FDA clears QuickVue Influenza A+B test, 4/18

April 2018—Quidel announced it has received FDA 510(k) clearance for its CLIA-waived QuickVue Influenza A+B assay. The assay allows for the rapid, qualitative detection of influenza type A and type B antigens directly in nasal swab and nasopharyngeal swab specimens from symptomatic patients in approximately 10 minutes. In a clinical study, the QuickVue Influenza A+B test was shown to meet the FDA's reclassification criteria for class II rapid influenza diagnostic tests.

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