FDA-cleared Bordetella assay, 8/17

August 2017—Luminex received FDA clearance for the Aries Bordetella Assay for direct detection and identification of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acid in nasopharyngeal swab specimens obtained from individuals suspected of having a respiratory tract infection attributable to *B. pertussis* or *B. parapertussis*. The company has also achieved CE-IVD marking for the Aries Bordetella Assay, is preparing to submit its *Clostridium difficile* assay to the FDA, and is in the process of completing a group A Streptococcus clinical trial.

The Aries Bordetella Assay is a real-time polymerase chain reaction-based qualitative in vitro diagnostic test that targets the pertussis toxin (ptxA) promoter and IS1001 repeat sequence in the genomes of *B. pertussis* and *B. parapertussis*, respectively.

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