labcorp

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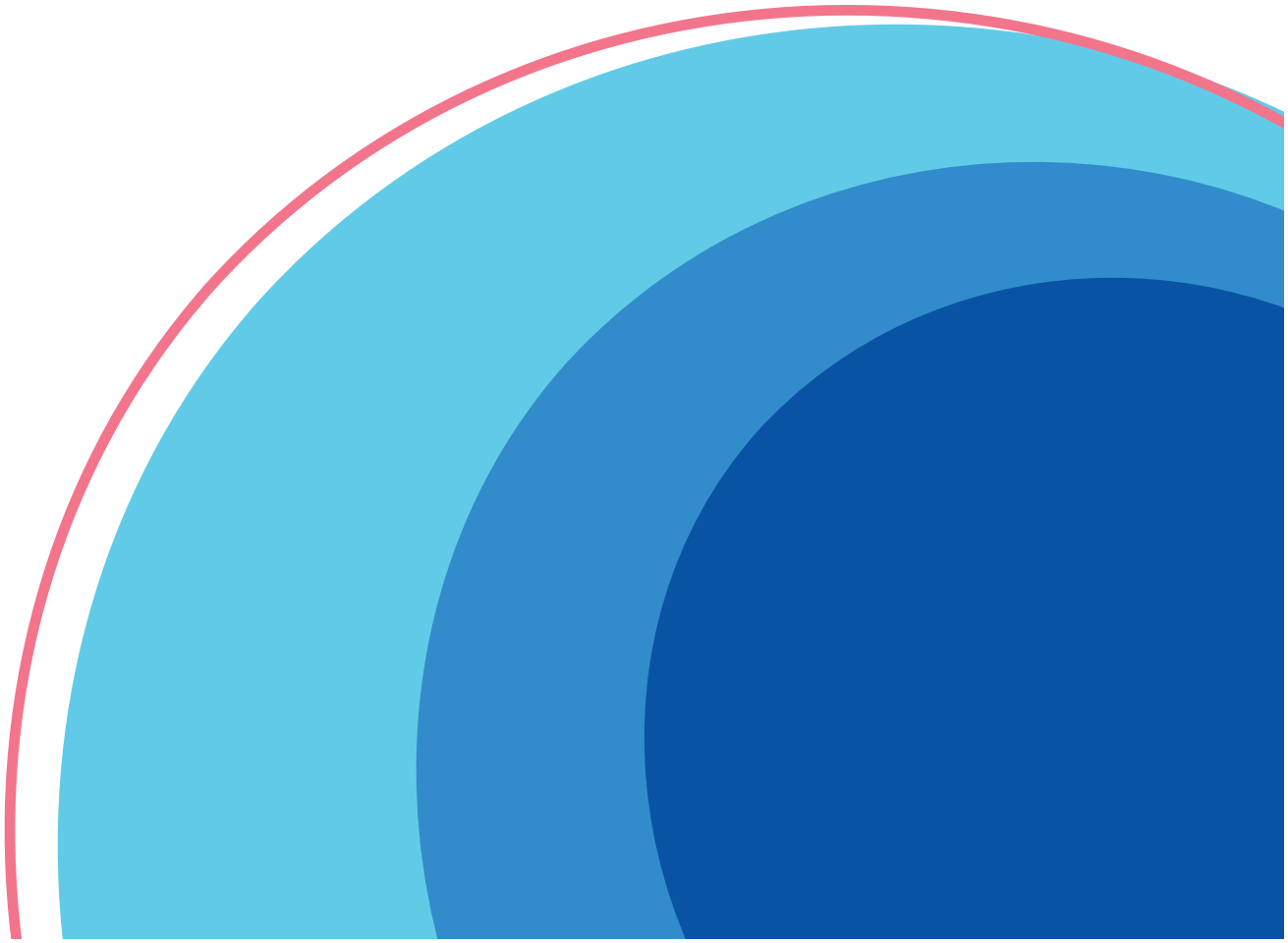
MONTHLY TEST UPDATES

Diagnostics Update



New Tests

Cutaneous Immunofluorescence IgA Antibody 160098

CPT 86255(x4)
Synonyms IgA Pemphigus; Cutaneous Indirect immunofluorescence IgA
Methodology Immunofluorescence
Use This test is intended for confirmation of IgA antibody presence to aid in the diagnosis of pemphigoid, pemphigus, epidermolysis bullosa acquisita and bullous lupus erythematosus. IgA antibodies directed against the basement membrane zone (BMZ) are produced in pemphigoid. When serum contains anti-BMZ antibodies, the fluorescence pattern on sodium chloride (NaCl)-split skin substrate assists in differentiating pemphigoid from epidermolysis bullosa acquisita (EBA) and bullous lupus erythematosus (LE). Fluorescence on the roof (epidermal side) or on both epidermal and dermal sides of the split indicates pemphigoid, whereas fluorescence restricted to the dermal side is consistent with EBA or bullous LE. Additionally, patients with pemphigus produce IgA epidermal cell antibodies. The titer of epidermal cell surface (Intercellular) antibodies generally correlates with pemphigus disease activity.
Special Instructions If reflex test is performed, additional charges/CPT code(s) may apply.
Limitations This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Specimen Serum
Volume 1.0 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube, red-top tube, transfer tube
Collection Instructions If a tube other than a gel-barrier tube is used, transfer the separated serum to a plastic transport tube. Do **not** freeze the gel-barrier tube (pour off the serum first).
Stability

Temperature	Period
Room temperature	14 days
Refrigerated	14 days
Frozen	14 days
Freeze/thaw cycles	Stable x3

Storage Instructions Room temperature
Causes for Rejection Gross hemolysis; grossly lipemic; gross icterus

Cutaneous Immunofluorescence IgG Antibody 160111

CPT 86255(x4)
Synonyms Pemphigus and Pemphigoid Antibody; Cutaneous Indirect immunofluorescence IgG
Methodology Immunofluorescence
Use This test is used to detect circulating autoantibodies against epithelial cell surface and basement membrane zone antigens, aiding in the diagnosis and differentiation of autoimmune bullous diseases. Detection of anti-skin antibodies, both epithelial cell surface and basement membrane zone, plays an important role in diagnosing and sometimes assessing prognosis in autoimmune bullous diseases such as pemphigus, pemphigoid, cicatricial pemphigoid, anti Laminin 332 autoimmunity, epidermolysis bullosa acquisita (EBA), and bullous lupus erythematosus (LE). Epithelial cell surface antibodies are highly specific for pemphigus and are present in more than 90% of patients with active disease. Basement membrane antibodies occur in approximately 70% of active bullous pemphigoid cases, 50% of EBA cases and about 10% of cicatricial pemphigoid cases. EBA can closely resemble bullous pemphigoid clinically, histologically and immunologically. Indirect immunofluorescence on salt split skin helps differentiate these conditions by identifying whether antibodies bind to the epidermal roof or dermal floor of the split at the lamina lucida. This test, along with additional follow-up assays, is essential for distinguishing EBA, bullous LE and cicatricial pemphigoid from bullous pemphigoid.
Special Instructions If reflex test is performed, additional charges/CPT code(s) may apply.
Limitations This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Specimen Serum
Volume 1.0 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube, red-top tube, transfer tube
Collection Instructions If a tube other than a gel-barrier tube is used, transfer the separated serum to a plastic transport tube. Do **not** freeze the gel-barrier tube (pour off the serum first).
Stability

Temperature	Period
Room temperature	14 days
Refrigerated	14 days
Frozen	14 days
Freeze/thaw cycles	Stable x3

Storage Instructions Room temperature
Causes for Rejection Gross hemolysis; grossly lipemic; gross icterus

New Tests

DHEA by Ionify LC-MS/MS 004389

CPT 82626
Synonyms DHEA; unconjugated DHEA
Methodology Ionify LC-MS/MS
Result Turnaround Time 3 - 5 days
Use This test is used to evaluate adrenal carcinomas that frequently secrete large amounts of dehydroepiandrosterone (DHEA).
Additional Information DHEA is a steroid that is produced by both the adrenal cortex and the testis.[1] The levels of this steroid increase before the onset of puberty (adrenarche) and decrease significantly with age.[2] DHEA and DHEA-S are the major precursors of 17-ketosteroids.
Specimen Serum (preferred) **or** plasma
Volume 1.5 mL
Minimum Volume 0.7 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube **or** red-top tube is preferred. Green-top (lithium heparin-no gel) is acceptable.
Collection Instructions
Gel-barrier tube or red-top tube: Centrifuge sample after clotting is complete.
Red-top tube or green-top tube: Transfer separated serum or plasma to a plastic transport tube.
Stability

Temperature	Period
Room temperature	Unstable (stability provided by manufacturer or literature reference)
Refrigerated	7 days (stability provided by manufacturer or literature reference)
Frozen	7 days (stability provided by manufacturer or literature reference)
Freeze/thaw cycles	Stable x1 (stability provided by manufacturer or literature reference)

