SUMMIT PATHOLOGY
Offices located at Medical Center of the Rockies
2500 Rocky Mountain Avenue
Loveland, CO 80538
Tel: (970) 624-1500
Fax: (970) 624-1593

ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: VANDERLINDEN, J D
Med Rec#: **3451340** PV: **183438720**
DOB: **11/29/1948** Age: **71** Sex: **M**
Physician(s):
PFEIFER LYLE MD MEDICAL CENTER OF THE ROCKIES
Attn: **ALISTAIR JORDAN, DO**

Accession #: 12150090
Date Collected: **08/20/2020**
Date Received: **08/20/2020**
Date Reported: **08/24/2020**
Report Modified: **10/19/2020**

Test Requested: **MCR Surgical**

Result ID: RS20-03342

Revision (10/19/2020)
ADDENDUM:
NEOGENOMICS MOLECULR GENETICS REPORT RECEIVED

FGFR CDx Molecular Analysis

Results:
FGFR CDx Molecular Analysis TNP - Test Not Performed

Comments:
TESTING HAS BEEN CANCELED DUE TO INSUFFICIENT TISSUE AND/OR TUMOR IN THE SPECIMEN SUBMITTED BASED ON MICROSCOPIC EXAMINATION BY NEOGENOMICS PATHOLOGIST(S). Note: This FDA-approved companion diagnostic assay requires a minimum of 80% tumor content as well as a minimum input of 100 square millimeters of tissue.

(Please see full report for details. Report linked and attached). ly

NOTE: This test was attempted on block A1. Block A2 will be sent for attempted testing, and results will be reported as another addendum.

Carrie Pizzi, MD
Pathologist, Electronic Signature

Revision (09/25/2020)
ADDENDUM:

NEOGENOMICS LABORATORIES - MOLECULAR GENETICS - REPORT RECEIVED

NTRK NGS FUSION PROFILE

RESULT SUMMARY:

THERE IS NO EVIDENCE OF EXPRESSION OF FUSION RNA OR MUTATION INVOLVING NTRK1, NTRK2 AND NTRK3 GENES BY NEXT GENERATION SEQUENCING.

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ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: VANDERLINDEN, J D
Med Rec#: **3451340** PV: **183438720**
DOB: **11/29/1948** Age: **71** Sex: **M**
Physician(s):
PFEIFER LYLE MD MEDICAL CENTER OF THE ROCKIES
Attn: **ALISTAIR JORDAN, DO**

Accession #: 12150090
Date Collected: **08/20/2020**
Date Received: **08/20/2020**
Date Reported: **08/24/2020**
Report Modified: **10/19/2020**

(Please see full report for result details. Report is attached.) lr

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Carrie Pizzi, MD
Pathologist, Electronic Signature

Revision (09/14/2020)
ADDENDUM:
NEOGENOMICS HISTOLOGY ANALYSIS REPORT RECEIVED

HISTOLOGY ANALYSIS

PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA:
CPS >/=1 (PD-L1 EXPRESSION)
Combined Positive Score: 80

(Please see full report for details. Report linked and attached). ly

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NEOGENOMICS HISTOLOGY ANALYSIS REPORT RECEIVED

MOLECULAR GENETICS
EGFR Mutation Analysis by Sanger

Results:
EGFR Mutation EGFR Exon 18: Not Detected - Mutations N/A
EGFR Exon 19: Not Detected. Mutations - N/A.
EGFR Exon 20 T790M: Not Detected. Mutations - N/A.
EGFR Exon 20 Other Mutations: Not Detected. Mutations - N/A.
EGFR Exon 21: Not Detected. Mutations - N/A.

(Please see full report for details. Report linked and attached). ly

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Carrie Pizzi, MD
Pathologist, Electronic Signature

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ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: VANDERLINDEN, J D
Med Rec#: **3451340** PV: **183438720**
DOB: **11/29/1948** Age: **71** Sex: **M**
Physician(s):
PFEIFER LYLE MD MEDICAL CENTER OF THE ROCKIES
Attn: **ALISTAIR JORDAN, DO**

Accession #: 12150090
Date Collected: **08/20/2020**
Date Received: **08/20/2020**
Date Reported: **08/24/2020**
Report Modified: **10/19/2020**

FINAL DIAGNOSIS:

SOFT TISSUE, ABDOMEN, BIOPSY:
NON-SMALL CELL CARCINOMA; PLEASE SEE COMMENT.

