genestrat® genomic 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 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>	
GS Accession No: BDXAYYMMDDXXXX	**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>

GENESTRAT® GENOMIC TEST RESULTS

Test	Variant	Results
EGFR Mutations	Exon 19 ΔE746-A750	**POSITIVE**
	Exon 21 L858R	Negative
	Exon 18 G719A, G719C, G719S | Exon 20 S768I | Exon 21 L861Q	Negative
	Exon 20 T790M	Negative
ALK Fusions	EML4	Negative
KRAS Mutations	G12C	Negative
	G12D	Negative
	G12V	Negative
BRAF Mutation	V600E	Negative

RESULTS INTERPRETATION: EGFR | ALK | KRAS | BRAF

Positive: Presence of 2 or more copies of the variant

Negative: Presence of fewer than 2 copies of the variant

Quantity Not Sufficient (QNS): Test performed, and results not definitive – due to lack of sufficient amount of nucleic acid. No bill will be submitted for this gene. Redraw recommended.

Test Not Performed (TNP)

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

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GENESTRAT® TREATMENT IMPLICATIONS

Available Mutations	Treatment Implications for Early Stage NSCLC[1]	Treatment Implications for Advanced Stage NSCLC[1-17]
EGFR Mutations Exon 19 ΔE746-A750 | Exon 21 L858R	May benefit from adjuvant osimertinib	May benefit from treatment with osimertinib or erlotinib, afatinib, gefitinib, dacomitinib, erlotinib + ramucirumab, or erlotinib + bevacizumab
Exon 18 G719A, G719C, G719S Exon 20 S768I | Exon 21 L861Q	Consider clinical trial enrollment	May benefit from treatment with afatinib, osimertinib, or erlotinib, gefitinib, dacomitinib
Exon 20 T790M	Consider clinical trial enrollment	May benefit from treatment with osimertinib if previously treated with 1st or 2nd generation EGFR-TKIs
ALK Fusions EML4	Consider clinical trial enrollment	May benefit from treatment with alectinib, brigatinib, lorlatinib, or ceritinib, crizotinib
KRAS Mutations G12D | G12V	Consider clinical trial enrollment	KRAS mutations are associated with poorer prognosis
G12C	Consider clinical trial enrollment	May benefit from treatment with sotorasib or adagrasib
BRAF Mutation V600E	Consider clinical trial enrollment	May benefit from dabrafenib + trametinib, encorafenib + binimetinib, or vemurafenib, dabrafenib

GENESTRAT® ANALYSIS DESCRIPTION[18-24]:

GeneStrat genomic testing is a laboratory test service that determines the presence of somatic genetic variants in circulating nucleic acids (DNA and RNA) from the plasma of patients with lung cancer using the ddPCR™ system (Droplet Digital™ Polymerase Chain Reaction)*. In the ddPCR system process, a patient sample is dispersed in an emulsion so that individual nucleic acid molecules are isolated. After amplification, nucleic acids are quantified by counting the emulsion that contains PCR end-product, or positive reactions. The GeneStrat test is a genomic approach to detect somatic nucleotide variants, including insertions, deletions and point mutations, as well as fusion products.

The GeneStrat test solely reports the presence or absence of certain, limited genomic alterations which may be useful for physicians when considering different therapeutic options. The mutations detected using the GeneStrat test account for a large proportion of variants found in NSCLC, including EGFR (89% coverage), ALK (78%), KRAS (78%), and BRAF (54%). Accordingly, results are adjunctive to the ordering physician's workup and should be evaluated by a qualified healthcare professional in combination with the patient's clinical history, other diagnostic tests, and clinicopathological factors. For patients that test negative for all mutations, tissue biopsy can be considered. Values obtained with a different assay method or kit cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

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	G12D	Negative
	G12V	Negative
BRAF Mutation	V600E	Negative
ROS1 Fusions	CD74 | SDC4 | SLC34A2 | EZR | TPM3	Negative
RET Fusions	KIF5B | CCDC6 | TRIM33	Negative

