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Mesa Biotech gets FDA 510(k) approval and CLIA Waiver for influenza test

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The Company’s Flu A/Flu B test cassette will be its first available test in the U.S. market

Mesa Biotech is a privately held, molecular diagnostic company that has developed an affordable PCR (polymerase chain reaction) testing platform designed specifically for point-of-care (POC) infectious disease diagnosis.

The company announced that it has received 510(k) clearance and Clinical Laboratory Improvements Amendments (CLIA) waiver from the U.S. Food and Drug Administration (FDA) for its Accula™ Flu A/Flu B test.

The company's Flu A/Flu B test cassette will be its first available test in the U.S. market.

CLIA establishes quality standards for laboratory testing to ensure the accuracy and reliability of patient test results.

CLIA waived tests must meet stringent quality requirements to be used in non-laboratory POC settings.

The CLIA-waived Accula Flu A/Flu B test brings PCR testing to the POC providing a qualitative result in approximately 30 minutes to guide same day treatment decisions.

The Accula Testing System offers the simplicity, convenience and procedural familiarity of traditional POC rapid immunoassays, while providing the superior sensitivity, specificity and information content of laboratory-based PCR testing.

The Accula Flu A/Flu B test is indicated for use with nasal swab collection that is less invasive than nasopharyngeal swabs and allows for a more comfortable specimen collection experience for the patient.