COMMENT:

The biopsy shows non-small cell carcinoma with squamous differentiation. The clinical history of urothelial carcinoma involving the proximal ureter resected in 2018 is noted. The differential diagnosis for the carcinoma in this abdominal mass includes a squamous component of urothelial carcinoma, but a squamous cell carcinoma from a different source cannot be excluded. The immunostain findings are not specific in differentiating these two entities. Clinical and radiologic correlation is required. If ancillary testing is requested, both blocks contain carcinoma.

A message regarding the diagnosis is left for Dr. Pfeifer with Crystal Bradley, nurse clinic lead in his office, on 8/22/2020.

Carrie Pizzi, MD
Pathologist, Electronic Signature

The case has been reviewed with the following pathologist(s) who concur with the interpretation: Michael Walts, MD

Clinical History:
Soft tissue mass measuring 12.1 cm in the anterior abdomen just left of midline and 3.8 cm in the right paracolic region. These are highly concerning for recurrent tumor.

Per EPIC: Patient had prior nephroureterectomy at Longs Peak Hospital in September of 2018, showing high-grade papillary urothelial carcinoma of proximal ureter, invading muscularis, pT2, pNX.

Per a urology note from February, 2019: Patient does also have a history of prostate cancer with a radical prostatectomy performed by a Dr. Henderson in 2002.

GROSS DESCRIPTION:

Received in a formalin filled bottle/container, which has been verified to belong to patient: VANDERLINDEN, J D and labeled "ABD bx" are multiple tan-white, irregular soft tissues ranging from less than 0.1 to 0.8 cm. The tissues are filtered, and submitted in toto in blocks A1-A2, with block A2 to be conserved.

Please note additional cores are received in RPMI and are sent for flow cytometry.

MICROSCOPIC DESCRIPTION:

2 blocks, 1 slide examined each block. Immunostains are performed on block A1 in order to further characterize the carcinoma. Controls stain appropriately. The carcinoma is positive for p63, cytokeratin 5/6, GATA-3, with focal rare cells staining for S100p.

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ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: VANDERLINDEN, J D
Med Rec#: **3451340** PV: **183438720**
DOB: **11/29/1948** Age: **71** Sex: **M**
Physician(s):
PFEIFER LYLE MD MEDICAL CENTER OF THE ROCKIES
Attn: **ALISTAIR JORDAN, DO**

Accession #: 12150090
Date Collected: **08/20/2020**
Date Received: **08/20/2020**
Date Reported: **08/24/2020**
Report Modified: **10/19/2020**

The carcinoma is negative for uroplakin and NKX-3.1. The Ki-67 proliferative index is moderately increased.

NOTE: The immunoperoxidase tests utilized in this examination were developed and their performance characteristics determined by the laboratory at Summit Pathology. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

CPT Code(s): 88341 x6, 88305, 88342

Specimen grossed and processed at: Summit Pathology 5802 Wright Dr., Loveland, CO, 80538
Specimen interpreted at: Medical Center Rockies 2500 Rocky Mountain Avenue, Loveland, CO 80538

866.776.5907, option 3

Molecular Genetics
FGFR CDx Molecular Analysis

Client 5982
UC Health Medical Center of the Rockies

2500 Rocky Mountain Ave
Loveland, CO 80538
Phone: (970) 495-8740
Fax: (970) 624-1593

FX 4

Patient Name: **Vanderlinder**, **J D**
Patient DOB / Sex: **11/29/1948 / M**
Specimen Type: **Paraffin Tissue**
Body Site: **ABDOMEN**
Specimen ID: **RS20-03342/RS20-03342-A1**
MRN: **3451340**
Reason for Referral: **SEE ATTACHED**

Ordering Physician(s): **Carrie Pizzi, M.D.**
Treating Physician(s): **James Moore, MD**
Accession / CaseNo: **3332279 / MOL20-545408**
Collection Date: **08/20/2020**
Received Date: **10/07/2020 06:17:00 PM PDT**
Report Date: **10/16/2020 08:24:36 PM EST**

Results:

Test	Result
FGFR CDx Molecular Analysis	TNP - Test Not Performed

Comments:
TESTING HAS BEEN CANCELED DUE TO INSUFFICIENT TISSUE AND/OR TUMOR IN THE SPECIMEN SUBMITTED BASED ON MICROSCOPIC EXAMINATION BY NEOGENOMICS PATHOLOGIST(S). Note: This FDA-approved companion diagnostic assay requires a minimum of 80% tumor content as well as a minimum input of 100 square millimeters of tissue.

Please contact NeoGenomics with any questions or concerns.