Reference Range See table.[3]

Age	Male ((ng/mL)	Female (ng/mL)
<2 y	0.24–2.89	0.24–2.89
2 to 4 y	0.22–2.12	0.22–2.12
5 to 7 y	0.31–2.78	0.31–2.78
8 to 10 y	0.38–3.15	0.47–3.40
11 to 12 y	0.49–3.45	0.72–4.74
13 to 14 y	0.64–3.94	1.03–6.09
15 to 16 y	0.92–5.21	1.22–7.05
17 to 19 y	1.27–6.29	1.43–8.02
20 y	1.53–6.43	1.49–8.35
21 to 30 y	1.23–6.22	1.32–7.18
31 to 40 y	0.84–4.92	0.90–5.30
41 to 50 y	0.56–3.93	0.61–4.33
51 to 60 y	0.37–3.38	0.43–3.75
61 to 70 y	0.23–2.61	0.34–3.53
71 to 80 y	0.25–2.26	0.29–2.85
>80 y	0.16–1.49	0.24–2.08

Storage Instructions Sample must be refrigerated. **Freeze** if unable to maintain refrigerated.
Causes for Rejection Shipped or received in lab at room temperature, unspun sample
Footnotes
1. de Peretti E, Forest M. Unconjugated dehydroepiandrosterone plasma levels in normal subjects from birth to adolescence in humans: The use of a sensitive radioimmunoassay. *J Clin Endocrinol Metab*. 1976 Nov;43(5):982-991. PubMed 186482
2. Carlstrom K, Brady S, Lunell NO, et al. Dehydroepiandrosterone sulphate and dehydroepiandrosterone in serum: Differences related to age and sex. *Maturitas*. 1988 Dec;10(4):297-306. PubMed 2976116
3. Labcorp in-house data.

Envoplakin, IgG Antibody 160085

CPT 83516
Synonyms Paraneoplastic Pemphigus; Paraneoplastic Autoimmune Multiorgan Syndrome
Methodology ELISA
Use The intended use of the assay is semiquantitative determination of human IgG antibodies against envoplakin in serum and supports the delimitation of a paraneoplastic pemphigus from bullous pemphigoid, pemphigus vulgaris or pemphigus foliaceus. Paraneoplastic pemphigus (PNP), also referred to as paraneoplastic autoimmune multiorgan syndrome (PAMS), is a rare condition associated with lymphoproliferative disorders and other malignancies. It can occur at any age and typically presents with severe pemphigus like clinical features and a high mortality rate. Patients with PNP/PAMS produce serum antibodies against multiple epithelial types (simple, columnar, transitional), targeting several antigens, with envoplakin being a major one. Measurement of IgG envoplakin antibody levels by ELISA, whether elevated or normal, cannot independently confirm or exclude PNP/PAMS; rather, it serves as a supportive marker when interpreted alongside other diagnostic indicators. Elevated IgG envoplakin levels may correlate with disease severity and activity, making them useful for monitoring disease progression.
Limitations This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Limitations This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Specimen Serum
Volume 1.0 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube, red-top tube, serum transfer tube
Collection Instructions If a tube other than a gel-barrier tube is used, transfer the separated serum to a plastic transport tube. Do **not** freeze the gel-barrier tube (pour off the serum first).
Stability

Temperature	Period
Room temperature	14 days
Refrigerated	14 days
Frozen	14 days
Freeze/thaw cycles	Stable x3

Storage Instructions Room temperature
Causes for Rejection Gross hemolysis; grossly lipemic; gross icterus

GeneSeq® Connective Tissue: Ehlers-Danlos Syndrome Panel 630978

CPT 81408(x2); 81479
Synonyms EDS
Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)
Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests
Test Includes This test includes the following genes: *ADAMTS2, AEBP1, B3GALT6, B4GALT7, C1R, C1S, CHST14, COL12A1, COL1A1, COL1A2, COL3A1, COL5A1, COL5A2, DSE, FKBP14, PLOD1, PRDM5, SLC39A13, TNXB* and *ZNF469*.
Use This test is used for diagnostic testing for Ehlers-Danlos syndrome.

New Tests

Special Instructions This test currently is not approved for use in New York state.

In cases in which there is a known variant documented in the family, the physician may prefer to order GeneSeq® Connective Tissue: Targeted Variant Analysis [631277].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Bowen JM, Sobey GJ, Burrows NP, et al. Ehlers-Danlos syndrome, classical type. *Am J Med Genet C Semin Med Genet*. 2017 Mar;175(1):27-39. PubMed 28192633

GeneSeq® Connective Tissue: Single Gene Analysis 631264

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.

Synonyms Full gene sequencing, gene specific sequencing

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests

Test Includes This test includes all genes included in any GeneSeq® Connective Tissue panels.

Use Single gene analysis is available for all genes included in any GeneSeq® Connective Tissue panels.

Special Instructions This test currently is not approved for use in New York state.

The specific gene(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene(s) will result in testing delays. Variants of uncertain significance (VUS) will be reported.

To test fetal specimens, including cord blood, order GeneSeq® Connective Tissue: Single Gene, Fetal Analysis [631303].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Bowen JM, Sobey GJ, Burrows NP, et al. Ehlers-Danlos syndrome, classical type. *Am J Med Genet C Semin Med Genet*. 2017 Mar;175(1):27-39. PubMed 28192633

GeneSeq® Connective Tissue: Single Gene, Fetal Analysis 631303

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.

Synonyms Full gene sequencing, gene specific sequencing

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs).

Maternal cell contamination (MCC) analysis includes analysis of short tandem repeat markers by multiplex fluorescent polymerase chain reaction (PCR) and capillary electrophoresis.

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests. If culture is needed, an additional 14-21 days may be required. Additional culture fee may be applied.

Test Includes This test includes all genes included in any GeneSeq® Connective Tissue panels.

Use This test is used for prenatal diagnosis for pregnancies at risk for genes included in any GeneSeq® Connective Tissue panels.

Special Instructions This test currently is not approved for use in New York state.

The specific gene(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene(s) will result in testing delays. Variants of uncertain significance (VUS) will be reported.

Labcorp clients with eight-digit client account numbers should call 800-345-4363, and Labcorp Genetics & Women's Health clients with six-digit client/subclient account numbers should call 800-255-7357 to speak with a laboratory genetic coordinator before collecting specimens. In some circumstances, specimens from both parents and other family members may be required. All

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fetal specimens, including cord blood, must be accompanied by a maternal blood, PurFlock buccal swab kit or Oragene Dx 500 saliva kit for maternal cell contamination (MCC). A separate requisition should be submitted with the maternal specimen.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Amniotic fluid **or** chorionic villus sample (CVS) **or** cultured cells **or** cord blood (direct amniotic fluid or CVS specimen may be submitted; additional culture fee may be applied)

Volume Amniotic fluid: 20 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 4 mL cord blood (if amniotic fluid or CVS are cultured at another facility, please maintain back-up cultures)

Minimum Volume Amniotic fluid: 20 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 3 mL cord blood

Container

Amniotic fluid **or** CVS: sterile plastic conical tube or T-25 flask
Cord blood: yellow-top (ACD-A) or lavender-top (EDTA) tubes

Collection Instructions Standard sterile techniques; transfer aseptically to sterile tubes.

Amniotic fluid: Discard first 2 mL of fluid aspirated to avoid maternal cell contamination.

Stability Please ship expedited at room temperature.

Storage Instructions Maintain specimen at room temperature. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Bowen JM, Sobey GJ, Burrows NP, et al. Ehlers-Danlos syndrome, classical type. *Am J Med Genet C Semin Med Genet*. 2017 Mar;175(1):27-39. PubMed 28192633

GeneSeq® Connective Tissue: Targeted Variant Analysis 631277

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.

Synonyms Mutation-specific sequencing, family testing, known familial variant

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests

Test Includes This test includes all genes included in any GeneSeq® Connective Tissue panels.

Use This test is used for testing for a known variant documented in the family and is available only for genes included in GeneSeq® Connective Tissue panels.

Special Instructions This test currently is not approved for use in New York state.

The specific gene and variant(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene and variant will result in testing delays. Please include a copy of the previously tested family member's laboratory report for documentation.

Please call 800-345-4363 to speak with a laboratory genetic coordinator before submitting specimens for targeted variant analysis. If previous testing was performed at an outside laboratory, submitting a positive control sample is highly recommended.

To test fetal specimens, including cord blood, order GeneSeq® Connective Tissue: Targeted Variant, Fetal Analysis [631319].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Bowen JM, Sobey GJ, Burrows NP, et al. Ehlers-Danlos syndrome, classical type. *Am J Med Genet C Semin Med Genet*. 2017 Mar;175(1):27-39. PubMed 28192633

GeneSeq® Connective Tissue: Targeted Variant, Fetal Analysis 631319

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.

Synonyms Mutation-specific sequencing, known familial variant

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs).

