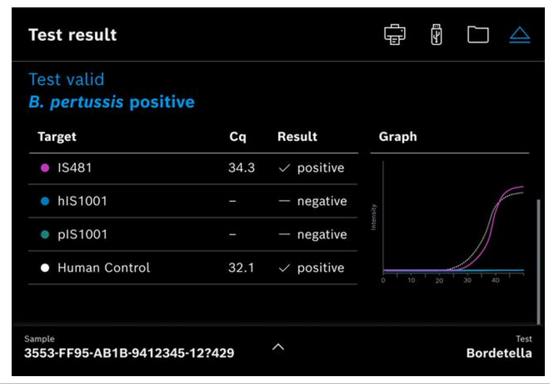
	CHU Nantes	CHU Angers	Institut Pasteur Paris (NRC)
Automated devices	BDMAX (BD)	Panther Fusion	LC480
Kits	Bordetella Speciation Plus Toxin-OSR kit (BioGX)	Panther fusion Bordetella test	High Pure PCR Template Preparation (ROCHE) Kits Argene Bordetella

- **Results compared with those obtained during routine diagnostic**

300 µL

Vivalytic

- **RT-PCR**
- **Targeted bacteria**
  B. pertussis,
  B. parpertussis,
  B. holmesii
- **Result in 47 min**



* *Study supported by **Bosch** and **Randox***

Results

The nasopharyngeal swabs in UTM medium showed a sensitivity of 77.78% (95% Confidence Interval [CI]: 57.74%-91.38%) , while **the nasopharyngeal aspirates exhibited a higher sensitivity** of 92% (95% CI: 73.97%-99.02%).

► **More nasopharyngeal aspirates will be included in the ongoing evaluation at Institut Pasteur National Reference Center for Whooping Cough and other Bordetella infections .**

	Nasopharygeal swabs in UTM	Nasopharyngeal aspirates
Sensitivity	77.78%	92.00%
95%-Confidence interval [CI]	57.74%-91.38%	73.97%-99.02%

Conclusion

The **Vivalytic Bordetella test** is an **easy-to use assay for the rapid detection of *Bordetella* species in <1h.** Our results showed a suboptimal sensitivity for nasopharyngeal samples in UTM. Therefore, it is more suitable for this sample type to use the recommended eNAT transport medium. However, we could show for the first time that **aspirates from infants and young children with a sensitivity of more than 90%** are a suitable sample type for the Vivalytic assay. Additionally, the ease-to use and the rapid time to result make **Vivalytic a valuable tool for the diagnosis of whooping cough** and eventually disease management.