Electronic Signature

Reviewed by: Jamie Boone, D.O., Pathologist - NeoGenomics Lab

The Technical Component Processing and Analysis of this test was completed at NeoGenomics Rutherford, 2110 Rutherford Road, Carlsbad, CA / 92008 / 800-755-0802 / CLIA #05D1018666 / Medical Director(s): Derek D. Lyle, M.D. The Professional Component of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA #05D1021650 / Medical Director(s): Sally Agersborg, M.D.
This laboratory is CLIA certified to perform high complexity clinical testing
Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.
The CPT codes provided with our test descriptions are based on MolDX and AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

866.776.5907, option 3

Molecular Genetics
NTRK NGS Fusion Profile

Client 5982
UC Health Medical Center of the Rockies

2500 Rocky Mountain Ave
Loveland, CO 80538
Phone: (970) 495-8740
Fax: (970) 624-1593

FX 4

Patient Name: **Vanderlinden, J D**
Patient DOB / Sex: **11/29/1948 / M**
Specimen Type: **Paraffin Tissue**
Body Site: **Abdomen**
Specimen ID: **RS20-03342/RS20-03342-A1**
MRN: **3451340**
Reason for Referral: **SEE ATTACHED**

Ordering Physician(s): **Carrie Pizzi, M.D.**
Treating Physician(s): **James Moore, MD**
Accession / CaseNo: **3245479 / MOL20-495297**
Collection Date: **08/20/2020**
Received Date: **09/05/2020 02:18:00 AM PDT**
Report Date: **09/25/2020 02:56:15 PM EST**

Result Summary: THERE IS NO EVIDENCE OF EXPRESSION OF FUSION RNA OR MUTATION INVOLVING NTRK1, NTRK2 AND NTRK3 GENES BY NEXT GENERATION SEQUENCING.

Results:

Fusion	Results	Fusion Partner	Fusion Read (%)	Mutation in Fused genes
NTRK1	Not Detected	Not Detected	Not Detected	Not Detected
NTRK2	Not Detected	Not Detected	Not Detected	Not Detected
NTRK3	Not Detected	Not Detected	Not Detected	Not Detected

Other point mutations found in genes with no fusions:

Gene	Point Mutations
NTRK1	Not Detected
NTRK2	Not Detected
NTRK3	Not Detected

Clinical Significance:

Rearrangements of the genes tested and fusions with partner genes, leading to gene activation and overexpression, have been observed in a variety of cancers. Such fusions and other mutations may be targetable with selective kinase inhibitors. Point mutations associated with acquired resistance have been reported and their detection may suggest appropriate second- or third-generation inhibitor therapies.

Methodology:

Nucleic acid is extracted from formalin-fixed, paraffin-embedded tissue (FFPE). The NTRK NGS Fusion Profile uses target anchored massively parallel RNA sequencing for the detection of fusions and single nucleotide variants involving select exons of NTRK1, NTRK2, and NTRK3 genes. Translocation partners of fusions in these genes will be identified. Possible translocations and mutations outside the ranges analyzed by this test will not be detected. The limit of detection in this assay is approximately 5% abnormal mRNA in a background of total RNA.

References:

1. Lange AM, Lo HW. Inhibiting TRK Proteins in Clinical Cancer Therapy. Cancers (Basel). 2018;10(4). pii: E105.
2. Cocco E, Scaltriti M, Drilon A. NTRK fusion-positive cancers and TRK inhibitor therapy. Nat Rev Clin Oncol. 2018;15(12):731-747. PMID: 30333516.

Test/Panel	MolDX CPT	AMA CPT
NTRK NGS Fusion Profile	81479	81479

Electronic Signature

Jamie Boone, D.O., Pathologist - NeoGenomics Lab

The Technical Component Processing, Analysis and Professional Component of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA #05D1021650 / Medical Director(s): Sally Agersborg, M.D.
The performance characteristics of this test have been determined by NeoGenomics Laboratories. This test has not been approved by the FDA. The FDA has determined such clearance or approval is not necessary. This laboratory is CLIA certified to perform high complexity clinical testing.
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NEO GENOMICS

866.776.5907, option 3

Histology Analysis

PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA

Client 5982
UC Health Medical Center of the Rockies

2500 Rocky Mountain Ave
Loveland, CO 80538
Phone: (970) 495-8740
Fax: (970) 624-1593

FX 4

Patient Name: **Vanderlinden, J D**
Patient DOB / Sex: **11/29/1948 / M**
Specimen Type: **Paraffin Tissue**
Body Site: **Abdomen**
Specimen ID: **RS20-03342/RS20-03342-A1**
MRN: **3451340**
Reason for Referral: **SEE ATTACHED**

