LABHORIZONS
A NEWSLETTER FOR CLIENTS
Volume XIX, No. 6 — June 2019

New Procedures

HER-2/CEP17 FISH, Breast With Reflex to Immunohistochemistry (IHC) if Group 2, 3, 4 by FISH 483333

CPT 88271(x2); 88274
Special Instructions Direct any questions regarding this test to Oncology Customer Service at 800-345-4363.
Specimen Formalin-fixed, paraffin-embedded (FFPE) tumor
Volume One paraffin block **or** seven unstained, positively-charged tissue slides cut at 4-5 microns and dried for one hour at 60°C.
Container Paraffin block transport pouch **or** slide mailer
Collection Specimen should be fixed in 10% neutral-buffered formalin. Fixation time should be between 6 and 72 hours according to ASCO/CAP guidelines; however, the package insert indicates optimum fixation time between 18 and 24 hours.
Storage Instructions Maintain specimen at room temperature.
Causes for Rejection Tumor other than breast tumor
Use Tissues are evaluated for gene amplification status by FISH. Specimens demonstrating a classification of Group 2, 3, 4 by FISH are evaluated by immunohistochemistry.
Limitations Use of fixatives other than 10% neutral-buffered formalin or fixation times less than six hours or more than 48 hours may not yield equivalent or satisfactory results.
Methodology Fluorescence in situ hybridization (FISH), Immunohistochemistry (IHC)
References

Dybdal N, Lieberman G, Anderson S, et al. Determination of HER2 gene amplification by fluorescence in situ hybridization and concordance with the clinical trials immunohistochemical assay in women with metastatic breast cancer evaluated for treatment With trastuzumab. *Breast Cancer Res Treat.* 2005 Sep;93(1):3-11. PubMed 16184453

Mass RD, Press MF, Anderson S, et al. Evaluation of clinical outcomes according to HER2 detection by fluorescence in situ hybridization in women with metastatic breast cancer treated with trastuzumab. *Clin Breast Cancer.* 2005 Aug;6(3):240- 246. PubMed 16137435

Wolff AC, Hammond MEH, Allison K, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. *J Clin Oncol. 2018* Jul 10;36(20):2105-2122. PubMed 29846122

Oxidized Low-density Lipoprotein (OxLDL) 123023

CPT 83721
Synonyms Oxidized LDL; OxLDL
Specimen Plasma (preferred) **or** serum (acceptable)
Volume 0.5 mL
Minimum Volume 0.2 mL
Container Lavender-top (EDTA) tube **or** gel-barrier tube
Collection Plasma must be separated from cells within 45 minutes of venipuncture. Send plasma in a plastic transfer tube.
Storage Instructions Refrigerate
Stability

Temperature	Period
Room temperature	3 days
Refrigerated	7 days
Frozen	3 months

Patient Preparation Fasting for 10 to 12 hours is recommended.
Causes for Rejection Specimen other than EDTA plasma or serum; improper labeling; specimen not stored properly; specimen older than stability limits
Use For the in vitro quantitative measurement of oxidized low density lipoproteins (oxidized LDL) in human serum or plasma.

Measurement of oxidized LDL (oxLDL) has been incorporated into clinical practice in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, especially as it pertains to the evaluation of oxidative stress. Oxidized LDL-particles are considered to be an important driving factor in the pathophysiology of atherosclerosis and oxLDL measurement has been used to test the efficacy of CVD drugs (eg, statins) to reduce oxidative stress.[9]

Limitations Lipemic or hemolytic samples may give erroneous results and should not be used for analysis.
Methodology Enzyme-linked immunoassay (ELISA)
Reference Interval 10–170 ng/mL
Additional Information The oxidative conversion of low density lipoproteins (LDL) to oxidized low density lipoproteins (oxidized LDL) is now considered to be a key event in the biological process that initiates and accelerates the development of the early atherosclerotic lesion, the fatty streak.[1-5]

