veristrat®
proteomic test

Phone: **1.866.432.5930** | Fax: **1.866.432.3338**
Email: **custcare@biodesix.com**

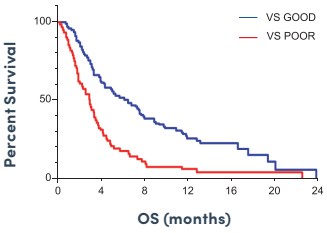
Test Result Report

PATIENT INFORMATION		PHYSICIAN INFORMATION	
Patient: <First and LastName>		**Physician:** Dr. <First and LastName>	
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: VSLC########-XXX	**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 POOR

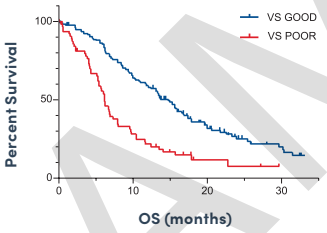
Results Interpretation: In patients with non-small cell lung cancer, published data demonstrate that VeriStrat® proteomic test results are predictive of outcomes, independent of ECOG performance status, mutation status, PD-L1 expression, treatment choice, and line of therapy.[1,2] VeriStrat Poor patients derive less clinical benefit from standard of care therapies as compared to VeriStrat Good patients. Patients with a VeriStrat Poor result may benefit from an alternative treatment strategy, including clinical trials, novel therapy combinations, or palliative care. Additionally, if active treatment is being considered, expediting treatment initiation is of particular importance for these patients.

PLACEBO[2]



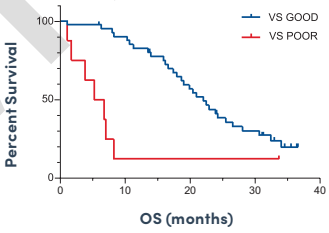
	N	Median OS (Mo)
VS Good	83	6.6
VS Poor	61	3.1
HR=0.44	(95% CI:0.31-0.63), p<0.0001	

CHEMOTHERAPY[3]



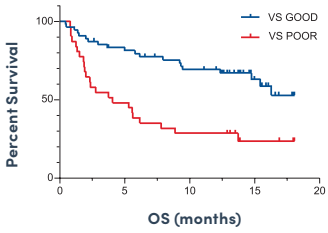
	N	Median OS (Mo)
VS Good	136	14.7
VS Poor	66	6.3
HR=0.41	(95% CI:0.30-0.58), p<0.001	

TARGETED THERAPY[1]



	N	Median OS (Mo)
VS Good	41	22.8
VS Poor	8	6.5
HR=0.27	(95% CI:0.12-0.64), p<0.0001	

IMMUNOTHERAPY[4]



	N	Median OS (Mo)
VS Good	54	NR*
VS Poor	31	4.1
HR=0.33	(95% CI:0.18-0.61), p<0.001	

*Not Reached

SAMPLE

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CAP Accredited CLIA Laboratory Director