Maternal cell contamination (MCC) analysis includes analysis of short tandem repeat markers by multiplex fluorescent polymerase chain reaction (PCR) and capillary electrophoresis.

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests. If culture is needed, an additional 14-21 days may be required. Additional culture fee may be applied.

Test Includes This test includes all genes included in any GeneSeq® Connective Tissue panels.

Use This test is used for prenatal diagnosis for pregnancies at risk for known variants in genes included in any GeneSeq® Connective Tissue panels.

Special Instructions This test currently is not approved for use in New York state.

The specific gene and variant(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene and variant will result in testing delays. Please include a copy of the previously tested family member's laboratory report for documentation.

Labcorp clients with eight-digit client account numbers should call 800-345-

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4363, and Labcorp Genetics & Women's Health clients with six-digit client/subclient account numbers should call 800-255-7357 to speak with a laboratory genetic coordinator before collecting specimens. In some circumstances, specimens from both parents and other family members may be required. All fetal specimens, including cord blood, must be accompanied by a maternal blood, PurFlock buccal swab kit or Oragene Dx 500 saliva kit for maternal cell contamination (MCC). A separate requisition should be submitted with the maternal specimen.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Amniotic fluid **or** chorionic villus sample (CVS) **or** cultured cells **or** cord blood (direct amniotic fluid or CVS specimen may be submitted; additional culture fee may be applied)

Volume Amniotic fluid: 10 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 4 mL cord blood (if amniotic fluid or CVS are cultured at another facility, please maintain back-up cultures)

Minimum Volume Amniotic fluid: 10 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 3 mL cord blood

Container

Amniotic fluid **or** CVS: sterile plastic conical tube or T-25 flask

Cord blood: yellow-top (ACD-A) or lavender-top (EDTA) tubes

Collection Instructions Standard sterile techniques; transfer aseptically to sterile tubes.

Amniotic fluid: Discard first 2 mL of fluid aspirated to avoid maternal cell contamination.

Stability Please ship expedited at room temperature.

Storage Instructions Maintain specimen at room temperature. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Bowen JM, Sobey GJ, Burrows NP, et al. Ehlers-Danlos syndrome, classical type. *Am J Med Genet C Semin Med Genet*. 2017 Mar;175(1):27-39. PubMed 28192633

GeneSeq® Immuno: Anhidrotic Ectodermodysplasia with Immunodeficiency 483816

CPT 81479

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests

Test Includes This test includes the following genes: *IKBKB, IKBKG* and *NFKBIA*.

Use This test is used for diagnostic testing for anhidrotic ectodermodysplasia with immunodeficiency.

Special Instructions This test currently is not approved for use in New York state.

In cases in which there is a known variant documented in the family, the physician may prefer to order GeneSeq® Immuno: Targeted Variant Analysis [484069].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Chronic Granulomatous Disease 483846

CPT 81479

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests

Test Includes This test includes the following genes: *CYBA, CYBB, CYBC1, G6PD, NCF2* and *NCF4*.

Use This test is used for diagnostic testing for chronic granulomatous disease.

Special Instructions This test currently is not approved for use in New York state.

In cases in which there is a known variant documented in the family, the physician may prefer to order GeneSeq® Immuno: Targeted Variant Analysis [484069].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

New Tests

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Leukocyte Adhesion Deficiency 483942

CPT 81479

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests.

Test Includes This test includes the following genes: *FERMT3, ITGB2* and *SLC35C1*.

Use This test is used for diagnostic testing for leukocyte adhesion deficiency.

Special Instructions This test currently is not available for use in New York state.

In cases in which there is a known variant documented in the family, the physician may prefer to order GeneSeq® Immuno: Targeted Variant Analysis [484069].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Periodic Fever Syndromes Panel 483786

CPT 81404; 81479

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests

Test Includes This test includes the following genes: *ACP5, ADA2, ADAM17, ADAR, ALPK1, C2orf69, CARD14, CDC42, CEBPE, COPA, DNASE1L3, DNASE2, ELANE, ELF4, HAVCR2, HCK, IFIH1, IKBKG, IL1RN, IL36RN, LPIN2, LSM11, MEFV, MVK, NCKAP1L, NLRC4, NLRP1, NLRP12, NLRP3, NOD2, OAS1, OTULIN, PLCG2, POLA1, POMP, PSMA3, PSMB4, PSMB8, PSMB9, PSMB10, PSMG2, PSTPIP1, RIPK1, RNASEH2A, RNASEH2B, RNASEH2C, RNU7-1, SAMHD1, SH3BP2, SLC29A3, STAT2, STING1, SYK, TBK1, TNFAIP3, TNFRSF1A* and *TREX1*.

Use This test is used for diagnostic testing for periodic fever syndromes.

Special Instructions This test currently is not approved for use in New York state.

In cases in which there is a known variant documented in the family, the physician may prefer to order GeneSeq® Immuno: Targeted Variant Analysis [484069].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

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Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.
Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container
References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Single Gene Analysis 483991

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.
Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)
Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests
Test Includes This test includes all genes included in any GeneSeq® Immuno panel.
Use Single gene analysis is available for all genes included in any GeneSeq® Immuno Panels.
Special Instructions This test currently is not available for use in New York state.

The specific gene(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene(s) will result in testing delays. Variants of uncertain significance (VUS) will be reported.

To test fetal specimens, including cord blood, order GeneSeq® Immuno: Single Gene, Fetal Analysis [484051].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit
Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit
Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit
Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit
Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.
Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.
Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container
References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Single Gene, Fetal Analysis 484051

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.
Synonyms Full gene sequencing, gene specific sequencing
Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs).

Maternal cell contamination (MCC) analysis includes analysis of short tandem repeat markers by multiplex fluorescent polymerase chain reaction (PCR) and capillary electrophoresis.

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests. If culture is needed, an additional 14-21 days may be required. Additional culture fee may be applied.
Test Includes This test includes all genes included in any GeneSeq® Immuno panel.
Use This test is used for prenatal diagnosis for pregnancies at risk for genes included in any GeneSeq® Immuno panels.
Special Instructions This test currently is not approved for use in New York state.

The specific gene(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene(s) will result in testing delays. Variants of uncertain significance (VUS) will be reported.

Labcorp clients with eight-digit client account numbers should call 800-345-4363, and Labcorp Genetics & Women's Health clients with six-digit client/subclient account numbers should call 800-255-7357 to speak with a laboratory genetic coordinator before collecting specimens. In some circumstances, specimens from both parents and other family members may be required. All fetal specimens, including cord blood, must be accompanied by a maternal blood, PurFlock buccal swab kit or Oragene Dx 500 saliva kit for maternal cell contamination (MCC). A separate requisition should be submitted with the maternal specimen.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Amniotic fluid **or** chorionic villus sample (CVS) **or** cultured cells **or** cord blood (direct amniotic fluid or CVS specimen may be submitted; additional culture fee may be applied)
Volume Amniotic fluid: 20 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 4 mL cord blood (if amniotic fluid or CVS are cultured at another facility, please maintain back-up cultures)
Minimum Volume Amniotic fluid: 20 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 3 mL cord blood
Container

Amniotic fluid **or** CVS: sterile plastic conical tube or T-25 flask
Cord blood: yellow-top (ACD-A) or lavender-top (EDTA) tubes

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Collection Instructions Standard sterile techniques; transfer aseptically to sterile tubes.

Amniotic fluid: Discard first 2 mL of fluid aspirated to avoid maternal cell contamination.

Stability Please ship expedited at room temperature.

Storage Instructions Maintain specimen at room temperature. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Targeted Variant Analysis 484069

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.

Synonyms Mutation-specific sequencing, family testing, known familial variant

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs)

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests

Test Includes This test includes all genes included in any GeneSeq® Immuno panel.

Use This testing is for a known variant documented in the family and is available only for genes included in GeneSeq® Immuno panels.

Special Instructions This test currently is not approved for use in New York state.

The specific gene and variant(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene and variant will result in testing delays. Please include a copy of the previously tested family member's laboratory report for documentation.

Please call 800-345-4363 to speak with a laboratory genetic coordinator before submitting specimens for targeted variant analysis. If previous testing was performed at an outside laboratory, submitting a positive control sample is highly recommended.

To test fetal specimens, including cord blood, order GeneSeq® Immuno: Targeted Variant, Fetal Analysis [483083].

Test orders must include an attestation that the provider has the patient's informed consent for genetic testing.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Volume 4 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Minimum Volume 3 mL whole blood **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Container Lavender-top (EDTA) tube **or** yellow-top (ACD-A) tube **or** PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit

Collection Instructions Standard phlebotomy; follow PurFlock buccal swab kit **or** Oragene Dx 500 saliva kit collection instructions. Do **not** eat, drink, smoke or chew gum 30 minutes prior to collection.

Stability

Temperature	Period
Room temperature	Whole blood: 14 days; buccal swab: 60 days; saliva: 60 days
Refrigerated	Whole blood: 30 days; buccal swab: unstable; saliva: unstable

Storage Instructions Maintain specimen at room temperature or refrigerate at 4°C. Do **not** freeze.

Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container

References

Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

GeneSeq® Immuno: Targeted Variant, Fetal Analysis 484083

CPT Contact CPT coding department at 800-222-7566, ext. 6-8400.

Synonyms Mutation-specific sequencing, family testing, known familial variant

Methodology Next-generation sequencing to identify genetic variants, including small nucleotide variants (SNVs), insertions, deletions and copy number variants (CNVs).

Maternal cell contamination (MCC) analysis includes analysis of short tandem repeat markers by multiplex fluorescent polymerase chain reaction (PCR) and capillary electrophoresis.

Result Turnaround Time 14 - 21 days; in some cases, additional time may be required for confirmatory or reflex tests. If culture is needed, an additional 14-21 days may be required. Additional culture fee may be applied.

Test Includes This test includes all genes included in any GeneSeq® Immuno panel.

Use This test is used for prenatal diagnosis for pregnancies at risk for known variants in genes included in any GeneSeq® Immuno panels.

Special Instructions This test currently is not approved for use in New York state.

The specific gene and variant(s) to be analyzed must be indicated on the test requisition form. Failure to indicate the gene and variant will result in testing delays. Please include a copy of the previously tested family member's laboratory report for documentation.

Labcorp clients with eight-digit client account numbers should call 800-345-4363, and Labcorp Genetics & Women's Health clients with six-digit client/subclient account numbers should call 800-255-7357 to speak with a laboratory genetic coordinator before collecting specimens. In some circumstances, specimens from both parents and other family members may be required. All fetal specimens, including cord blood, must be accompanied by a maternal blood, PurFlock buccal swab kit or Oragene Dx 500 saliva kit for maternal cell contamination (MCC). A separate requisition should be submitted with the maternal specimen.

Limitations Technologies used do not detect germline mosaicism and do not rule out the presence of large chromosomal aberrations, including rearrangements and gene fusions, or variants in regions or genes not included in this test, or possible inter/intragenic interactions between variants or repeat expansions. Variant classification and/or interpretation may change over time if more information becomes available. False positive or false negative results may occur for reasons that include rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Specimen Amniotic fluid **or** chorionic villus sample (CVS) **or** cultured cells **or** cord blood (direct amniotic fluid or CVS specimen may be submitted; additional

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culture fee may be applied)
Volume Amniotic fluid: 10 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 4 mL cord blood (if amniotic fluid or CVS are cultured at another facility, please maintain back-up cultures)
Minimum Volume Amniotic fluid: 10 mL **or** CVS: 10 mg **or** cultured amniotic fluid: two confluent T-25 flasks **or** cultured CVS: two confluent T-25 flasks **or** 3 mL cord blood
Container
Amniotic fluid **or** CVS: sterile plastic conical tube or T-25 flask
Cord blood: yellow-top (ACD-A) or lavender-top (EDTA) tubes
Collection Instructions Standard sterile techniques; transfer aseptically to sterile tubes.
Amniotic fluid: Discard first 2 mL of fluid aspirated to avoid maternal cell contamination.
Stability Please ship expedited at room temperature.
Storage Instructions Maintain specimen at room temperature. Do **not** freeze.
Causes for Rejection Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container
References
Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022 Oct;42(7):1473-1507. PubMed 35748970

Immunobullous Disease Comprehensive Antibody Profile 160112

CPT 83516(x5); 86255(x8)
Synonyms Pemphigus and Pemphigoid Antibody; Skin Antibody
Methodology Semi-Quantitative Indirect Immunofluorescence (IIF)/Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)
Use This test is used to support the diagnosis of epithelial antibody-associated immunobullous diseases in individuals who present with blisters, bullae, vesicles or erosive lesions involving the skin and/or mucous membranes. Clinical presentations may also include pruritus, secondary lesions or mimicking conditions such as eczema or urticaria, even when blistering is not evident. This testing is also appropriate for ongoing evaluation and monitoring of disease activity following a confirmed diagnosis of an immunobullous disorder. This assay is intended for comprehensive initial evaluation to support the diagnosis and differentiation of blistering, eczematous, erosive, pruritic or urticarial conditions affecting the skin and mucous membranes. It assists in identifying epithelial antibody-mediated immunobullous disorders, including pemphigoid, pemphigus and their variants, which may demonstrate nonspecific or overlapping clinical features. It is also recommended for monitoring the emergence of epithelial antibodies associated with immune checkpoint inhibitor treatments anti-PD-1 and anti-PD-L1.
Limitations This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Specimen Serum
Volume 1.0 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube, red-top tube, transfer tube
Collection Instructions Serum samples may be stored for up to eight hours at room temperature before freezing at -20°C. Samples should **not** be repeatedly frozen and thawed.
Stability

Temperature	Period
Room temperature	14 days
Refrigerated	14 days
Frozen	14 days
Freeze/thaw cycles	Stable x3

Storage Instructions Room temperature
Causes for Rejection Bacterial contamination, hemolysis, lipemia