Experimental studies have shown that native LDL becomes atherogenic when it is converted to oxidized LDL, and that oxidized LDL is more atherogenic than native LDL.[1-5] Oxidized LDL is found in monocyte-derived macrophages in atherosclerotic lesions, but not in normal arteries.[6] The uptake of LDL into macrophages does not occur by way of the classic Brown/Goldstein LDL receptor.[7] Numerous studies[1-5,8] have established that LDL, the major carrier of blood cholesterol, must first be converted to oxidized LDL so that it can be recognized by "scavenger" or "oxidized LDL receptors" on monocyte-derived macrophages. The binding of oxidized LDL to macrophages is a necessary step by which oxidized LDL induces cholesterol accumulation in macrophages, thus transforming the macrophages into lipid-laden foam cells.[8]

Footnotes

1. Steinberg D. Low density lipoprotein oxidation and its pathobiological significance. *J Biol Chem.* 1997 Aug 22; 272(34):20963-20966. PubMed 9261091

2. Berliner JA, Navab M, Fogelman AM, et al. Atherosclerosis: basic mechanisms. Oxidation, inflammation, and genetics. *Circulation.* 1995 May 1; 91(9):2488-2496. PubMed 7729036

3. Steinberg D. Lewis A. Conner Memorial Lecture. Oxidative modification of LDL and atherogenesis. *Circulation.* 1997 Feb 18;95(4):1062-1071. PubMed 9054771

4. Heinecke JW. Oxidants and antioxidants in the pathogenesis of atherosclerosis: implications for the oxidized low density lipoprotein hypothesis. *Atherosclerosis.* 1998 Nov;141(1):1-15. PubMed 9863534

These new/revised publications are now available:

- **Pediatric Health Wellness brochure (L19516)**
- **Your Partner: Pregnancy Continuum brochure (L20541)**
- **PIK3CA Mutation Analysis flyer (L20694)**

Please ask your LabCorp service representative for these titles.

5. Witztum JL, Hörkkö S. The role of oxidized LDL in atherogenesis: immunological response and anti-phospholipid antibodies. *Ann N Y Acad Sci.* 1997 Apr 15;811:88-96; discussion 96-99. PubMed 9186588

6. Ylä-Herttuala S. Is oxidized low-density lipoprotein present in vivo? *Curr Opin Lipidol.* 1998 Aug;9(4):337-344. PubMed 9739490

7. Brown MS, Goldstein JL. Lipoprotein metabolism in the macrophage: implications for cholesterol deposition in atherosclerosis. *Annu Rev Biochem.* 1983;52:223-261. PubMed 6311077

8. Chisolm GM 3rd, Hazen SL, Fox PL, Cathcart MK. The oxidation of lipoproteins by monocytes-macrophages. Biochemical and biological mechanisms. *J Biol Chem.* 1999 Sep 10;274(37):25959-25962. PubMed 10473535

9. Pfützner A A, Efstrathios K, Löbig M, Armbruster FP, Hanefeld M, Forst T. Differences in the results and interpretation of oxidized LDL Cholesterol by two ELISA assays--an evaluation with samples from the PIOstat Study. *Clin Lab.* 2009;55(7-8):275-281. PubMed 19894406

PIK3CA Mutation Analysis, Breast Cancer 485113

CPT 81404; 88381

Synonyms PIK3CA

Special Instructions Please provide a copy of the pathology report. Testing will be delayed if the pathology report is **not** received. Please direct any questions regarding this test to customer service at 800-345-4363.

Expected Turnaround Time 5 - 7 days

Specimen Formalin-fixed, paraffin-embedded tissue (FFPE) block **or** slides from tissue resection **or** core needle biopsy (CNB)

Volume Formalin-fixed, paraffin-embedded tissue (FFPE) block **or** 6 unstained slides at 4-5m **and** one matching H&E-stained slide **or** 7 unstained slides

Minimum Volume 3 unstained slides at 4-5m **and** one matching H&E-stained slide **or** 4 unstained slides. Resection or Surgical Biopsies require > or =10% tumor content. Core Needle Biopsies require a minimum of > or = 20 mm2 tumor area total available for extraction. Minimum volume allows only one attempt at DNA extraction.

