

EpiSwitch® CiRT Technical Overview

EpiSwitch CiRT is a quantitative laboratory developed blood test to assess the likelihood of response to an Immune Checkpoint Inhibitor (ICI) therapy. The test evaluates eight (8) DNA regulatory (epigenetic) markers called chromatin-conformational signatures (CCS) and stratifies patients based on their probability of responding to an ICI. The test may be run at any stage of treatment, including post-initiation of an ICI.

Intended Use

Checkpoint inhibitor Response Test (CiRT) is a blood test that evaluates DNA conformational structures in the immune cells to assess the likelihood of response to immune checkpoint inhibitor (ICI) therapy targeting PD-L1 (Atezolizumab, Avelumab, Duralumab) and PD-1 (Pembrolizumab). The results are not specific to ICI agent or to type of tumor. The test is intended to provide supplemental information to cancer treatment professionals on the overall clinical picture. It should not be used as the sole data point in treatment decisions.

EpiSwitch CiRT Interpretation: Personalized Immune Health 3D-Genetic Profile

Low Probability

Low Probability Management Guidance

The **EpiSwitch Checkpoint inhibitor Response Test (CiRT)** result for this specimen is in the **Low Likelihood of Response** range to an ICI therapy. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

High Probability

High Probability Management Guidance

The **EpiSwitch Checkpoint inhibitor Response Test (CiRT)** result for this specimen is in the **High Likelihood of Response** range to an ICI therapy. Individuals in the group have a greater chance of benefiting from an ICI agent. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

A Validated Predictive Test to Stratify Individuals Based on Their Likelihood of Response to Immune Checkpoint Inhibitors (ICIs)

EpiSwitch CiRT delivers high sensitivity and specificity for predicting the beneficial use of an ICI agent. The blood test measures eight epigenetic markers to determine the most likely outcome of treatment.

Accuracy:  85%

Sensitivity:  93%

Positive Predictive Value:  64%

Specificity:  82%

Negative Predictive Value:  97%

References

1. Hunter, E., Dizfouli, M., et al., (2021). Development and validation of blood-based predictive biomarkers for response to PD-(L)-1 checkpoint inhibitors: evidence of a universal systemic core of 3D immunogenetic profiling across multiple oncological indications. MedRxiv. <https://doi.org/10.1101/2021.12.21.21268094>.
2. Shah, P., Hunter, E., et al., (2019). Development and validation of baseline predictive biomarkers for response to avelumab in second-line (2L) non-small cell lung cancer (NSCLC) using EpiSwitch epigenetic profiling. SITC, J. Immunotherapy Cancer 7(282) P142. <https://dx.doi.org/10.1186/s40425-019-0763-1>. Co-published by authors from Oxford BioDynamics, EMD Serono, Pfizer, and the Mayo Clinic.
3. Shah, P., Hunter, E., et al., (2019). Development and validation of baseline predictive biomarkers for response to immuno-checkpoint treatments in the context of multi-line and multi-therapy cohorts using EpiSwitch epigenetic profiling. SITC, J. Immunotherapy Cancer 7(282) P143. <https://dx.doi.org/10.1186/s40425-019-0763-1>. Co-published by authors from Oxford BioDynamics, EMD Serono, Pfizer, and the Mayo Clinic.

Disclaimer: The EpiSwitch CiRT Response Test is a laboratory developed test (LDT). It has not been reviewed or cleared 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.

Get Started With EpiSwitch® CiRT

Healthcare Provider & Patient Resources

Your online resource to learn more about EpiSwitch CiRT: www.mycirt.com

LEARN MORE by contacting your local EpiSwitch CiRT customer service representative by phoning **888-236-8896** or emailing us at CIRT.TEST@myOBDX.com

EpiSwitch CiRT Sample Report

Response Category

Response Category presented as *High Probability* or *Low Probability*.

Test interpretation

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

Assay Description

Giving detail into the eight biomarkers that are measured and combined into the single EpiSwitch CiRT score.

EpiSwitch® CiRT Response 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 CiRT Response Profile

Your Response Level

Low Probability

High Probability

The EpiSwitch Checkpoint inhibitor Response Test (CiRT) result for this specimen is in the **High Likelihood of Response** range to an Immune Checkpoint Inhibitor (ICI) therapy. Individuals in the group have a greater chance of benefiting from an ICI agent. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

EpiSwitch Checkpoint inhibitor Response Test Description

Intended Use: Checkpoint inhibitor Response Test (CiRT) is a blood test that evaluates DNA conformational structures in the immune cells to assess the likelihood of response to immune checkpoint inhibitor (ICI) therapy targeting PD-L1 (Atezolizumab, Avelumab, Durvalumab) and PD-1 (Pembrolizumab). The results are not specific to ICI agent or to type of tumor. The test is intended to provide supplemental information to cancer treatment professionals on the overall clinical picture. It should not be used as the sole data point in treatment decisions.

EpiSwitch CiRT Response Test is a quantitative laboratory developed blood test to assess the likelihood of response to an ICI therapy. The test evaluates eight (8) DNA regulatory (epigenetic) markers called chromatin-conformational signatures (CCS) and stratifies patients based on their probability of responding to an ICI. The test may be run at any stage of treatment, including post-initiation of an ICI.

References

1. Hunter, E, Dizfouli, M, et al., (2021). Development and validation of blood-based predictive biomarkers for response to PD-(L)-1 checkpoint inhibitors: evidence of a universal systemic core of 3D immunogenetic profiling across multiple oncological indications. MedRxiv. <https://doi.org/10.1101/2021.12.21.21268094>.
2. Shah, P, Hunter, E, et al., (2019). Development and validation of baseline predictive biomarkers for response to avelumab in second-line (2L) non-small cell lung cancer (NSCLC) using EpiSwitch epigenetic profiling. SITC, 3. Immunotherapy Cancer 7(282) P142. <https://dx.doi.org/10.1186/s40425-019-0763-1>. Co-published by authors from Oxford BioDynamics, EMD Serono, Pfizer, and the Mayo Clinic.
3. Shah, P, Hunter, E, et al., (2019). Development and validation of baseline predictive biomarkers for response to immuno-checkpoint treatments in the context of multi-line and multi-therapy cohorts using EpiSwitch epigenetic profiling. SITC, 3. Immunotherapy Cancer 7(282) P143. <https://dx.doi.org/10.1186/s40425-019-0763-1>. Co-published by authors from Oxford BioDynamics, EMD Serono, Pfizer, and the Mayo Clinic.

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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 CIRT.TEST@myOBDX.com or call 1.888.236.8896.

Medical Director Signature

Date

CIRT 102-01-01-01

High Likelihood
of Response
example

The Benefits of Using EpiSwitch CiRT in Your Clinic



Personalized insight into
ICI therapy response



Easy to
implement



Impactful
actionable guidance



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