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Activated Protein C Resistance (APCR)	**117762**	**Methodology** This assay measures the effect of adding aPC on the activated partial thromboplastin time (aPTT) of the patient sample.[6-9] An aPTT is performed twice, once with and again without added aPC. The ratio of the two clotting times is reported. The patient sample is diluted with factor V-deficient plasma. This serves to correct for any factor deficiencies in the patient sample and allows the test to be used for patients on oral anticoagulants. The reaction mixture also contains a heparin neutralizer to allow this test to be performed on patients receiving heparin therapy. This assay employs predilution of patient plasma in factor V-deficient plasma, enhancing sensitivity and specificity for factor V-dependent APC resistance and permitting testing in patients receiving oral anticoagulants or heparin at permitted levels. **Limitations** A low APCR ratio in the absence of factor V Leiden most commonly reflects acquired or non-Leiden influences on the protein C pathway. These include antiphospholipid antibodies, particularly lupus anticoagulant, which can directly induce an acquired APCR phenotype, as well as autoantibodies against protein S that impair the APC cofactor function. In addition, elevated procoagulant factor levels, especially factor VIII (and to a lesser extent factors II, IX and X), reduce APC sensitivity and are a recognized mechanism of acquired resistance. Physiologic or hormonal states such as pregnancy and estrogen exposure (e.g., oral contraceptives) can also produce APCR through shifts in coagulation factor and protein S levels. Less commonly, other factor V variants (e.g., HR2 haplotype or non-Leiden mutations) and inherited or acquired reductions in protein S activity contribute to a low APCR ratio. Collectively, these conditions alter the balance between APC and its substrates or cofactors, yielding a functionally resistant phenotype despite absence of the classic FVL mutation. A reduced APCR should be interpreted in the appropriate clinical context and confirmed, if clinically indicated, by molecular testing for the factor V Leiden mutation (Labcorp Test No. 511154), as well as correlation with personal or family history of venous thromboembolism. This test should not be performed on individuals with extended baseline aPTT values due to the presence of lupus anticoagulants.[6] This test should not be used for patients receiving thrombin inhibitors such as hirudin and argatroban.[6] In some cases, this test will fail to distinguish individuals who are heterozygous for the factor V Leiden mutation from normals.[7] Genetic testing may be required to distinguish between heterozygous and homozygous factor V Leiden mutation.[7] Elevated factor VIII levels, as can be seen in acute phase reaction, can normalize the aPTT and effectively reduce the anticoagulant effect of aPC.[7] Abnormal results can also be seen in pregnancy, especially during the third trimester, due to decreased levels of protein S and increased levels of factors V and VIII.[7] **References** Bertina RM, Koeleman BP, Koster T, et al. Mutation in blood coagulation factor V associated with resistance to activated protein C. *Nature*. 1994 May 5;369(6475):64-67. PubMed 8164741 Dahlbäck B. Resistance to activated protein C as a basis for venous thrombosis. *N Engl J Med*. 1994 Feb 24;330(8):517-522. PubMed 8302317 Favaloro EJ, Mohammed S, Vong R, Pasalic L. Laboratory testing for activated protein C resistance (APCR): an update. *Methods Mol Biol*. 2023:2663:203-210. PubMed 37204711 Gennari LC, Blanco AN, Domínguez MP, Grosso SH, Lazzari MA. Endogenous coagulation factor levels and the response to activated protein C. *Thromb Res*. 2006;118(2):269-273. PubMed 16143372 Nojima J, Kuratsune H, Suehisa E, et al. Acquired activated protein C resistance associated with anti-protein S antibodies. *Thromb Haemost*. 2002 Nov;88(5):716-722. PubMed 12428083 Saenz AJ, Johnson NV, Van Cott EM. Acquired activated protein C resistance caused by lupus anticoagulants. *Am J Clin Pathol*. 2011 Sep;136(3):344-349. PubMed 21846908 Sedano-Balbás S, Lyons M, Cleary B, Murray M, Gaffney G, Maher M. Acquired activated protein C resistance, thrombophilia and adverse pregnancy outcomes. *J Pregnancy*. 2011:2011:232840. PubMed 21869933 Tripodi A. Activated protein C resistance. In: Laboratory Techniques in Thrombosis. Springer; 2020. **Footnotes** (*updated*) 7. Chromogenix. Coatest APC Resistance V: Instructions for Use. Insert revision 03/2013. Instrumentation Laboratory; 2013.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
α2-Antiplasmin	**117739**	**Synonyms** a2-plasmin inhibitor; Alpha-2-Antiplasmin; Antiplasmin; Plasmin inhibitor **Methodology** Berichrom® α2-Antiplasmin is a chromogenic activity assay in which patient plasma is incubated with excess plasmin; α2-antiplasmin inhibits a portion of this enzyme, and the remaining plasmin cleaves a chromogenic substrate to release p-nitroaniline measured spectrophotometrically. The generated signal is inversely proportional to α2-antiplasmin activity. **Use** This test is used as an aid in the diagnosis of inherited or acquired deficiencies of α2-antiplasmin and in management of fibrinolytic therapy. **Additional Information** Measurement of α2-antiplasmin (α2AP), the principal physiologic inhibitor of plasmin, provides clinically useful information in the evaluation of disorders of fibrinolysis, particularly when there is discordance between bleeding symptoms and routine coagulation assays.1 By rapidly forming plasmin–antiplasmin complexes and becoming cross-linked to fibrin, α2AP is a major determinant of clot stability and resistance to lysis; thus, reduced activity results in accelerated fibrinolysis and a tendency toward delayed or excessive bleeding despite normal PT and aPTT, making targeted measurement essential for diagnosis.[1,2] Quantitative or functional α2AP assays are therefore primarily indicated to confirm congenital or acquired α2AP deficiency—rare conditions characterized by hyperfibrinolysis, postoperative hemorrhage or delayed wound bleeding—and may be necessary when global assays (e.g., euglobulin lysis time) suggest increased fibrinolytic activity but the etiology remains unclear.[2,3] Beyond rare inherited deficiency, α2AP measurement has broader utility in the assessment of acquired hyperfibrinolytic states, including disseminated intravascular coagulation (DIC), trauma-associated coagulopathy and advanced liver disease, in which decreased α2AP levels may reflect either impaired hepatic synthesis or consumption during ongoing plasmin generation.[4,5] In these settings, interpretation is most informative when integrated with fibrinogen, D-dimer, fibrin degradation products and plasminogen levels, as α2AP contributes to a more complete evaluation of the balance between coagulation and fibrinolysis rather than functioning as a standalone diagnostic marker.[3] Additionally, α2AP assays may be used to monitor the effects of fibrinolytic or antifibrinolytic therapies, as circulating levels influence the efficacy of thrombolysis by directly inhibiting plasmin and modulating clot dissolution kinetics.[3,6] Emerging data also suggest a role for α2AP as a biomarker of thrombotic risk and therapeutic responsiveness. Elevated α2AP levels have been associated with reduced endogenous fibrinolysis and increased risk of venous and arterial thrombosis, including ischemic stroke, and may contribute to resistance to thrombolytic therapy by limiting plasmin activity.1,6 Although not currently recommended as a first-line test for thrombophilia evaluation, measurement of α2AP may provide adjunctive information in selected patients with unexplained thrombosis or suspected hypofibrinolysis, particularly in research or specialized clinical contexts.[3,6] Overall, the clinical utility of α2AP testing lies in targeted evaluation of suspected fibrinolytic disorders, clarification of bleeding phenotypes with normal routine assays and adjunctive assessment of conditions characterized by dysregulated fibrinolysis, rather than in routine hemostasis screening. **Collection** (*superscript renumbering*) Citrated plasma samples should be collected by double centrifugation. Blood should be collected in a blue-top tube containing 3.2% buffered sodium citrate.[7] Evacuated collection tubes must be filled to completion to ensure a proper blood to anticoagulant ratio.[8,9] The sample should be mixed immediately by gentle inversion at least six times to ensure adequate mixing of the anticoagulant with the blood. A discard tube is not required prior to collection of coagulation samples, except when using a winged blood collection device (i.e., "butterfly"), in which case a discard tube should be used.[10,11] When noncitrate tubes are collected for other tests, collect sterile and nonadditive (red-top) tubes prior to citrate (blue-top) tubes. Any tube containing an alternate anticoagulant should be collected after the blue-top tube. Gel-barrier tubes and serum tubes with clot initiators should also be collected after the citrate tubes. Centrifuge for 10 minutes and carefully remove 2/3 of the plasma using a plastic transfer pipette, being careful not to disturb the cells. Deliver to a plastic transport tube, cap, and recentrifuge for 10 minutes. Use a second plastic pipette to remove the plasma, staying clear of the platelets at the bottom of the tube. Transfer the plasma into a Labcorp PP transpak frozen purple tube with screw cap (Labcorp No. 49482). Freeze immediately and maintain frozen until tested. To avoid delays in turnaround time when requesting multiple tests on frozen samples, please submit separate frozen specimens for each test requested. Please print and use the Volume Guide for Coagulation Testing to ensure proper draw volume. **Reference Range** (*added superscript*) 88–163%[12] **References** Al-Ghafry M, Abou-Ismail MY, Acharya SS. Inherited Disorders of the Fibrinolytic Pathway: Pathogenic Phenotypes and Diagnostic Considerations of Extremely Rare Disorders. Semin Thromb Hemost. 2025 Mar;51(2):227-235. PubMed 39299257 Carpenter SL, Mathew P. Alpha2-antiplasmin and its deficiency: fibrinolysis out of balance. Haemophilia. 2008 Nov;14(6):1250-1254. PubMed 19141165 Reed GL, Houng AK, Wang D. Microvascular thrombosis, fibrinolysis, ischemic injury and death after cerebral thromboembolism are affected by circulating α2-antiplasmin levels. **Arterioscler Thromb Vasc Biol**. 2014 Dec;34(12):2586-2593. PubMed 25256235 Saes JL, Schols SEM, van Heerde WL, Nijziel MR. Hemorrhagic disorders of fibrinolysis: a clinical review. *J Thromb Haemost*. 2018 May 30. Epub ahead of print. PubMed 29847021

