AAP News™

Advances made in OTC in vitro diagnostic tests for infectious pathogens

March 1, 2024

from the Food and Drug Administration

Article type: FDA Update

Topics: COVID-19, Infectious Diseases, Influenza, Pharmacology, RSV, Therapeutics

At-home over-the-counter (OTC) in vitro diagnostic tests allow families to test children for infectious illnesses, such as SARS-CoV-2, influenza and respiratory syncytial virus (RSV). Families then can use the results to take action for their child's health or seek their pediatrician's advice.

Interest in OTC diagnostic tests exploded during the COVID-19 pandemic. Since 2020, the Food and Drug Administration (FDA) has issued many emergency use authorizations (EUAs) for OTC diagnostic tests for SARS-CoV-2, including dozens of tests that can be performed and interpreted completely at home (https://bit.ly/3O28PrW).

It also has issued EUAs for OTC diagnostic tests capable of detecting and differentiating multiple respiratory viruses.

The Labcorp Seasonal Respiratory Virus RT-PCR DTC Test can detect and differentiate RSV, SARS-CoV-2 and influenza A and B (https://bit.ly/3S8Q0oq). Nasal swab samples are collected at home and then shipped to Labcorp for testing. Results are delivered through an online portal, with follow-up by a health care provider in cases of positive or invalid test results. The test can be used in individuals as young as 2 years with adult assistance.

The Lucira COVID-19 & Flu Home Test from Pfizer can differentiate and detect influenza A and B and SARS-CoV-2 (https://bit.ly/3RVAADI). Users collect nasal swab samples and interpret results within

approximately 30 minutes. The test can be used in individuals as young as 2 years with adult assistance.

“Giving families more access to at-home diagnostic testing and empowering them to engage in their child’s health care is an important step for improving public health. We’re enthusiastic about the innovation and progress we’re seeing,” said Courtney Lias, Ph.D., director of the FDA’s Office of In Vitro Diagnostics in the Center for Devices and Radiological Health.

The FDA also recently authorized OTC diagnostic tests via traditional marketing pathways.

In June 2023, the Cue COVID-19 Molecular Test for use in individuals 18 years and older became the first at-home OTC diagnostic test for a respiratory illness authorized through a traditional marketing review process.

In November 2023, the FDA cleared two OTC diagnostic tests for marketing — ACON Laboratories’ Flowflex COVID-19 Antigen Home Test and Simple 2 Test from LetsGetChecked.

Flowflex is the first OTC antigen diagnostic test for COVID-19 to complete a traditional FDA premarket review pathway and the first indicated for use in children under 18.

The Simple 2 Test is the first OTC diagnostic test with at-home sample collection for chlamydia and gonorrhea. The user activates the collection kit online, fills out a health questionnaire, collects a vaginal or urine specimen as appropriate and sends it to a designated laboratory. Results are delivered online, with follow-up by a health care provider in cases of positive or invalid test results. The test is intended for use in individuals 18 years and older.

Potential risks and benefits

Even before the COVID-19 pandemic, the FDA was seeing growing interest from device manufacturers to develop OTC in vitro diagnostic tests for infectious pathogens, including tests that involve at-home sample collection.

In August 2016, an FDA advisory committee discussed the potential risks and benefits of OTC diagnostic tests for influenza, group A streptococcus, chlamydia and gonorrhea (https://bit.ly/422KqZ8).

The committee noted that potential benefits include helping to address barriers to health care access and missed opportunities for early detection and treatment, particularly in medically underserved communities. Potential risks include the consequences of false positive or false negative results, potential user error when performing or interpreting the test, and the absence of clinical assessment by a health care provider.

While the committee generally agreed that the potential benefits likely would outweigh the potential risks in many cases, the FDA has taken steps to address these risks and help ensure the safety and effectiveness of OTC diagnostic tests.

When it reviews an application for an OTC diagnostic test, the FDA assesses not only the analytical and clinical validity of the test, but also the user’s ability to collect the sample, perform the test and, when applicable, interpret the results. The FDA also has worked with manufacturers to incorporate risk-mitigation strategies such as online clinical consultation services to help ensure users understand test results and access appropriate treatment.

“We are eager to continue supporting greater consumer access to diagnostic testing and helping device developers consider the needs of children,” Dr. Lias said.

The FDA's Office of Pediatric Therapeutics, Office of New Drug's Division of Pediatrics and Maternal Health and Office of In Vitro Diagnostics, Center for Devices and Radiological Health, contributed to this article.

Resources

- Information on the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test
- Information on the Lucira by Pfizer COVID-19 & Flu Home Test
- Information on the Cue COVID-19 Molecular Test
- Information on the Flowflex COVID-19 Antigen Home Test
- Information on the Simple 2 Test