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Thermo Fisher announces 510(k) clearance of molecular clinical test for SARS-CoV-2, Flu A, Flu B, and RSV

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Offering a single clinical testing solution for four of the most common respiratory viruses circulating in flu season

Thermo Fisher Scientific has received 510(k) clearance from the US Food & Drug Administration (FDA) for the Applied Biosystems TaqPath COVID-19, Flu A, Flu B, RSV Select Panel, offering a single clinical testing solution for four of the most common respiratory viruses circulating in flu season.

This real-time PCR-based multiplex test covers the detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) and enables detection of co-infection.

Respiratory infections often present with overlapping signs of infection, making it difficult to accurately differentiate between common respiratory viral infections and therefore detect the specific pathogen responsible for the illness based on clinical presentation alone. Building on the proven reliability of Thermo Fisher's COVID-19 test, the TaqPath COVID-19, Flu A, Flu B, RSV Select Panel enables detection and differentiation of common respiratory viruses in one patient sample. This helps clinicians get fast, accurate results in as little as three hours that enable them to make informed decisions on patient treatment.

This solution includes a fully diagnostic workflow from sample extraction to results interpretation. KingFisher Apex Dx system is designed to be a part of a streamlined modular workflow providing precise results, seamless data management, and robust security features per diagnostic regulatory standards.