510(k)-cleared, CLIA-waived Accula Strep A test

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January 2021—Mesa Biotech received 510(k) clearance and CLIA waiver from the FDA for its Accula Strep A test. The strep A cassette, for the molecular detection of group A *Streptococcus* bacterial nucleic acid, is cleared for diagnosing children and adults and provides results in 30 minutes at the point of care.

The palm-size test uses RT-PCR technology to detect strep A via throat, nasal, or nasopharyngeal swab samples and runs on the company's Accula platform.

Mesa Biotech, 858-800-4929