28th ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES
Madrid, Spain
21 – 24 April 2018

P0552 Molecular detection of Bordetella pertussis by DiaSorin Molecular and Meridian Bioscience assays directly on primary clinical specimens: a comparative study

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Background: Whooping cough is a respiratory infection marked by severe spasmodic coughing episodes caused by *Bordetella pertussis* and, less frequently, *Bordetella parapertussis.* A timely and accurate diagnosis is especially relevant for infants, too young to be adequately vaccinated, for whom *pertussis* can have serious complications. Molecular tests are now available for diagnosis of *B. pertussis* and they can optimize the standard diagnostic work-up at early phases after infection, frequently based on culture. The aim of this study was to compare the performance of the new Simplexa Bordetella Direct assay developed by DiaSorin Molecular in comparison with the commercial LAMP-based *Illumigene* Assay (Meridian Bioscience).

Materials/methods: The Simplexa Bordetella Direct assay is a multiplex real-time PCR that enables the detection and differentiation of *B. pertussis* and *B. parapertussis* DNA from unprocessed nasopharyngeal (NP) swabs without nucleic acid extraction. The system is intended to be performed on the LIAISON MDX instrument (DiaSorin) and is associated to reusable 8-well discs for direct amplification of the targets in about one hour. The assay also includes the simultaneous amplification of an internal control in order to validate negative samples and to rule out PCR failure or inhibition. This study analyzed 40 archived samples (20 negative and 20 positive *for B. pertussis*). The respiratory samples, collected from the Regional Reference Laboratory for pertussis surveillance (Bologna-IT), were NP swabs (ESwab, Copan Diagnostics), with the exception of one NP aspirate and one NP swab collected in viral transport medium (UTM, Copan Diagnostics).

Results: Forty samples originally analyzed with *Illumigene* were tested by Simplexa Bordetella Direct assay, showing a 100% concordance between the two methods. The average threshold time (Ct) for positives was 23.3 and all negative samples were validated by the amplification of the internal control with an average Ct of 28.7.

Conclusions: Simplexa Bordetella Direct assay showed a complete agreement with *Illumigene* system with an improved work-flow in terms of hands-on time and a decreased risk of false negatives, thanks to the internal control. In addition, Simplexa Bordetella Direct assay can also identify *B. parapertussis*, improving *Bordetella* diagnostic coverage, unlike *Illumigene*.