Quidel tests cleared for use on QuantStudio Dx, 12/13

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December 2013—Quidel and Life Technologies announced that the FDA has granted 510(k) clearances to the Quidel Molecular Influenza A+B assay and the Quidel Molecular RSV+hMPV assay, both for use on the QuantStudio Dx Real-Time PCR instrument by Life Technologies.

The QuantStudio Dx is Life Technologies' flagship instrument for the diagnostics market, offering advanced capabilities in flexible sample batching needed by higher-volume hospital and reference laboratories. The two 510(k) clearances add to the infectious disease menu available on the QuantStudio Dx instrument with assays for the diagnosis of some of the more common respiratory tract infections that often share similar influenza-like symptoms and that can be difficult to distinguish based on clinical symptoms alone.

The Quidel Molecular Influenza A+B assay reports the presence or absence of influenza A or B virus, or both. It does not differentiate influenza A subtypes. However, the assay does demonstrate the analytical detection of subtype H7N9, and it was also cleared to include the analytical detection of variant influenza virus H3N2v.

The Quidel Molecular RSV+hMPV assay detects the presence of respiratory syncytial virus or human metapneumovirus, or both. Because most Quidel molecular assays share a common extraction protocol, the RSV and hMPV assay can be performed using the same extracted RNA as the Quidel Molecular Influenza A+B assay.

Life Technologies' QuantStudio Dx combines multiple system capabilities in a single footprint. It provides a touchscreen, reagent and sample tracking, and LIMS interface specifically designed for ease of use in diagnostic laboratories.

The Quidel Molecular Influenza A+B and RSV+hMPV assays and QuantStudio Dx will be sold and distributed by both Quidel and Life Technologies in the United States and Europe. Both the assays and instrument are CE-IVD marked for diagnostic use in Europe.

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