EpiSwitch® CST COVID-19 Severity Risk Report

Personalized Immune Health 3D-Genetic Profile



The **EpiSwitch COVID-19 Severity Test** result of **high-risk** for this specimen is indicative of the patient's likelihood of developing critical disease resulting from **UNTREATED** SARS-CoV-2 virus infection. This result does not inform on the risk of becoming infected. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

Patient Information

Gender	Female
Medical Record #	c14456d0
Report #	CIRT0254

Physician Release

Physician Name	Christopher Smith, MD, MS
Facility Name	XXX-XXX-XXX-XXX
Address	[Address line] [City], [State] [Zip]
Phone	811-555-4210
Account Ref	FL

Specimen Information

Report Date	28-FEB-2021
Receipt Date	28-FEB-2021
Collection Date	20-FEB-2021
Specimen Type	WB EDTA K3
Specimen ID	D000097422

EpiSwitch COVID-19 Severity Risk Assay Description

EpiSwitch COVID-19 Severity Test evaluates six unique Chromosome Conformational Signatures (CCSs) shown to be associated with immunity and are prognostic for critical COVID-19 disease.

Intended Use: The blood test is intended to assess the risk level for developing critical COVID-19 disease resulting from untreated SARS-CoV-2 virus infection. The test is not intended to evaluate an individual's risk of infection.

References

- Hunter, E., Koutsothanasi, C., et al. (2021). 3D genomic capture of regulatory immuno-genetic profiles in COVID-19 patients for prognosis of severe COVID disease outcome. BioRxiv. https://doi.org/10.1101/2021.03.14.435295. Co-published by authors from Oxford BioDynamics, University of Oxford, West Hertfordshire NHS Trust, Oregon Health & Science University, and Norwich Medical School at the University of East Anglia.
- Hunter, E., Koutsothanasi, C., et al. (2021). Development and validation of blood-based prognostic biomarkers for severity of COVID disease outcome using EpiSwitch 3D genomic regulatory immuno-genetic profiling. MedRxiv. https://doi.org/10.1101/2021.06.21.21259145. Co-published by authors from Oxford BioDynamics, University of Oxford, West Hertfordshire NHS Trust, Oregon Health & Science University, and Norwich Medical School at the University of East Anglia.
- 3. Clinical Spectrum of SARS-CoV-2 Infection. https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/
- 4. Therapeutic Management of Adults With COVID-19. https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/

Disclaimer: The EpiSwitch COVID-19 Severity Test is a laboratory-developed test (LDT). It has not been cleared or approved by the US Food and Drug Administration. The laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity clinical testing. Decisions regarding patient care and treatment should not be solely based on a single test such as this test, rather, on the independent medical judgment of the treating physician taking into consideration all available information concerning the patient's conditions, including other clinical tests, in accordance with the standard of care in each healthcare setting.

This test was performed at NEXT Bio Research Services, LLC, 11601 Ironbridge Rd, Chester, VA 23831 – CLIA #41D2104154. For questions about the report, email CST.TEST@myOBDX.com or call 888-236-8896.

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