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
α2-Antiplasmin *(continued)*	**117739**	**Footnotes** 1. Abdul S, Leebeek FWG, Rijken DC, Uitte de Willige S. Natural heterogeneity of α2-antiplasmin: functional and clinical consequences. *Blood*. 2016 Feb 4;127(5):538-545. PubMed 26626994 2. Benzakour M, Fadli Y, Wafqui MT, Cherkab RD, Kettani CE. α2 antiplasmin deficiency: case report and literature review. *EAS J Anesthesiol Crit Care*. 2025;7(2):31-35. doi.org/10.36349/easjacc.2025.v07i02.001 3. Mayo Clinic Laboratories. Alpha-2 plasmin inhibitor, plasma. Mayo Clinic Laboratories website: https://www.mayocliniclabs.com/test-catalog/overview/602169. Accessed May 30, 2026. 4. Marongiu F, Mamusa AM, Mameli G, et al. α2-antiplasmin and disseminated intravascular coagulation in liver cirrhosis. *Thromb Res*. 1985 Jan 15;37(2):287-294. PubMed 3975873 5. Haisma B, Rijpma SR, Cnossen MH, et al. Enhanced thrombin and plasmin generation profiles in α2-antiplasmin–deficient patients. *Res Pract Thromb Haemost*. 2024 Oct 23;8(7):102604. PubMed 39628652 6. Singh S, Saleem S, Reed GL. Alpha2-antiplasmin in cerebrovascular and cardiovascular disease. *Front Cardiovasc Med*. 2020 Dec 23;7:608899. PubMed 33426005 7. Adcock DM, Kressin DC, Marlar RA. Effect of 3.2% vs 3.8% sodium citrate concentration on routine coagulation testing. *Am J Clin Pathol*. 1997 Jan;107(1):105-110. PubMed 8980376 8. Reneke J, Etzell J, Leslie S, NG, VL, Gottfried EL. Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/L (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998 Jun;109(6):754-757. PubMed 9620035 9. Clinical Laboratory Standards Institute (CLSI). Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays. 6th ed. CLSI guideline H21. Clinical and Laboratory Standards Institute; 2024. 10. Gottfried EL, Adachi MM. Prothrombin time and activated partial thromboplastin time can be performed on the first tube. *Am J Clin Patho*l. 1997 Jun;107(6):681-683. PubMed 9169665 11. McGlasson DL, More L, Best HA, Norris WL, Doe RH, Ray H. Drawing specimens for coagulation testing: Is a second tube necessary? *Clin Lab Sci*. 1999 May-Jun;12(3):137-139. PubMed 10539100 12. Labcorp internal data.
***APOE* Alzheimer's Disease Risk**	**125536**	**Limitations** *APOE* E2, E3 and E4 are validated for this analysis. The rare *APOE* E1/E1, E1/E2 are reported as failed results. E2/E4 and E1/E3 genotypes cannot be distinguished by this assay. Molecular-based testing is highly accurate, but as in any laboratory test, rare errors may occur. False positive or false negative results may occur for reasons that include genetic variants, blood transfusions, bone marrow trans plantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.
***APOE* Genotyping: Cardio Risk**	**125561**	**Limitations** *APOE* E2, E3 and E4 are validated for this analysis. The rare *APOE* E1/E1, E1/E2 are reported as failed results. E2/E4 and E1/E3 genotypes cannot be distinguished by this assay. Molecular-based testing is highly accurate, but as in any laboratory test, rare errors may occur. False positive or false negative results may occur for reasons that include genetic variants, blood transfusions, bone marrow trans plantation, somatic or tissue-specific mosaicism, mislabeled samples or erroneous representation of family relationships.
CD4:CD8 Ratio Profile	**505271**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
***Chlamydia/Gonococcus*, Pharyngeal Swab, NAA**	**188698**	**Specimen** Pharyngeal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube **Container** Aptima® swab specimen transport tube **Collection** Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit. Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube. **Causes for Rejection** Inappropriate transport conditions; bacterial swabs; swabs from sites other than pharyngeal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Chlamydia/Gonococcus, Rectal Swab, NAA</td><td>188672</td><td>Specimen Rectal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube
Container Aptima® swab specimen transport tube
Collection Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the rectum about 1 to 2 inches (3 to 5 cm) past the anal margin and gently rotate the swab clockwise for five to 10 seconds. Withdraw the swab without touching the skin. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube.
Causes for Rejection Inappropriate transport conditions; bacterial swabs; swabs from sites other than rectal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport</td></tr>
<tr><td>Chlamydia trachomatis, Pharyngeal Swab, NAA</td><td>188714</td><td>Specimen Pharyngeal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube
Container Aptima® swab specimen transport tube
Collection Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube.
Causes for Rejection Inappropriate transport conditions; bacterial swabs; swabs from sites other than pharyngeal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport</td></tr>
<tr><td>Chlamydia trachomatis, Rectal Swab, NAA</td><td>188706</td><td>Specimen Rectal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube
Container Aptima® swab specimen transport tube
Collection Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the rectum about 1 to 2 inches (3 to 5 cm) past the anal margin and gently rotate the swab clockwise for five to 10 seconds. Withdraw the swab without touching the skin. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube.
Causes for Rejection Inappropriate transport conditions; bacterial swabs; swabs from sites other than rectal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport</td></tr>
<tr><td>C-Telopeptide (Endocrine Sciences)</td><td>500089</td><td>Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>Serum: 6 hours
Li-heparin plasma: 4 hours
Lavender-top and pink-top (K2-EDTA) plasma: 24 hours</td></tr>
<tr><td>Refrigerated</td><td>Serum: 2 days
Li-heparin plasma: 8 hours
Lavender-top and pink-top (K2-EDTA) plasma: 8 days</td></tr>
<tr><td>Frozen</td><td>Serum: 3 months
Li-heparin plasma: 3 months
Lavender-top and pink-top (K2-EDTA) plasma: 3 months</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x1</td></tr>
</table></td></tr>
</table>

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>D-Dimer</td><td>115188</td><td>
Use The D-dimer test is intended for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) and deep venous thrombosis (DVT) in outpatients suspected of PE or DVT.[6]
Limitations In outpatients with a low or moderate clinical pretest probability (PTP), a D-dimer result below the selected threshold is consistent with absence of significant intravascular fibrin formation and supports exclusion of venous thromboembolism when interpreted in conjunction with an appropriate validated clinical assessment model. In this population, an elevated result does not confirm pulmonary embolism or deep vein thrombosis but indicates that further imaging may be warranted. D-dimer may also be elevated in non-thrombotic conditions such as disseminated intravascular coagulation, malignancy, infection, recent surgery or trauma, pregnancy and with increasing age.
This assay is not suitable for excluding venous thromboembolism in patients with high PTP as false-positive results are common and specificity is limited. Analytical interferences including fibrinogen degradation products, rheumatoid factor and heterophile antibodies may also cause overestimation. Accordingly, an elevated D-dimer should be interpreted as evidence of coagulation and fibrinolytic activity rather than a disease-specific diagnostic result.
Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings. DVT clinical diagnosis should not be based on the result of Innovance® D-dimer alone.
D-dimer levels can be elevated in many clinical circumstances, especially in hospitalized patients. D-dimer should not be used as an aid for exclusion of venous thrombosis or pulmonary embolism in pediatric patients in any circumstance and adult patients with[6-8]:
• Therapeutic dose anticoagulant administered for >24 hours before D-dimer is measured
• Thrombosis distal to the knee only
• Fibrinolytic therapy within previous seven days
• Upper extremity thrombosis
• D-dimer levels may be falsely negative if the elapsed time between thrombosis onset and D-dimer measurement is sufficient such that D-dimer has been cleared from the circulation
The following conditions are associated with an increase in D-dimer concentrations, even in the absence of venous thrombosis:
• Aortic aneurysm
• Trauma or surgery within previous four weeks
• Disseminated malignancies
• Disseminated intravascular coagulation
• Sickle cell disease
• Sepsis, severe infections, pneumonia, severe skin infections
• Liver cirrhosis
• Pregnancy
Also note[6]:
• Patient samples may contain heterophilic antibodies (e.g., human antimouse antibodies [HAMA] and rheumatoid factors) that could react in immunoassays to yield falsely elevated results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.
• Patients with subsegmental/peripheral PE or distal DVT may have a normal D-dimer result.[9,10]
• Exclusionary claim of PE in patients with high PTP scores has not been established.
References
Adam SS, Key NS, Greenberg CS. D-dimer antigen: current concepts and future prospects. Blood. 2009 Mar 26;113(13):2878-2887. PubMed 19008457
Bates SM. D-dimer assays in diagnosis and management of thrombotic and bleeding disorders. Semin Thromb Hemost. 2012 Oct;38(7):673-682. PubMed 23041982
Clinical and Laboratory Standards Institute (CLSI). Quantitative D-Dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline (H59-A). Wayne, PA: CLSI; 2011.
Righini M, Perrier A, De Moerloose P, Bounameaux H. D-dimer for venous thromboembolism diagnosis: 20 years later. J Thromb Haemost. 2008 Jul;6(7):1059-1071. PubMed 18419743
Footnotes (updated)
6. Diagnostica Stago SAS. STA®-Liatest® D-Di: Immunoturbidimetric Assay of D-Dimer—Instructions for Use. Asnières-sur-Seine, France; 2021.
</td></tr>
<tr><td>Fatty Acid Profile, Comprehensive C8-C26</td><td>070405</td><td>
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Frozen</td><td>Red-top serum: <-10°C for 31 days
Red-top serum: <-70°C for 54 days
Lithium heparin plasma, sodium heparin plasma, EDTA plasma and gel-separated serum: <-10°C for 30 days</td></tr>
</table>
Causes for Rejection Specimen thawed or not frozen; grossly lipemic or grossly hemolyzed specimen
</td></tr>
<tr><td colspan="3">NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.</td></tr>
</table>