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veristrat® proteomic test

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VERISTRAT® DATA OVERVIEW

Study	N	Population	Treatment Regimens	Median OS: VS Good	Median OS: VS Poor	Hazard Ratio	P Value
TREATMENT NAIVE							
Rich, et al (INSIGHT)[2]	85	Multiple histologies	Immunotherapy-Based*	NR**	4.1	0.33 (0.18-0.61)	<0.001
Rich, et al (INSIGHT)[2]	237	Multiple histologies	Platinum-Based***	14.3	7.9	0.63 (0.43-0.92)	0.016
Grossi, et al (NEXUS)[4]	202	Adenocarcinoma	Platinum Doublet	14.7	6.3	0.41 (0.30-0.58)	<0.001
Grossi, et al[5]	76	Adenocarcinoma	Platinum Doublet	10.8	3.4	0.26 (0.15-0.47)	<0.0001
Amman, et al[6]	88	Multiple histologies	Erlotinib	10.8	3.9	0.36 (0.21-0.60)	0.001
PREVIOUSLY TREATED							
Rich, et al (INSIGHT)[2]	117	Multiple histologies	Single Agent Immunotherapy	14.9	6.0	0.32 (0.19-0.55)	<0.001
Rich, et al (INSIGHT)[2]	84	Multiple histologies	Chemotherapy	15.6	5.2	0.26 (0.14-0.46)	<0.001
Buttigliero, et. al (MARQUEE)[1]	1,046	Adenocarcinoma	Tivantinib + Erlotinib	11.6	4.0	0.33 (0.26-0.42)	<0.0001
Buttigliero, et. al (MARQUEE)[1]	1,046	Adenocarcinoma	Placebo + Erlotinib	10.2	4.0	0.45 (0.35-0.57)	<0.0001
Gadgeel, et al (LL8)[7]	336	Squamous	Afatinib	11.5	4.7	0.40 (0.31-0.51)	<0.0001
Gadgeel, et al (LL8)[7]	339	Squamous	Erlotinib	8.9	4.8	0.43 (0.34-0.55)	<0.0001
Grossi, et al[8]	60	Multiple histologies	Nivolumab	9.9	4.0	0.50 (0.25-1.00)	0.046
Gregorc, et al (PROSE)[9]	134	Multiple histologies	Erlotinib	11.0	3.0	0.28 (0.19-0.43)	<0.0001
Gregorc, et al (PROSE)[9]	129	Multiple histologies	Chemotherapy	10.9	6.4	0.50 (0.34-0.76)	0.0008
Carbone, et al (BR.21)[3]	292	Multiple histologies	Erlotinib	10.5	5.0	0.37 (0.28-0.48)	<0.0001
Carbone, et al (BR.21)[3]	144	Multiple histologies	Placebo	6.6	3.1	0.44 (0.31-0.63)	<0.0001

SAMPLE

VERISTRAT® ANALYSIS DESCRIPTION:

Protein expression analysis utilizing MALDI-ToF mass spectrometry and data algorithms were performed on the submitted patient serum sample. A test result of VeriStrat Good, VeriStrat Poor, or Indeterminate was assigned. Inadequate sample quality (evidence of hemolysis on the Biodesix Collection Device) may limit ability to obtain a VeriStrat result.

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 to be used for clinical purposes and should not be regarded as research use only or investigational. Any questions regarding the use or interpretation of the VeriStrat test should be directed to Biodesix Customer Care at 1.866.432.5930.

REFERENCES****:

1. Buttigliero C, et al. The Oncologist. 2018 Aug 23
2. Rich, et al. 2019 Multidisciplinary Thoracic Cancers Symposium Poster.
3. Carbone DP et al. J Thorac Oncol. 2012;7(11):1653-1660.
4. Grossi, et al. Lung Cancer 117 (2018): 64–69.
5. Grossi F et al. British Journal of Cancer 116.1 (2017): 36.
6. Amann, et al. J Thorac Oncol. 2010: 5(2):169-178.
7. Gadgeel S, et al. Lung Cancer 109 (2017): 101-108.
8. Grossi, F, et al. J Thorac Oncol. 2017; 12 (S1322 P3.02c-074)
9. Gregorc V et al. Lancet Oncol. 2014;15(7):713-721.

*Includes patients treated with immune checkpoint inhibitors, both as a single agent and in combination with chemotherapy.

**Not reached

***Includes patients treated with platinum-based chemotherapy regimens.

****For other tumor types, references and available data on file can be provided upon request.

VeriStrat was developed and its performance characteristics were determined by Biodesix, Inc. The laboratory meets the requirements for high complexity tests under the Clinical Laboratory Improvement Amendments of 1988, as amended, and its implementing regulations.

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 Biodesix, Inc. Additional terms and conditions related to this VS TRR can be found at www.biodesix.com.

Patient:
<First and LastName>

VS Accession No:
VSLC########-XXX

Date Performed | Reported:
<Mon DD, YYYY>

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