

A Healthcare Provider's Guide

EpiSwitch[®] CST

Prognostic Test To Assess Personalized Risk of Severe
Illness Due to SARS-CoV-2 Virus



OXFORD BIODYNAMICS

EpiSwitch CST

EpiSwitch COVID-19 Severity Test (CST) Is a Blood Test for All Adults

EpiSwitch CST delivers critical information based on genetic markers to aid in determining an individual's risk of severe illness requiring critical care due to COVID-19:



EpiSwitch CST is the best predictor of a severe reaction to SARS-CoV-2 infection.



Helps identify persons that would most likely require critical care.



EpiSwitch CST is the only predictor of clinical course, current tests focus only on the detection of COVID-19.



Independent of COVID-19 status (pre-infected, infected or post-infected).



Knowledge of the EpiSwitch CST score allows the doctor and patient to formulate an effective management plan.



qPCR test using a routine blood draw, with results reported in 48-72 hours.

The Benefits of Using EpiSwitch CST in Your Clinic



Easy to implement



Personalized insight into COVID-19 risk



Impactful actionable guidance

EpiSwitch CST Interpretation: Personalized Risk Guidance

Average Risk

Average Risk Management Guidance

The **EpiSwitch COVID-19 Severity Test** result is in the **average-risk range**. If this individual has or becomes infected with the SARS-CoV-2 virus, the likelihood of a presentation requiring critical care is low. This result does not inform on the risk of becoming infected. Those with an Average Score must continue to follow government and local health department guidelines. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

High Risk

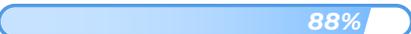
High Risk Management Guidance

The **EpiSwitch COVID-19 Severity Test** result for this specimen is in the **high-risk range**. This individual is predicted to be at high risk to require critical care (ICU) in response to an UNTREATED SARS-CoV-2 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.

A Validated Prognostic Test for Predicting Severe Illness Due to COVID-19

EpiSwitch CST delivers high sensitivity and specificity for predicting severe illness requiring critical care in individuals infected with SARS-CoV-2†. The blood test measures six genetic markers and combines them into a risk category. EpiSwitch CST was developed using a global study of COVID-19 patients from North America, South America and Europe.

Accuracy:  88%

Sensitivity:  88%

Positive Predictive Value:  93%

Specificity:  88%

Negative Predictive Value:  80%

† 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>

† 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>

Both journal articles were 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.

Intended Use: The test is intended to identify people who are at the highest risk of critical COVID-19 disease resulting from untreated SARS-CoV-2 virus. People with a high risk of severe or critical disease may benefit from increased infection mitigation and in the event of infection, early use of medications or other interventions. An average risk with a lower score should not be construed as lower severity probability; complications not requiring critical care are possible. The test is not intended to evaluate an individual's risk of infection.

Disclaimer: The EpiSwitch Covid-19 Severity Test was developed, and its performance characteristics determined by the clinical lab. It has not been cleared or approved by the US Food and Drug Administration. The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigation or for research. The laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity clinical testing. Decisions regarding care and treatment should not be based on a single test such as this test. Rather, decisions on care and treatment should be based on the independent medical judgment of the treating physician taking into consideration all available information concerning the patient's condition, including other clinical tests, in accordance with the standard of care in a given community.

EpiSwitch CST Sample report

High risk example

Risk Category

Risk Category presented as Average Risk or High Risk.

Risk interpretation

Specific to the patient's Risk Category, presented as an aid to the physician.

Assay Description

Giving detail into the six biomarkers that are measured and combined into the single EpiSwitch CST score.

EpiSwitch® CST COVID-19 Severity Risk Report

Personalized Immune Health 3D-Genetic Profile

Patient Name Peterson, Janette	Date of Birth 22-DEC-1975
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Patient Information
Gender Female
Patient ID D000097422
Medical Record # c14456d0
Report # COVID0254
Physician Release
Physician Name Christopher Smith, MD, MS
Account 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 Score

Your Risk Level

Average Risk **High Risk**

The EpiSwitch COVID-19 Severity Test result for this specimen is in the **high-risk range**. This individual is predicted to be at high risk to require critical care (ICU) in response to an **UNTREATED** SARS-CoV-2 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.

