

### **Test 9192 Influenza A, Influenza B, and SARS-CoV-2 Test Note**

The CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay is a real-time RT-PCR multiplexed test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acid in upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. The Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay is intended for use in the detection and differentiation of SARS-CoV-2, influenza A, and/or influenza B viral RNA in patient specimens, and is not intended to detect influenza C. RNA from influenza A, influenza B, and/or SARS-CoV-2 viruses is generally detectable in upper and/or lower respiratory specimens during infection. Positive results are indicative of active infection but do not rule out bacterial infection or coinfection with other viruses; 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. Negative Flu SC2 Multiplex Assay results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information. Negative results obtained from individuals who are not exhibiting clinical signs and symptoms associated with respiratory viral infection at the time of specimen collections should be interpreted with particular caution. Negative results in asymptomatic individuals cannot be used as definitive evidence that an individual has not been exposed to SARS-CoV-2 or influenza viruses and has not been infected with any of these viruses.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay reported here. Per this authorization, fact sheets for health care providers and patients should be accessed at ≤ <https://www.fda.gov/media/139742/download>> and ≤ <https://www.fda.gov/media/139745/download>>.

For a Negative result (Not Detected), the provider may consider testing for other respiratory viruses. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation suggest that 2019-nCoV infection is possible, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected, re-testing should be considered in consultation with public health authorities. Invalid results indicate that there was an error in the generation of the result. The specimen was retested and yielded the same result. For a result of "Invalid," the provider may consider collecting a new specimen from the patient. Negative test results from specimens not stored in transport media per the manufacturer instructions, such as stored longer than 72 hours after collection at 2-8°C or not stored at -70°C beyond 72 hours after collection for most types of media, may be unreliable and the patient may be subject to extra precautions such as additional clinical monitoring, including collection of an additional specimen.