siParadigm
diagnostic informatics

SPECIMEN

Your No : -------	**Case No :** TV22-827	**Req No :**
Collected : 02/24/2022, ---- hr	**Sent :** 02/23/2022, 1630 hr	**Received :** , 1938hr
Prelim : None	**Final :** 04/15/2022	**Addendum :** None

PATIENT

Name : c481, ab491

DOB : 06/09/1990 (31 yrs.) **Sex :** Unspecified

ID #: xxx-xxx-xxxx **Tell :**

PHYSICIAN

Facility : Harismain12 **Account :** 2131231231

Administrator : Harry Hoti **Tel :** (111)111-1111 **Fax :** (120)425-1235

Address : . mardan2. Colorado Springs. Colorado. 12312312

DIAGNOSIS

Nasopharyngeal - Sawb: Indeterminate for SARS-CoV-2 (COVID-19)

COMMENT: We have not been able to determine if this sample is negative or positive for the presence of COVID-19 RNA because results are indeterminate “equivocal/borderline”. Results are confirmed by repeat analysis. Possible causes of indeterminate results include - but are not limited to -: suboptimal sample collection, improper specimen handling or shipping, low quantity of viral target in the clinical specimen approaching the Limit of Detection (LoD) of the assay, the presence of RT-PCR inhibitors in the sample, reagents or supplies, specimen mix-up, and/or low level non-specific nucleic acid amplifications. Please resubmit an additional specimen at no charge, if pertinent.

The TaqPath™ COVID-19 Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR). The test is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva, nasal, oropharyngeal, and nasopharyngeal swabs, nasopharyngeal and tracheal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. For this setting only, the FDA has not fully evaluated the TaqPath™ COVID-19 Combo Kit, but has approved it for use only under Emergency Use Authorization (EUA).

A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is presumptively infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. The TaqPath™ COVID-19 Combo Kit has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include any of the following: a recommendation for isolation of the individual, monitoring of household or other close contacts for symptoms, individual isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, and/or other unintended adverse effects. Reasons for false positive results include - but are not limited to – cross-reactivity with other non-SARS-CoV-2 “COVID-19” family of Corona viruses, specimen mix-up, RNA contamination during product handling and/or cross contamination during specimen handling, preparation or testing.

A negative test result means that SARSCoV-2 “COVID-19” RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. No evidence-based guidelines are established to determine the clinical sensitivity of the test in detecting carrier status or infection with SARS-CoV-2 COVID-19, particularly in the ambulatory setting (individuals with no symptoms). Nasopharyngeal specimens are most sensitive in an ambulatory setting. The limited available data suggests that the sensitivity of nasopharyngeal swabs may be in the range of 70-75%. Therefore, when diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient’s recent exposures and/or the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient’s recent exposures or clinical presentation indicate that COVID19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history and/or other clinical findings, re-testing should be considered in consultation with public health authorities. In the event of a false negative result, risks to patients could include any of the following: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, and/or other unintended adverse events. Causes for false negative results include - but are not limited to -: improper sample collection, degradation of the SARS-CoV-2 RNA during shipping/storage, the presence of RT-PCR inhibitors in the sample, reagents or supplies, specimen mix-up, significant mutation in the SARS-CoV-2 virus and specimen collection after SARS-CoV-2 RNA can no longer be found in the site sampled. The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. For additional information, please contact your healthcare provider.

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Patient Name : c481, ab491 **Case # :** TV22-827

*This test has not been FDA cleared or approved. The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

End of Report