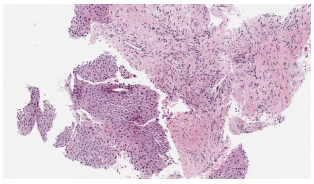
Ordering Physician(s): **Carrie Pizzi, M.D.**
Treating Physician(s): **James Moore, MD**
Accession / CaseNo: **3245479 / HSG20-050661**
Collection Date: **08/20/2020**
Received Date: **09/05/2020 02:18:00 AM PDT**
Report Date: **09/11/2020 05:51:33 PM EST**

Comments:

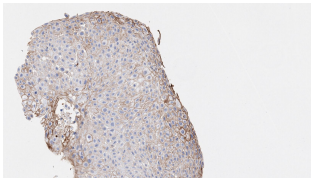
Some tumor cells show faint to weak membrane staining with PD-L1, which are also included in scoring.

Results

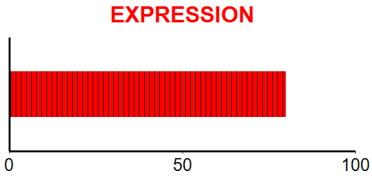
Specimen ID: **RS20-03342/RS20-03342-A1**



H&E Image for Reference only



PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA: CPS >/=1 (PD-L1 EXPRESSION)
Combined Positive Score: 80



Reference Ranges	
Expression	**CPS >/=1**
No Expression	**CPS < 1**

Intended Use:

Stains were scored by a pathologist using manual microscopy.
All controls were reviewed and showed appropriate positive and negative immunoreactivity.

PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA:

PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using monoclonal mouse Anti-PD-L1, clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) gastric or gastroesophageal junction adenocarcinoma tissue using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying patients with metastatic gastric or GEJ cancer whose tumors express PD-L1. KEYTRUDA® (pembrolizumab) is indicated for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) >=1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy. In the context of Clinic Trial KN059, specimens that were >42 days were classified as archival. If PD-L1 expression is not detected in an archival gastric or GEJ adenocarcinoma specimen, then evaluate the feasibility of obtaining an additional tumor biopsy for PD-L1 testing. The performance characteristics of this assay have not been validated for decalcified specimens. Results should be interpreted with caution given the likelihood of false negativity on decalcified specimens. See PD-L1 22C3 pharmDx™ kit (package insert) and Keytruda® product label for additional information. Use of this test in an off-label manner invalidates the FDA approval for the test. DAKO an Agilent Technologies Company, 6392 Via Real, Carpinteria, CA 93013; P03951_06/SK006/2017.09 p. 3

Methodology:

PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA:

PD-L1 staining was performed utilizing the DAKO FDA-approved PD-L1, 22C3 pharmDx™ protocol using the Dako Automated Link 48 platform. Following incubation with the primary monoclonal antibody to PD-L1, specimens were incubated with a Linker antibody specific to the host species of the primary antibody, and then were incubated with a ready-to-use visualization reagent consisting of secondary antibody molecules and horseradish peroxidase molecules coupled to a dextran polymer backbone. PD-L1 protein expression is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells divided by the total number of viable tumor cells and then multiplied by 100. PD-L1 staining cells is defined as: tumor cells showing partial or complete membrane staining at any intensity plus PD-L1 staining in tumor infiltrating or tumor adjacent mononuclear inflammatory cells (lymphocytes and macrophages) with membrane and/or cytoplasmic staining at any intensity. Although the result of the calculation may exceed 100, the maximum score is defined as CPS 100. The specimen should be considered to have PD-L1 expression if CPS >=1 and no PD-L1 expression if CPS <1.

Stain	CPT Code	Quantity
PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA	88360	1

Electronic Signature

Yae K (Kay) Suh, M.D., Pathologist

The Technical Component Processing, Analysis and Professional Component of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA #05D1021650 / Medical Director(s): Sally Agersborg, M.D.
The performance characteristics of the IHC/ISH assays have been validated on formalin-fixed paraffin embedded tissues only. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") as qualified to perform high complexity clinical laboratory testing. For the classifications of IHC antibodies, please contact the Client Services team.
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866.776.5907, option 3

