

Test Result Report

PATIENT INFORMATION		PHYSICIAN INFORMATION	
Patient: <First and Last Name>	MRN (if provided): <#####>	Physician: Dr. <First and Last Name>	
Date of Birth: <Mon DD, YYYY>	Gender: <Gender>	Facility: <Ordering Facility Name>	
Tumor: <Tumor Type>	Specimen Type: <Sample Format>	Address: <Street Address, City, State, Postal Code>	
VS Accession No: VSLCYMMDDXXXX	Date of Collection: <Mon DD, YYYY>	Country: <Country Code>	
Date Received: <Mon DD, YYYY>	Date Performed Reported: <Mon DD, YYYY>	Phone: <Phone Number>	Fax: <Fax Number>

TEST RESULT: VERISTRAT GOOD

RESULTS INTERPRETATION^{1,2}:

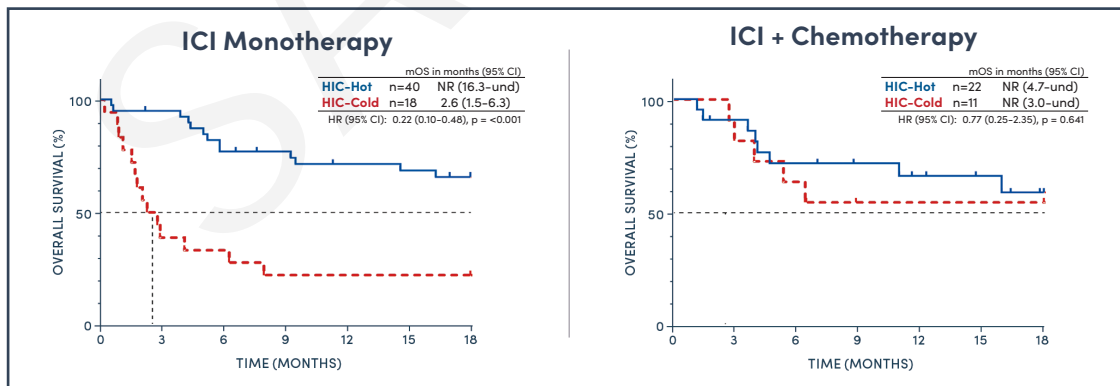
The VeriStrat test is a novel blood-based host immune classifier (HIC) for patients with non-small cell lung cancer. Clinical studies have shown that the test is predictive and prognostic of outcomes independent of ECOG performance status, mutation status, PD-L1 expression, treatment choice, and line of therapy.

A classification of **VeriStrat Good**, also known as HIC-Hot, implies that tumor directed immunity is not suppressed and patients are potentially responsive to therapies that boost immune response. Patients with a **VeriStrat Good** classification had better outcomes, on average living 2-2.5 times longer when compared to patients classified as VeriStrat Poor.

Patients with a **VeriStrat Good** classification are likely to benefit from standard of care therapies, including immunotherapy regimens.

PD-L1: programmed death ligand 1; PD-L1 high: PD-L1 expression \geq 50%; PS: performance status; und: undefined; ICI: immune checkpoint inhibitors; mOS: median overall survival; NR: not reached; **VeriStrat Good: HIC-Hot or HIC-H;** **VeriStrat Poor: HIC-Cold or HIC-C.**

Kaplan-Meier analysis of overall survival in patients with advanced stage NSCLC receiving ICI as monotherapy or ICI in combination with chemotherapy by HIC classification in the subsets of patients with high PD-L1 expression and ECOG PS 0-1.¹



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biodesix.com
919 W Dillon Road, Louisville, CO 80027
CLIA Number 06D2085730

Donald Joe Chaffin, M.D., CAP Accredited CLIA Laboratory Director



BIOLOGICAL UNDERPINNINGS OF THE VERISTRAT TEST³

The VeriStrat test is a multivariate test that incorporates the measurements of the proteoforms of serum amyloid A, beta-2 microglobulin, and C-reactive protein, which are the primary constituents of the spectral features measured in the test. The proteins assayed have individual prognostic value for oncology and immuno-oncology outcomes and have been shown to have a direct effect on a patient's immune activity. VeriStrat signatures are determined using Artificial Intelligence (AI) algorithms and individual test results can feature varying expressions of the proteins in the signature.

In a **VeriStrat Good (HIC-Hot)** signature, these proteins are commonly seen at endogenous levels.

In a **VeriStrat Poor (HIC-Cold)** signature, a combination of these proteins are commonly seen at increased levels.

PROTEIN IN VERISTRAT SIGNATURE	MECHANISM OF ACTION
Serum Amyloid A (SAA1, SAA2, SAA4)	SAA's are a component of the acute phase inflammatory response that activate myeloid derived suppressor cells. Elevated levels detected in blood may indicate that the immune response to the tumor is suppressed.
Beta-2-Microglobulin (B2M)	B2M is critical for presentation of antigens by MHC Class I molecules to cytotoxic T-cells. Elevated levels detected in blood may indicate defective antigen presentation.
C-Reactive Protein (CRP)	CRP is the prototypic acute phase reactant protein that suppresses CD8 and CD4 T-cells as well as B-cells. Elevated levels detected in blood may indicate a reduction in the immune response to the tumor.

