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Spokane, WA 99220-3405

Medical Director:
Alden Webb, DO

Ask the Pathologist:
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MOLECULAR DIAGNOSTIC REPORT

LABSENDER, KEN P	**ACCESSION #: CW-21-99997**
Patient ID:	Collected: 11/23/2021
Gender: M / Age: 17	Received: 11/23/2021
Birthdate: 5/12/2004	Reported: 11/23/2021
P. 5092175258	Reference #:

REFERRING PROVIDER: George Papanicolaou, MD | Clinic Phone: (509)892-2700

COPY TO:

DELIVERY ADDRESS: George Papanicolaou, MD | Incyte Diagnostics - Spokane | PO Box 3405 13103 E Mansfield Spokane Valley WA, 99216

SPECIMEN SOURCE: A. SARS-CoV2 NAAT by PCR,
PROVIDED INFORMATION:

MOLECULAR DIAGNOSTIC RESULTS:
SARS-CoV-2 Not Detected

ADDITIONAL NOTES:
The Panther Fusion SARS-CoV-2 Assay is a multiplex real-time PCR (RT-PCR) in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 from individuals who meet COVID-19 clinical and/or epidemiological criteria. In general, SARS-CoV-2 RNA can be detected during the acute phase of infection.
Positive results indicate the presence of SARS-CoV-2 RNA. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.
Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with other clinical observations, patient history, and epidemiological information.

The Panther Fusion SARS-CoV-2 Assay is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA, after which the test may no longer be used. The Panther Fusion SARS-CoV-2 Assay is for use only under EUA in US laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests. Incyte Diagnostics is certified under CLIA to perform high complexity clinical laboratory testing.

PERFORMING LABORATORY:
Differential testing was performed by Incyte Diagnostics, 15912 E. Marietta Ave. Suite 200, Spokane, WA 99216, 509-892-2700, CLIA #: 50D2172899.

FINAL DIAGNOSIS PERFORMED BY: TAMTRON PATHOLOGIST, M.D., Pathologist Nov 23 2021 12:40PM