Container FFPE block **or** slides

Collection Ship specimen at room temperature. Please direct any questions regarding this test to customer service at 800-345-4363.

Storage Instructions Maintain blocks/slides at room temperature.

Causes for Rejection Specimen does not meet all of the above criteria for sample type, container, minimum volume, collection and storage; specimens containing suspicious foreign material; no tumor tissue in FFPE block or slides; broken or stained slides; fixative other than formalin

Use The therascreen PIK3CA RGQ RT-PCR Kit is a real-time, qualitative PCR assay for the detection of 11 mutations in the phosphatidyl 3-kinases catalytic subunit alpha (PIK3CA) gene (Exon 7: C420R; Exon 9: E542K; E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and Exon 20: H1047L, H1047R, H1047Y) using genomic DNA (gDNA) extracted from formalin-fixed paraffin-embedded (FFPE) breast tumor tissue. The test is intended to aid clinicians in identifying breast cancer patients who may be eligible for treatment with PIQRAY(R) (alpelisib) based on a PIK3CA Mutation Detected result. Patients whose FFPE tissue produce a positive therascreen PIK3CA RGQ PCR Kit test result for the presence of one or more PIK3CA mutations are eligible for treatment with PIQRAY® (alpelisib).

Table 1. List of mutations detected and COSMIC identities

Exon	Mutation	COSMIC* ID	Base Change
7	C420R	757	1258 T>C
9	E542K	760	1624 G>A
9	E545A	12458	1634 A>C
9	E545D	765	1635G>T
9	E545G	764	1634A>G
9	E545K	763	1633 G>A
9	Q546E	6147	1636 A>G
9	Q546R	12459	1637 A>G
20	H1047L	776	3140 A>T
20	H1047R	775	3140 A>G
20	H1047Y	774	3139 C>T

* COSMIC: Catalogue of somatic mutations in cancer: https://cancer.sanger.ac.uk/cosmic

Limitations Results from the product must be interpreted within the context of all relevant clinical and laboratory findings and are not to be used alone for diagnosis.

Samples with results reported as "No Mutation Detected" may harbor PIK3CA mutations not detected by the therascreen PIK3CA RGQ PCR Kit.

Detection of mutations is dependent on sample integrity and the amount of amplifiable DNA present. The test procedure should be repeated if analysis of the DNA in the sample indicates that the quantity and/or quality is either not sufficient or the concentration is too high for mutation analysis.

The therascreen PIK3CA RGQ PCR Kit is used in a PCR procedure. As with all PCR procedures, samples may become contaminated by external sources of DNA in the test environment and the DNA in the positive control. Use caution to avoid contamination of samples and kit reagents.

If the sample contains less than the percentage of mutant alleles that is able to be detected by the therascreen PIK3CA RGQ PCR Kit, it will lead to a result of "No Nutation Detected."

It is not known whether the therascreen PIK3CA RGQ PCR Kit shows cross-reactivity (results of "Mutation Detected") to additional PIK3CA mutations different than those included in the kit.

The therascreen PIK3CA RGQ PCR Kit is a qualitative test. The test will not provide quantitative measurements of the Mutant Allele Frequency (MAF) present in a sample.

The impact of the performance of the therascreen PIK3CA RGQ PCR Kit is unknown if microbial contamination is introduced during assay procedures; operators must exercise due caution to avoid introduction of microbial contaminants during testing procedures and should not use kit components if evidence of microbial growth is observed.

The therascreen PIK3CA RGQ PCR Kit is only for use with DNA extracted from formalin-fixed, paraffin-embedded breast cancer tissue.

The therascreen PIK3CA RGQ PCR Kit is only for use with the QIAamp DSP DNA FFPE Tissue Kit (for tissue specimens).

