「Abbott Receives FDA EUA for COVID-19, flu, and RSV combo assay」

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On the 5th March, Abbott announced that its "Alinity m Resp-4-Plex molecular assay" has obtained the U.S. FDA Emergency Use Authorization (EUA). "Four Viruses, One Swab, One Report"-- as declared by their release, this assay can simultaneously detect and identify four respiratory viruses, including SARS-CoV-2, influenza A, influenza B and Respiratory Syncytial Virus (RSV).

Although social distancing and wearing masks have significantly reduced the flu epidemic this year, it is still important to simplify the diagnosis process and detect the correct disease, because these viruses have similar symptoms but require different treatments.

The Alinity m Resp-4-Plex assay is a multiplex real-time reverse transcription (RT) polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of RNA from influenza A virus (flu A), influenza B virus (flu B), Respiratory Syncytial Virus (RSV) and SARS-CoV-2 in nasal or nasopharyngeal swab specimens collected by a healthcare provider or in nasal swab specimens that are self-collected at a healthcare location. Clinical signs and symptoms of respiratory viral infection due to these viruses can be similar and RNA from these viruses is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Negative results do not preclude influenza A, influenza B, RSV, or SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
The company said that, along with providing diagnostic results for four separate viruses, offering flexibility and efficiency, the four-way test will also help ease the resource strain on sample collection and preparation devices. “Abbott has been developing and introducing tests that have been playing a critical role in fighting the pandemic. The need for a combination of testing methods in different settings has never been more clear,” Andrea Wainer, Abbott executive vice president of rapid & molecular diagnostics, said in the release. “This newest test will allow for fast and efficient diagnosis and triage of patients who present with respiratory symptoms so they can be given the right care.”

The diagnostic’s authorization was also updated by Abbott to allow for the testing of pooled samples, enabling the screening of five people at once while conserving resources. It is estimated that more than

60% of COVID-19 cases may be asymptomatic. Together, the two tests support a strategy of catching a wider range of cases, and to distinguish COVID-19 infections from seemingly similar diseases.

Reference:

1. Conor Hale. 05 Mar 2021" Abbott scores testing green lights for symptomless COVID-19 cases, plus flu, RSV " *FIERCE Biotech news.*
2. 05 Mar 2021. "Four Viruses, One Swab, One Report" *Abbott News Room.*
3. ALINITY m RESP-4-PLEX ASSAY : https://www.molecular.abbott/int/en/alinity-m-resp-4-plex-assay

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