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Fibrinogen Activity	**001610**	**Additional Information** (*added*) Elevated fibrinogen activity is most consistent with an acute phase response, seen in infection, systemic inflammation, tissue injury, autoimmune disease, or malignancy. Increases may occur during pregnancy or with estrogen exposure. Persistent elevation may be associated with increased cardiovascular risk related to prothrombotic clot architecture. A number of clinical and epidemiological studies have revealed a consistent association between elevated fibrinogen levels and increased risk for atherosclerotic vascular disease;[11] however, it remains to be determined whether increased fibrinogen acts as a mediator of arterial thrombosis or simply reflects the inflammation associated with atherosclerosis.[11] Marked hyperfibrinogenemia can reduce lupus anticoagulant (LA) assay sensitivity by shortening phospholipid-dependent clotting times (e.g., aPTT and sometimes dRVVT), partially offsetting inhibitor-mediated prolongation and yielding false-negative or borderline results.[15,16] **References** (*added*) Besser MW, MacDonald SG. Acquired hypofibrinogenemia: current perspectives. *J Blood Med*. 2016 Sep 26;7:217-225. PubMed 27713652 Casini A, Undas A, Palla R, Thachil J, de Moerloose P; Subcommittee on Factor XIII and Fibrinogen. Diagnosis and classification of congenital fibrinogen disorders: communication from the SSC of the ISTH. *J Thromb Haemost*. 2018 Sep;16(9):1887-1890. PubMed 30076675 Fuja C, Eby C. An Overview of Dysfibrinogenemia: Pathogenesis, Diagnosis, and Management. *Clin Lab Med*. 2026 Jun;46(2):199-211. PubMed 42140680 Hugon-Rodin J, Carrière C, Claeyssens S et al. Obstetrical complications in hereditary fibrinogen disorders: the Fibrinogest study. *J Thromb Haemost*. 2023 Aug;21(8):2126-2136. PubMed 37172732 Scarlatescu E, Levy JH, Moore H, et al. Disseminated intravascular coagulation and cirrhotic coagulopathy: overlap and differences. The current state of knowledge. Communication from the SSC of the ISTH. *J Thromb Haemost*. 2025 Mar;23(3):1085-1106. PubMed 39662873 **Footnotes** (*added*) 15. Marco-Rico A. Update on the Laboratory Diagnosis of Lupus Anticoagulant: Current Challenges and Clinical Involvement. *J Clin Med*. 2025 Apr 18;14(8):2791. PubMed 40283621 16. Devreese KMJ, de Groot PG, de Laat B, et al. Guidance from the Scientific and Standardization Committee for lupus anticoagulant/antiphospholipid antibodies of the International Society on Thrombosis and Haemostasis: Update of the guidelines for lupus anticoagulant detection and interpretation. *J Thromb Haemost*. 2020 Nov;18(11):2828-2839. PubMed 33462974
Fibrinogen Antigen	**117052**	**Container** Blue-top (sodium citrate) tube (preferred), lavender-top (EDTA) tube **Collection** Citrated plasma samples should be collected by double centrifugation. Blood should be collected in a blue-top tube containing 3.2% buffered sodium citrate. Evacuated collection tubes must be filled to completion to ensure a proper blood to anticoagulant ratio. The sample should be mixed immediately by gentle inversion at least six times to ensure adequate mixing of the anticoagulant with the blood. A discard tube is not required prior to collection of coagulation samples unless the sample is collected using a winged (butterfly) collection system. With a winged blood collection set, a discard tube should be drawn first to account for the dead space of the tubing and prevent under-filling of the evacuated tube. When non-citrate tubes are collected for other tests, collect sterile and nonadditive (red-top) tubes prior to citrate (blue-top) tubes. Any tube containing an alternate anticoagulant should be collected after the blue-top tube. Gel-barrier tubes and serum tubes with clot initiators should also be collected after the citrate tubes. Centrifuge for 10 minutes and carefully remove 2/3 of the plasma using a plastic transfer pipette, being careful not to disturb the cells. Deliver to a plastic transport tube, cap, and re-centrifuge for 10 minutes. Use a second plastic pipette to remove the plasma, staying clear of the platelets at the bottom of the tube. Transfer the plasma into a Labcorp PP transpak frozen purple tube with screw cap (Labcorp No. 49482). **Freeze** immediately and maintain **frozen** until tested. Please print and use the Volume Guide for Coagulation Testing to ensure proper draw volume.
Helper/Suppressor and Natural Killer Cell Profile	**259317**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
Helper T-Lymphocyte Marker CD4	**505008**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
Hepatitis B Surface Antigen (HBsAg) Screen, Qualitative With Reflex to Hepatitis D Virus (HDV) Antibody	**006514**	**Limitations** The performance of the HBsAg assay has not been established with cadaveric specimens, heat-inactivated specimens or body fluids other than serum and EDTA plasma. HDV antibody reactive specimens should be further tested for HDV RNA to differentiate between active and resolved HDV infection. A nonreactive test result for HDV antibodies does not exclude the possibility of exposure to or infection with HDV. Further investigations with alternative HDV-specific tests are suggested in case of suspected infection despite the negative finding.
Hepatitis B Virus (HBV) Triple Panel With Reflex to Hepatitis D Virus (HDV) Antibody	**144103**	**Limitations** The performance of the HBV assays included in this panel has not been established with cadaveric specimens, heat-inactivated specimens or body fluids other than serum and EDTA plasma. HDV antibody reactive specimens should be further tested for HDV RNA to differentiate between active and resolved HDV infection. A nonreactive test result for HDV antibodies does not exclude the possibility of exposure to or infection with HDV. Further investigations with alternative HDV-specific tests are suggested in case of suspected infection despite the negative finding.

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Hepatitis D Virus (HDV) Antibody, IgG and IgM</td><td>144012</td><td>Limitations A reactive specimen should be investigated further with sensitive, supplemental HDV-specific tests, such as identification of HDV RNA, to be matched with the clinical story of the subject and with markers of a previous HBV infection (HBsAg, anti-HB Core, HBV DNA, etc.).
Like all immunoassays, this assay may occasionally yield nonspecific reactions due to other causes. A nonreactive test result for HDV antibodies does not exclude the possibility of exposure to or infection with HDV. Further investigations with alternative HDV-specific tests are suggested in case of suspected infection despite the negative finding.</td></tr>
<tr><td>Lipoprotein(a)</td><td>120188</td><td>Limitations Measurement of lipoprotein(a) is now recommended in several patient subgroups for whom excess lipoprotein(a) may have important clinical consequences: (1) patients with premature atherosclerosis, (2) patients with a strong family history of premature coronary heart disease (CHD), (3) patients with elevated LDL-C and greater than or equal to two risk factors, (4) patients who have had coronary angioplasty in whom lipoprotein(a) excess may increase the risk of restenosis, and (5) patients who have undergone coronary bypass graft surgery in whom Lp(a) excess may be associated with graft stenosis.[2,3]
Lipoprotein(a) has been called a powerful predictor of premature atherosclerotic vascular disease.[2] As an independent risk factor for premature coronary artery disease, excess Lp(a) concentrations are associated with an increased risk of cardiac death in patients with acute coronary syndromes and with restenosis after angioplasty (PTCA) and coronary bypass procedures. In general, concentrations greater than or equal to 75 nmol/L of Lp(a) in serum are associated with a two- to sixfold increase in risk, depending on the presence of other risk factors.
Volume 1 mL
Minimum Volume 0.5 mL (Note: This volume does not allow for repeat testing.)
Container Red-top tube, gel-barrier tube, lavender-top (EDTA) tube
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>5 days (stability provided by manufacturer or literature reference)</td></tr>
<tr><td>Refrigerated</td><td>20 days (stability provided by manufacturer or literature reference)</td></tr>
<tr><td>Frozen</td><td>13 weeks (stability provided by manufacturer or literature reference)</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x1 (stability provided by manufacturer or literature reference)</td></tr>
</table>
Reference Range
<table>
<tr><th>Concentration</th><th>Risk</th></tr>
<tr><td><75 nmol/L</td><td>Low Lp(a)-attributable ASCVD risk</td></tr>
<tr><td>75 – <125 nmol/L</td><td>Intermediate Lp(a)-attributable ASCVD risk</td></tr>
<tr><td>≥125 nmol/L</td><td>High Lp(a)-attributable ASCVD risk, with increasing risk with higher Lp(a) values</td></tr>
</table></td></tr>
<tr><td>Lymphocyte Activity Profile</td><td>505321</td><td>Collection Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.</td></tr>
<tr><td>Natural Killer Cell and Activated T-Cell Profile/IL-2r</td><td>502500</td><td>Collection Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.</td></tr>
<tr><td>Natural Killer Cell Surface Antigen (CD3-CD56+ Marker Analysis)</td><td>505016</td><td>Collection Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.</td></tr>
<tr><td colspan="3">NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.</td></tr>
</table>

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
***Neisseria gonorrhoeae*, Pharyngeal Swab, NAA**	**188748**	**Specimen** Pharyngeal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube **Container** Aptima® swab specimen transport tube **Collection** Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit. Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube. **Causes for Rejection** Inappropriate transport conditions; bacterial swabs; swabs from sites other than pharyngeal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport
***Neisseria gonorrhoeae*, Rectal Swab, NAA**	**188730**	**Specimen** Rectal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube **Container** Aptima® swab specimen transport tube **Collection** Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the rectum about 1 to 2 inches (3 to 5 cm) past the anal margin and gently rotate the swab clockwise for five to 10 seconds. Withdraw the swab without touching the skin. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit. Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube. **Causes for Rejection** Inappropriate transport conditions; bacterial swabs; swabs from sites other than rectal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport
PrEP Use Only: *Chlamydia/ Gonococcus*, Pharyngeal Swab, NAA	**188710**	**Specimen** Pharyngeal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube **Container** Aptima® swab specimen transport tube **Collection** Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit. Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube. **Causes for Rejection** Inappropriate transport conditions; bacterial swabs; swabs from sites other than pharyngeal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport
PrEP Use Only: *Chlamydia/ Gonococcus*, Rectal Swab, NAA	**188725**	**Specimen** Rectal specimen collected with Aptima® Multitest collection swab and submitted in Aptima® swab specimen transport tube **Container** Aptima® swab specimen transport tube **Collection** Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line. Carefully insert the swab into the rectum about 1 to 2 inches (3 to 5 cm) past the anal margin and gently rotate the swab clockwise for five to 10 seconds. Withdraw the swab without touching the skin. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit. Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Immediately discard the top portion of the swab shaft. Tightly screw the cap onto the tube. **Causes for Rejection** Inappropriate transport conditions; bacterial swabs; swabs from sites other than rectal sources; unlabeled specimens or those with a discrepancy between the specimen label and the test request form; Aptima® swab transport tube with no swab or multiple swabs; swab not supplied by Hologic; Aptima® swabs greater than 60 days from collection; any transport device other an Aptima® swab transport