RESULTS INTERPRETATION: EGFR | ALK | KRAS | BRAF | ROS1* | RET*

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*For a Positive Result, presence of 10 or more copies of the variant
For a Negative Result, presence of fewer than 10 copies of the variant

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Exon 18 G719A, G719C, G719S Exon 20 S768I | Exon 21 L861Q	Consider clinical trial enrollment	May benefit from treatment with afatinib, osimertinib, or erlotinib, gefitinib, dacomitinib
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ALK Fusions EML4	Consider clinical trial enrollment	May benefit from treatment with alectinib, brigatinib, lorlatinib, or ceritinib, crizotinib
KRAS Mutations G12D | G12V	Consider clinical trial enrollment	KRAS mutations are associated with poorer prognosis
G12C	Consider clinical trial enrollment	May benefit from treatment with sotorasib or adagrasib
BRAF Mutation V600E	Consider clinical trial enrollment	May benefit from dabrafenib + trametinib, encorafenib + binimetinib, or vemurafenib, dabrafenib
ROS1 Fusions CD74 | SDC4 | SLC34A2 | EZR | TPM3	Consider clinical trial enrollment	May benefit from treatment with crizotinib, ceritinib, entrectinib, or lorlatinib
RET Fusions KIF5B | CCDC6 | TRIM33	Consider clinical trial enrollment	May benefit from treatment with selpercatinib, pralsetinib, or cabozantinib

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Gary Pestano, Ph.D., New York Laboratory Director

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

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Negative: Presence of fewer than 2 copies of the variant

Quantity Not Sufficient (QNS): Test performed, and results not definitive — due to lack of sufficient amount of nucleic acid. No bill will be submitted for this gene. Redraw recommended.

Test Not Performed (TNP)

*For a Positive Result, presence of 10 or more copies of the variant
For a Negative Result, presence of fewer than 10 copies of the variant

biodesix.com
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Permanent Facility Identifier (PFI) 8471

Gary Pestano, Ph.D., New York Laboratory Director

biodesix®

genestrat® genomic test

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GENESTRAT® TREATMENT IMPLICATIONS

Available Mutations	Treatment Implications for Early Stage NSCLC[1]	Treatment Implications for Advanced Stage NSCLC[1-21]
EGFR Mutations Exon 19 ΔE746-A750 | Exon 21 L858R	May benefit from adjuvant osimertinib	May benefit from treatment with osimertinib or erlotinib, afatinib, gefitinib, dacomitinib, erlotinib + ramucirumab, or erlotinib + bevacizumab
Exon 18 G719A, G719C, G719S Exon 20 S768I | Exon 21 L861Q	Consider clinical trial enrollment	May benefit from treatment with afatinib, osimertinib, or erlotinib, gefitinib, dacomitinib
Exon 20 T790M	Consider clinical trial enrollment	May benefit from treatment with osimertinib if previously treated with 1st or 2nd generation EGFR-TKIs
ALK Fusions EML4	Consider clinical trial enrollment	May benefit from treatment with alectinib, brigatinib, lorlatinib, or ceritinib, crizotinib
KRAS Mutations G12D | G12V	Consider clinical trial enrollment	KRAS mutations are associated with poorer prognosis
G12C	Consider clinical trial enrollment	May benefit from treatment with sotorasib or adagrasib
BRAF Mutation V600E	Consider clinical trial enrollment	May benefit from dabrafenib + trametinib, encorafenib + binimetinib, or vemurafenib, dabrafenib
ROS1 Fusions CD74 | SDC4 | SLC34A2 | EZR | TPM3	Consider clinical trial enrollment	May benefit from treatment with crizotinib, ceritinib, entrectinib, or lorlatinib
RET Fusions KIF5B | CCDC6 | TRIM33	Consider clinical trial enrollment	May benefit from treatment with selpercatinib, pralsetinib, or cabozantinib