Molecular Genetics

EGFR Mutation Analysis by Sanger

Client 5982
UC Health Medical Center of the Rockies

2500 Rocky Mountain Ave
Loveland, CO 80538
Phone: (970) 495-8740
Fax: (970) 624-1593

FX 4

Patient Name: **Vanderlinden, J D**
Patient DOB / Sex: **11/29/1948 / M**
Specimen Type: **Paraffin Tissue**
Body Site: **Abdomen**
Specimen ID: **RS20-03342/RS20-03342-A1**
MRN: **3451340**
Reason for Referral: **SEE ATTACHED**

Ordering Physician(s): **Carrie Pizzi, M.D.**
Treating Physician(s): **James Moore, MD**
Accession / CaseNo: **3245479 / MOL20-495298**
Collection Date: **08/20/2020**
Received Date: **09/05/2020 02:18:00 AM PDT**
Report Date: **09/13/2020 12:48:49 PM EST**

Results:

Test	Result	Mutations
EGFR Mutation		
EGFR Exon 18	Not Detected	N/A
EGFR Exon 19	Not Detected	N/A
EGFR Exon 20 T790M	Not Detected	N/A
EGFR Exon 20 Other Mutations	Not Detected	N/A
EGFR Exon 21	Not Detected	N/A

Clinical Significance:

Patients with non-small cell lung cancer (NSCLC) and mutations in EGFR exons 18, 19, 20 or 21 usually respond to anti-EGFR tyrosine kinase inhibitors (TKIs) and have longer survival when compared to EGFR mutation-negative patients. However, patients being treated with TKIs may develop acquired resistance with secondary mutations in exon 20, such as T790M or, less commonly, L747S, D761Y and T854A.

NSCLCs with exon 20 mutations, such as T790M mutation, are usually resistant to first generation (erlotinib, gefitinib) and second generation (afatinib, dacomitinib, neratinib) anti-EGFR TKIs, but may respond to third generation TKIs, such as osimertinib. The less common resistance mutations (e.g. L747S, D761Y and T854A) may respond to second or third generation irreversible TKIs based on early studies. Most EGFR exon 20 insertions are resistant to EGFR TKIs with the exception of p.A763_Y764insFQEA, which is associated with increased sensitivity to EGFR TKIs.

Methodology:

DNA was isolated from cells or microdissection-enriched FFPE tissue. Formalin-fixed, paraffin-embedded tumor tissue sections were deparaffinized and DNA was isolated. EGFR tyrosine kinase domain mutations were evaluated in the entirety of exons 18 to 21. The patient's sequence is compared to the EGFR sequence database NM_005228. This assay is by Sanger sequencing method with Locked Nucleic Acid (LNA) for T790M. The sensitivity for detecting the T790M mutation in exon 20 is at least 3% with the remaining mutations having a sensitivity of 10 to 15% for detecting mutated EGFR DNA in a wild-type background. Various factors including quantity and quality of nucleic acid, sample preparation and sample age can affect assay performance.

References:

1. Jänne PA, et al. Epidermal growth factor receptor mutations in non-small-cell lung cancer: implications for treatment and tumor biology. J Clin Oncol. 2005; 23:3227-34.
2. Lynch TJ, et al. Activating mutations in the epidermal growth factor receptor underlying responsiveness of non-small-cell lung cancer to gefitinib. N Engl J Med. 2004; 350:2129-39.
3. Sequist LV, et al. Response to treatment and survival of patients with non-small cell lung cancer undergoing somatic EGFR mutation testing. Oncologist. 2007;12:90-8.
4. Paez JG, et al. EGFR mutations in lung cancer: correlation with clinical response to gefitinib therapy. Science. 2004; 304:1497-1500.
5. Costa DB, et al. Differential responses to erlotinib in epidermal growth factor receptor (EGFR)-mutated lung cancers with acquired resistance to gefitinib carrying the L747S and T790M secondary mutations. J Clin Oncol. 2008; 26:1182-4.
6. Felip E, Barlesi F, Besse B, et al. Phase 2 Study of the HSP-90 Inhibitor AUY922 in Previously Treated and Molecularly Defined Patients with Advanced Non-Small Cell Lung Cancer. J Thorac Oncol. 2018;13(4):576-584.

Test/Panel	MolDX CPT	AMA CPT
EGFR Mutation Analysis by Sanger	81235	81235

Electronic Signature

Jamie Boone, D.O., Pathologist - NeoGenomics Lab

The Technical Component Processing, Analysis and Professional Component of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA #05D1021650 / Medical Director(s): Sally Agersborg, M.D.
The performance characteristics of this test have been determined by NeoGenomics Laboratories. This test has not been approved by the FDA. The FDA has determined such clearance or approval is not necessary. This laboratory is CLIA certified to perform high complexity clinical testing.
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