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Syphilis: RPR (Monitor) With Reflex to RPR Titer	**006072**	**Name** Changed from "Syphilis: RPR With Reflex to RPR Titer" **Synonyms** (*added*) Monitoring
T- and B-Lymphocyte and Natural Killer Cell Profile	**505370**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
T- and B-Lymphocyte Differential Profile	**096917**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
T-Cell Activation Profile, CD8 Subsets	**505750**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
T-Lymph Markers and NK	**505065**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
T-Lymphocyte Helper/Suppressor Profile	**096925**	**Collection** Immediately invert the tube eight to 10 times after collection. To maintain cellular viability, collect the specimen in either a yellow-top tube (ACD-A or ACD-B) for arrival at the laboratory within 48 hours of collection, or a lavender-top (EDTA) tube for arrival at the laboratory within 24 hours of collection. Record the date and time of venipuncture on both the tube(s) and the test requisition form.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Deleted Tests

Deleted Tests	Test No.	Labcorp Offers	Test No.
Autoimmune Polyglandular Syndrome Type 1 (APS1/APECED): AIRE (Full Gene Sequencing)	**252532**	GeneSeq® PLUS	482370
Autoimmune Polyglandular Syndrome Type 1 (APS1/APECED): AIRE (Known Mutation)	**252737**	Targeted Variant Analysis	482552
Breast Cancer Prognostic Gene Signature Assay (Prosigna®), IVD	**481210**	Please contact your Labcorp representative for testing options.	
Chronic Granulomatous Disease (CGD): CYBB (Full Gene Sequencing)	**252529**	GeneSeq® Immuno: Single Gene Analysis	483991
Chronic Granulomatous Disease (CGD): CYBB (Known Mutation)	**252733**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Common Variable Immunodeficiency Syndrome (CVID): TNFRSF13B (TACI) (Full Gene Sequencing)	**252456**	GeneSeq® Immuno: Single Gene Analysis	483991
Common Variable Immunodeficiency Syndrome (CVID): TNFRSF13B (TACI) (Known Mutation)	**252687**	GeneSeq® Immuno: Targeted Variant Analysis	484069
GeneSeq® Connective Tissue: Ehlers-Danlos Syndrome Panel	**630755**	GeneSeq® Connective Tissue: Ehlers-Danlos Syndrome Panel	630978
GeneSeq® Connective Tissue Single Gene Analysis	**631200**	GeneSeq® Connective Tissue: Single Gene Analysis	631264
GeneSeq® Immuno: Periodic Fever Syndromes Panel	**630763**	GeneSeq® Immuno: Periodic Fever Syndromes Panel	483786
Hyper-IgM Syndrome (HIGM): (AICDA for HIGM2) (Full Gene Sequencing)	**252425**	GeneSeq® Immuno: Single Gene Analysis	483991
Hyper-IgM Syndrome (HIGM): (AICDA for HIGM2) (Known Mutation)	**252663**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Hyper-IgM Syndrome (HIGM): (CD40 [TNFRSF5] for HIGM3) (Full Gene Sequencing)	**252432**	GeneSeq® Immuno: Single Gene Analysis	483991

Deleted Tests

Deleted Tests	Test No.	Labcorp Offers	Test No.
Hyper-IgM Syndrome (HIGM): (CD40 [TNFRSF5] for HIGM3) (Known Mutation)	**252670**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Hyper-IgM Syndrome (HIGM): (CD40LG [TNFSF5] for HIGM1) (Full Gene Sequencing)	**252435**	GeneSeq® Immuno: Single Gene Analysis	483991
Hyper-IgM Syndrome (HIGM): (CD40LG [TNFSF5] for HIGM1) (Known Mutation)	**252673**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Hypohidrotic Ectodermal Dysplasia With Immune Deficiency (HED-ID): IKBKG (NEMO) (Full Gene Sequencing)	**252539**	GeneSeq® Immuno: Single Gene Analysis	483991
Hypohidrotic Ectodermal Dysplasia With Immune Deficiency (HED-ID): IKBKG (NEMO) (Known Mutation)	**252744**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Interferon-γ Receptor Deficiency: IFNGR1 (Full Gene Sequencing)	**252519**	Please contact your Labcorp representative for testing options.	
Interferon-γ Receptor Deficiency: IFNGR1 (Known Mutation)	**252727**	Please contact your Labcorp representative for testing options.	
Interferon-γ Receptor Deficiency: IFNGR2 (Full Gene Sequencing)	**252522**	Please contact your Labcorp representative for testing options.	
Interferon-γ Receptor Deficiency: IFNGR2 (Known Mutation)	**252730**	Please contact your Labcorp representative for testing options.	
Interferon-γ Receptor Deficiency: Two-gene Profile (IFNGR1, IFNGR2) (Full Gene Sequencing)	**252525**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID): ADA (Full Gene Sequencing)	**252475**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): ADA (Known Mutation)	**252707**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID): CD3D (Full Gene Sequencing)	**252482**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): CD3D (Known Mutation)	**252713**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID): CD3E (Full Gene Sequencing)	**252485**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): CD3E (Known Mutation)	**252716**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID): IL2RG for XSCID (Full Gene Sequencing)	**252463**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): IL2RG for XSCID (Known Mutation)	**252694**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID): IL7R (Full Gene Sequencing)	**252479**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): IL7R (Known Mutation)	**252710**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID): JAK3 (Full Gene Sequencing)	**252466**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): JAK3 (Known Mutation)	**252697**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID): ZAP70 (Full Gene Sequencing)	**252489**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID): ZAP70 (Known Mutation)	**252720**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): DCLRE1C (Artemis) for RS-SCID or SCIDA (Full Gene Sequencing)	**252492**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): DCLRE1C (Artemis) for RS-SCID or SCIDA (Known Mutation)	**252723**	GeneSeq® Immuno: Targeted Variant Analysis	484069

Deleted Tests

Deleted Tests	Test No.	Labcorp Offers	Test No.
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): RAG1 (Full Gene Sequencing)	**252470**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): RAG1 (Known Mutation)	**252701**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): RAG2 (Full Gene Sequencing)	**252472**	GeneSeq® Immuno: Single Gene Analysis	483991
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): RAG2 (Known Mutation)	**252704**	GeneSeq® Immuno: Targeted Variant Analysis	484069
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): RAG1, RAG2, DCLRE1C (Artemis) (Full Gene Sequencing)	**252503**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): Two-gene Profile (RAG1, RAG2) (Full Gene Sequencing)	**252499**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): Three-gene Profile (IL2RG, ADA, IL7R) (Full Gene Sequencing)	**252509**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID): Two-gene Profile (IL2RG, JAK3) (Full Gene Sequencing)	**252496**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID): Three-gene Profile (IL7R, CD3D, CD3E) (Full Gene Sequencing)	**252506**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): Eight-gene Profile (IL2RG, JAK3, RAG1, RAG2, IL7R, ADA, CD3D, CD3E) (Full Gene Sequencing)	**252513**	Please contact your Labcorp representative for testing options.	
Severe Combined Immunodeficiency (SCID Including Omenn Syndrome): Nine-gene Profile (IL2RG, JAK3, RAG1, RAG2, IL7R, ADA, CD3D, CD3E, DCLRE1C [Artemis]) (Full Gene Sequencing)	**252516**	Please contact your Labcorp representative for testing options.	
X-linked Agammaglobulinemia (XLA): BTK (Full Gene Sequencing)	**252453**	GeneSeq® Immuno: Single Gene Analysis	483991
X-linked Agammaglobulinemia (XLA): BTK (Known Mutation)	**252683**	GeneSeq® Immuno: Targeted Variant Analysis	484069
X-linked Lymphoproliferative Disease (XLP): SH2D1A (Full Gene Sequencing)	**252535**	Please contact your Labcorp representative for testing options.	
X-linked Lymphoproliferative Disease (XLP): SH2D1A (Known Mutation)	**252740**	Please contact your Labcorp representative for testing options.	
Wiskott-Aldrich Syndrome (WAS): WAS (Full Gene Sequencing)	**252459**	GeneSeq® Immuno: Single Gene Analysis	483991
Wiskott-Aldrich Syndrome (WAS): WAS (Known Mutation)	**252690**	GeneSeq® Immuno: Targeted Variant Analysis	484069

The CPT codes listed are in accordance with the current edition of Current Procedural Terminology, a publication of the American Medical Association. CPT codes are provided for the convenience of our clients; however, correct coding often varies from one carrier to another. Consequently, the codes presented here are intended as general guidelines and should not be used without confirming with the applicable payer that their use is appropriate in each case.

LOINC® Map. The Logical Observation Identifiers Names and Codes (LOINC®) corresponding to individual Labcorp published assays is updated on a regular basis at www.labcorp.com.