GENESTRAT® ANALYSIS DESCRIPTION[22-29]:

GeneStrat genomic testing is a laboratory test service that determines the presence of somatic genetic variants in circulating nucleic acids (DNA and RNA) from the plasma of patients with lung cancer using the ddPCR™ system (Droplet Digital™ Polymerase Chain Reaction)*. In the ddPCR system process, a patient sample is dispersed in an emulsion so that individual nucleic acid molecules are isolated. After amplification, nucleic acids are quantified by counting the emulsion that contains PCR end-product, or positive reactions. The GeneStrat test is a genomic approach to detect somatic nucleotide variants, including insertions, deletions and point mutations, as well as fusion products.

The GeneStrat test solely reports the presence or absence of certain, limited genomic alterations which may be useful for physicians when considering different therapeutic options. The mutations detected using the GeneStrat test account for a large proportion of variants found in NSCLC, including EGFR (89% coverage), ALK (78%), ROS1 (88%), RET (99%), KRAS (78%), and BRAF (54%). Accordingly, results are adjunctive to the ordering physician's workup and should be evaluated by a qualified healthcare professional in combination with the patient's clinical history, other diagnostic tests, and clinicopathological factors. For patients that test negative for all mutations, tissue biopsy can be considered. Values obtained with a different assay method or kit cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

*ddPCR and Droplet Digital are trademarks of Bio-Rad Laboratories, Inc.

Any questions regarding the use of the GeneStrat test or interpretation of the test results should be directed to Biodesix Customer Care at 1.866.432.5930.

REFERENCES:

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2. TARCEVA® (erlotinib), Genentech, Inc., South San Francisco, CA, USA.
3. GILOTRIF® (afatinib), Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA.
4. IRESSA® (gefitinib), AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA.
5. VIZIMPRO® (dacomitinib), Pfizer Inc., New York, NY, USA.
6. CYRAMZA® (ramucirumab), Eli Lilly and Company, Indianapolis, IN, USA.
7. AVASTIN® (bevacizumab), Genentech, Inc., South San Francisco, CA, USA.
8. ALECENSA® (alectinib), Genentech, Inc., South San Francisco, CA, USA.
9. ALUNBRIG® (brigatinib), Takeda Oncology, Cambridge, MA, USA.
10. LORBRENA® (lorlatinib), Pfizer Inc., New York, NY, USA.
11. ZYKADIA® (ceritinib), Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA.
12. XALKORI® (crizotinib), Pfizer Inc., New York, NY, USA.
13. LUMAKRAS® (sotorasib), Amgen Inc., Thousand Oaks, CA, USA.
14. KRAZATI® (adagrasib), Mirati Therapeutics, Inc., San Diego, CA, USA.
15. TAFINLAR® (dabrafenib) + MEKINIST® (trametinib), Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA
16. BRAFTOVI® (encorafenib) + MEKTOVI® (binimetinib), Pfizer Inc., New York, NY, USA.
17. ZELBORAF® (vemurafenib), Genentech, Inc., South San Francisco, CA, USA.
18. ROZLYTREK® (entrectinib), Genentech, Inc., South San Francisco, CA, USA.
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The GeneStrat test was developed and its performance characteristics determined by Biodesix, 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 GeneStrat Test Result Report or any content derived from it ("GS TRR"), the ordering physician, institution of ordering physician, or any third parties to whom the GS TRR is transferred, agree the GS TRR may only be used for the clinical management of the patient identified in the GS TRR by the ordering physician. Any other use of the GS TRR including, without limitation, correlative studies, diagnostic development, derivative works or other analyses, is expressly prohibited. The results of any unauthorized use of the GS TRR shall belong solely and exclusively to Biodesix, Inc. Additional terms and conditions related to this GS TRR can be found at www.biodesix.com.

Patient:
<First and Last Name>

GS Accession No:
BDXAYYMMDDXXXX

Date Performed | Reported:
<Mon DD, YYYY>

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