Methodology The therascreen PIK3CA RGQ PCR Kit is a real-time qualitative PCR in vitro diagnostic test, performed on the Rotor-Gene Q MDx

(US) instrument. It uses allele refractory mutation system (ARMS) primers, hydrolysis probes and PCR clamp technologies to detect 11 mutations in exons 7, 9 and 20 of the PIK3CA oncogene against a background of wild-type gDNA.

References

Cancer Genome Atlas Network. Comprehensive molecular portraits of human breast tumors. *Nature.* 2012 Oct 4;490(7418):61-70. PubMed 23000897

Katso R, Okkenhaug K, Ahmadi K, White S, Timms J, Waterfield MD. Cellular function of phosphoinositide 3-kinases: implications for development, homeostasis, and cancer. *Annu Rev Cell Dev Biol.* 2001;17:615-675. PubMed 11687500

Malvezzi M, Carioli G, Bertuccio P, et al. European cancer mortality predictions for the year 2018 with focus on colorectal cancer. *Ann Oncol.* 2018 Apr 1;29(4):1016-1022. PubMed 29562308

National Breast Cancer Foundation. Breast cancer facts. National Breast Cancer Foundation web site: https://www.nationalbreastcancer.org/breast-cancer-facts. Accessed: January 2019.

Qiagen therascreen® PIK3CA RGQ PCR Kit Instructions for Use (Handbook). May 2019.

Samuels Y, Wang Z, Bardelli A, et al. High frequency of mutations of the PIK3CA gene in human cancers. *Science.* 2004 Apr 23;304(5670):554. PubMed 15016963

Siegel RL, Miller KD, Jemal A. Cancer statistics, 2018. *CA Cancer J Clin.* 2018 Jan;68(1):7-30. PubMed 29313949

Updates to the *Directory of Services and Interpretive Guide (DoS)*

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Abnormal PT/aPTT Reflexive Profile (Esoterix)	**503335**	**Special Instructions** • If PT is abnormal (above normal reference interval), the test will reflex to PT mixing studies and factor VII activity. • If aPTT is abnormal (above normal reference interval), the test will reflex to aPTT mixing studies, hexagonal phospholipid neutralization, factor XI activity, factor IX activity, and factor VIII activity. • If TT is abnormal (above normal reference interval), the test will reflex to fibrinogen activity and fibrinogen antigen. • If reflex testing is performed, concomitant CPT codes/charges will apply.
Angiotensin-converting Enzyme (ACE)	**010116**	**Collection** Separate serum from cells at the time of collection.
Bupropion and Hydroxybupropion, Serum or Plasma	**811083**	**Causes for Rejection** Gel-barrier tubes; specimen received not frozen; specimen not received in Bupropion Analysis Tube containing Sodium Citrate Monobasic
Calprotectin, Fecal	**123255**	**Methodology** Chemiluminescence
Carbamazepine Sensitivity HLA Associations	**167443**	**Methodology** Sequence-based typing (SBT or NGS), sequence-specific oligonucleotide probes (SSOP), and/or sequence-specific primers (SSP) as needed to obtain a high resolution typing
C-Reactive Protein (CRP), Quantitative	**006627**	**Reference Interval** See table. Age / Male (mg/L) / Female (mg/L) 0 to 30 d / Not established / Not established 1 m to 17 y / 0–7 / 0–9 >17 y / 0–10 / 0–10
D-Dimer	**115188**	**Stability** Temperature / Period Room temperature / Unacceptable Refrigerated / Unacceptable Frozen / 4 weeks Freeze/thaw cycles / Stable x1
Epidermal Growth Factor Receptor (EGFR) Gene Mutation Analysis, Non–Small-cell Lung Cancer (Single-base Extension)	**489360**	**Specimen** Formalin-fixed, paraffin-embedded (FFPE) tissue block **or** slides from NSCLC **Volume** Five unstained slides and one matching H&E-stained slide at 10 µM **or** formalin-fixed, paraffin-embedded tissue block **Storage Instructions** Submit blocks/slides at room temperature. **Limitations** (removed "The FDA has determined that such clearance or approval is not necessary.")
Factor VIII Activity	**086264**	**Reference Interval** 56% to 140%
Fatty Acids, Free (Nonester)	**081893**	**Stability** Temperature / Period Room temperature / 4 hours Refrigerated / 1 day Frozen / 105 days Freeze/thaw cycles / Stable x6
FLT3 Mutation Analysis	**485010**	**Special Instructions** (removed statement about testing not available to New York residents)

