Applied BioCode respiratory pathogen panel gets FDA clearance

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Jan. 9, 2020—Applied BioCode has received FDA 510(k) clearance for its BioCode Respiratory Pathogen Panel for use on the company's BioCode MDx-3000 system. The panel tests nasopharyngeal swabs for common viruses and bacteria, including influenza A and subtypes H1, H1N1 2009pdm, and H3; influenza B; respiratory syncytial virus A/B; parainfluenza virus types 1–4; human metapneumovirus A/B; adenovirus; rhinovirus/enterovirus; coronavirus (229E, NL63, OC43, and HKU1); *Mycoplasma pneumoniae*; *Chlamydia pneumoniae*; and *Bordetella pertussis*.

The BioCode MDx-3000 offers flexible ordering and flexible reporting capabilities to address variation in test-ordering patterns and potential changes in reimbursement. The system allows users to run the RPP and the company's FDA-cleared gastrointestinal pathogen panel at the same time. Designed for moderate to high-volume laboratories, the MDx-3000 has a throughput of 188 samples in eight hours.