Test System Details Review

Test: **RIT and *Bordatella Pertussis***

This is an FDA-approved assay based on PCR technology. This is a qualitative test designed to detect specific nucleic acid targets extracted from nasopharyngeal swabs collected in universal or viral transport medium.

Assay targets (viral and bacterial sequences) may persist *in vivo*, independent of organism viability. Detection of pathogen(s) does not imply that the corresponding organism(s) are infectious or are the causative agents for clinical symptoms. All results from this and other tests must be considered in conjunction with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Assay performance was established during the 2013/2014 and the 2014/2015 season. This device may not be able to differentiate newly emerging Influenza A subtypes. False negative results may occur due to the presence of strains with sequence variability or genetic rearrangements in the target regions of *Bordetella pertussis / parapertussis* assay.

The performance for some pathogens and subtypes may vary depending on the prevalence and population tested. There is a risk of false negative values due to the presence of sequence variants in the organism targets of the assay, procedural errors, amplification inhibitors in specimens, or inadequate numbers of organisms for amplification. There is a risk of false negative values resulting from improperly collected, transported, or handled specimens. A specimen yielding a negative result may contain respiratory pathogens not probed by the assay. This test cannot rule out infections caused by other pathogens not present on this panel. The effect of interfering substances has been evaluated only for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.

The performance of this assay was not established in immunocompromised patients. The performance of this device has not been evaluated for patients without signs and symptoms of infection. The performance of this device has not been evaluated for monitoring treatment of infection. The performance of this test has not been established for screening of blood or blood products. This device has been evaluated for use with human specimen material only.

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