EpiSwitch COVID-19 Severity Risk Assay Description

EpiSwitch COVID-19 Severity Test evaluates six unique Chromosome Conformational Signatures (CCS), that are prognostic for critical disease associated with genetic loci that have been shown to affect immune health.

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References

- Hunter, E., Koutsothanas, 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., Koutsothanas, 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.
- Clinical Spectrum of SARS-CoV-2 Infection. <https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/>
- Therapeutic Management of Adults With COVID-19. <https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/>

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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.

Medical Director Signature _____ Date (MM/DD/YYYY) _____

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CST 102-01-01-03

- EpiSwitch CST score provides a critical personalized measure of the risk of severe illness due to COVID-19 infection.
- Patient risk is presented as a single easy to read EpiSwitch CST score providing a quantitative aid in estimating the prognosis of patients when infected with SARS-CoV-2.

- EpiSwitch CST score report includes clear guidance for interpretation of the risk score by a healthcare professional.
- Decisions on care and treatment should be based on the independent medical judgement of the treating physician taking into consideration all available information.

EpiSwitch® CST Requisition Form

To order the test, fax the completed requisition form to 1.240.913.5681 For any questions, please call 1.888.236.8896 or email CST.TEST@myOBDX.com

For Laboratory Use Only

TESTING MAY BE DELAYED IF REQUIRED FIELDS ARE NOT PROVIDED

Patient Information

Gender: (optional) F M

First Name _____ MI _____ Last Name _____ Medical Record # (optional) _____ DOB (MM/DD/YYYY) _____

Address _____ City _____ State _____ Postal Code _____ Country _____ Primary Phone _____

Patient History

Has the patient been vaccinated for the SARS CoV-2 virus?

Y N

Vaccine Given (if known) _____

Additional Case information (optional)

Treating Physician Information

Please provide best contact information for case follow-up

Facility or Practice Name _____ Treating Physician (full legal name) _____ NPI Number _____

Facility/Practice Address _____ City _____ State _____ Postal Code _____ Country _____ Phone _____

Oxford BioDynamics Account # (optional) _____ Email _____ Fax _____

Additional Physician to be Copied (optional) _____ Facility Name (optional) _____ Email (optional) _____ Fax (optional) _____

Test Menu and Specimen Collection

Test	Description	Accepted Specimen Type	Minimum Volume Required
<input type="radio"/> EpiSwitch CST	Prognostic test for likelihood of severe immune reaction following SARS-CoV-2 infection	Whole blood, EDTA Tube	3 mL

Intended Use and Technical Information

Intended Use: The test is intended to identify people who are at the highest risk of critical COVID-19 disease resulting from untreated SARS-CoV-2 virus. People with a high risk of severe or critical disease may benefit from increased infection mitigation and in the event of infection, early use of medications or other interventions. An average risk with a lower score should not be construed as lower severity probability; complications not requiring critical care are possible. The test is not intended to evaluate an individual's risk of infection.

EpiSwitch CST is a quantitative 3D-genomic laboratory derived test for the determination of likely risk of severe immune reactions if a patient is infected with the SARS-CoV-2 coronavirus. The test analyzes six epigenomic features to derive a relative risk score for severe immune reactions following SARS-CoV-2 infection.

Billing Information

Contact Name _____ Email _____ Phone _____

Address _____ City _____ State _____ Postal Code _____ Country _____

Test Authorization and Physician Signature

The undersigned certifies that he/she is licensed to order the test(s) listed above and that such test(s) are medically necessary for the care/treatment of this patient

Treating Physician Signature

Printed Name (full legal name)

Date (MM/DD/YYYY)



Get Started With EpiSwitch CST

Healthcare Provider & Patient Resources

Your online resource to learn more about EpiSwitch CST Score
www.CovidSeverityTest.com

LEARN MORE by contacting a Clinical Customer Service representative at 888-236-8896

- Learn more about EpiSwitch CST and read healthcare provider testimonials.
- Securely access and manage your patients' EpiSwitch CST Score results in the online clinician portal.
- Find out how to create an account and offer the test to your patients.

Patient and Healthcare Provider Support



Email: CST.TEST@myOBDX.com

Phone: 888-236-8896