VERISTRAT[®] ANALYSIS DESCRIPTION:

Protein expression analysis utilizing MALDI-ToF mass spectrometry and data algorithms were performed on the submitted patient plasma sample. A test result of VeriStrat Good, VeriStrat Poor, or Indeterminate was assigned. Inadequate sample quality (for example, evidence of hemolysis on the Bodesix Collection Device) may limit our ability to obtain a VeriStrat result. Values obtained with a different assay method or kit cannot be used interchangeably.

VeriStrat proteomic test results are adjunctive to the ordering physician's workup and should be used in combination with the patient's clinical history, other diagnostic tests, and clinicopathological factors customarily evaluated by a qualified physician. VeriStrat results are intended to be used for clinical purposes and should not be regarded as research use only or investigational. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

Any questions regarding the use or interpretation of the VeriStrat test should be directed to Bodesix Customer Care at 1.866.432.5930.

REFERENCES:

- Rich, P. et al. Real-World Performance of Blood-Based Proteomic Profiling in First-Line Immunotherapy Treatment in Advanced Stage Non-Small Cell Lung Cancer. *Journal for ImmunoTherapy of Cancer*, 2021.
- Leal, T.A. et al. Prognostic Performance of Proteomic Testing in Advanced Non-Small Cell Lung Cancer: A Systematic Literature Review and Meta-Analysis. *Current Medical Research and Opinion*, 2020.
- Koc, M.A. et al. Molecular and Translational Biology of the Blood-Based VeriStrat Proteomic Test Used in Cancer Immunotherapy Treatment Guidance. *Journal of Mass Spectrometry and Advances in the Clinical Lab*, 2023.

The VeriStrat test was developed and its performance characteristics determined by Bodesix, Inc. as a laboratory developed test. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity clinical laboratory testing.

By accepting receipt of the VeriStrat Test Result Report or any content derived from it ("VS TRR"), the ordering physician, institution of ordering physician, or any third parties to whom the VS TRR is transferred, agree the VS TRR may only be used for the clinical management of the patient identified in the VS TRR by the physician. Any other use of the VS TRR including, without limitation, correlative studies, diagnostic development, derivative works or other analyses is expressly prohibited. The results of any unauthorized use of the VS TRR shall belong solely and exclusively to Bodesix, Inc. Additional terms and conditions related to this VS TRR can be found at www.biodesix.com.

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TEST RESULT: VERISTRAT POOR

RESULTS INTERPRETATION^{1,2}:

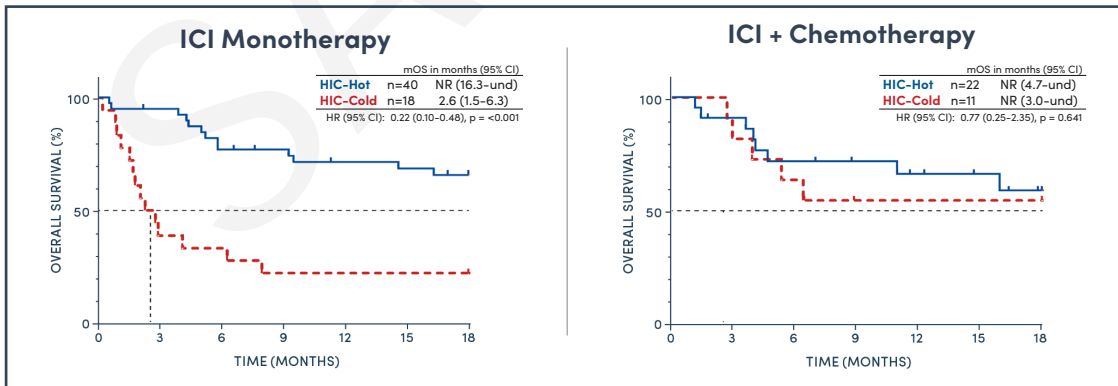
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A classification of **VeriStrat Poor**, also known as HIC-Cold, implies that the tumor directed immunity is compromised. Patients with a **VeriStrat Poor** classification have worse overall survival compared to patients classified as VeriStrat Good.

However, patients with a **VeriStrat Poor** classification being considered for immune checkpoint inhibitor (ICI) therapy may benefit from the addition of chemotherapy. A recent study demonstrated superior median overall survival in patients with high PD-L1 expression receiving ICI plus chemotherapy versus ICI alone (not reached vs. 2.6 months, respectively) as well as in all patients receiving immunotherapy regimens (6.4 months vs. 2.8 months, respectively).

PD-L1: programmed death ligand 1; PD-L1 high: PD-L1 expression \geq 50%; PS: performance status; und: undefined; ICI: immune checkpoint inhibitors; mOS: median overall survival; NR: not reached; **VeriStrat Good: HIC-Hot or HIC-H; VeriStrat Poor: HIC-Cold or HIC-C.**

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