

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 of **average-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.

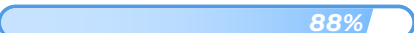
High Risk

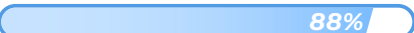
High Risk Management Guidance

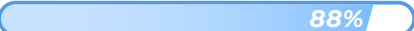
The **EpiSwitch COVID-19 Severity Test** result of **high-risk** for this specimen is indicative of the patient's likelihood of developing critical disease resulting from **UNTREATED** SARS-CoV-2 virus infection. This result does not inform on the risk of becoming infected. This result should be considered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

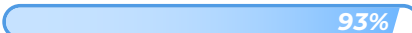
A Validated Prognostic Test for Predicting Severe Illness Due to COVID-19

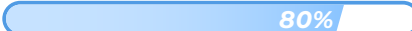
EpiSwitch CST delivers high sensitivity and specificity for predicting severe illness requiring critical care in individuals infected with SARS-CoV-2†. The blood test measures six genetic markers and combines them into a risk category. EpiSwitch CST was developed using a global study of COVID-19 patients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

Accuracy:  88%

Sensitivity:  88%

Specificity:  88%

Positive Predictive Value:  93%

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 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.

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.

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

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 Score

Your Risk Level

Average Risk

High Risk

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.

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

1. Hunter, E., Koutsathanasi, 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.
2. Hunter, E., Koutsathanasi, 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/>

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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

CST 102-01-01-05

- 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 (US)

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

TESTING MAY BE DELAYED IF REQUIRED FIELDS ARE NOT PROVIDED

For Lab Use

Order #

For Lab Use

Kit Barcode ID #

Patient Information

First Name	MI	Last Name	Medical Record # (optional)	DOB (DD-MMM-YYYY)	Gender: (optional) ☐ F ☐ M
Address		City	State	Postal Code	Country
					Primary Phone

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
☐ 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 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.

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.

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
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CST 101-01-01-06

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