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Gastrointestinal Stromal Tumors (GISTs), c-KIT Mutation Analysis</td><td>510870</td><td rowspan="2">Special Instructions This test is not New York State approved.</td></tr>
<tr><td>Gastrointestinal Stromal Tumors (GISTs), c-KIT Mutation Analysis With Reflex to PDGFRA Mutation Analysis</td><td>510985</td></tr>
<tr><td>Gastrointestinal Stromal Tumors (GISTs), PDGFRA Mutation Analysis</td><td>510860</td><td>Special Instructions (added "This test is not New York State approved.")</td></tr>
<tr><td>Group A Streptococcus Direct, DNA Probe</td><td>180786</td><td>Container Copan Double Dacron dry swab in transport tube without medium (red cap) preferred; Copan Double Dacron swab in liquid Amies or liquid Stuart medium</td></tr>
<tr><td>Hepatitis B Core Antibody, Total</td><td>006718</td><td>Use Aid in the diagnosis of acute or chronic hepatitis B virus (HBV) infection and in the determination of the clinical status of HBV infected individuals in conjunction with other HBV serological markers. Aid in differential diagnosis of hepatitis. The presence of anti-HBc total antibody indicates previous or ongoing infection with HBV in an undefined time frame.</td></tr>
<tr><td>IntelliGEN® Myeloid</td><td>451953</td><td>Limitations The sensitivity of this assay is 5 to 10% variant allele fraction for single nucleotide variants (SNV) and insertion/deletions (InDels). Insertions and deletions of any length are detected when at least one breakpoint is contained within an amplicon. Insertions up to 126 bp and deletions up to 52 bp have been detected in clinical specimens. Mutations outside the targeted regions and gene rearrangements will not be detected. Variants are categorized into Tiers based on their clinical impact, following a joint consensus recommendation from the AMP, ASCO, and CAP. Clinical and experimental evidence grouped into four levels (A-D) based on significance in clinical decision making (therapeutic, diagnosis, prognosis) is assigned to variants to determine their clinical significance. Tier 1, Variants with Strong Clinical Significance (level A and B evidence); Tier 2, Variants with Potential Clinical Significance (level C or D evidence); Tier 3, Variants of Unknown Clinical Significance, and Tier 4, Benign or Likely Benign. Results should be interpreted in conjunction with clinical and other laboratory findings for the most accurate interpretation.
This test was developed, and its performance characteristics determined, by LabCorp. It has not been cleared or approved by the US Food and Drug Administration (FDA).</td></tr>
<tr><td>Lyme Disease, Borrelia burgdorferi C6 Antigen With Reflex to Line Blot</td><td>015400</td><td>Name (changed from Lyme Disease, Borrelia burgdorferi C6 Antigen With Reflex to Western Blot)
Test Includes Reflex to Line blot
Container Gel barrier tube or red-top tube or serum transfer tube
Methodology Enzyme-linked immunosorbent assay (ELISA); reflex to Line Blot if equivocal or positive</td></tr>
<tr><td>Lyme Disease, IgM, Early Test With Reflex</td><td>160333</td><td>Test Includes Lyme disease antibodies, IgM, EIA; supplementary Line blots for all positives from antibody test
Special Instructions Additional fees will be added for Line blot analysis if the EIA test is positive.
Container Red-top tube or gel-barrier tube or serum transfer tube
Use Aid in the diagnosis of acute infection with the Lyme disease agent, Borrelia burgdorferi
Methodology Enzyme immunoassay (EIA); Line blot
Additonal Information Combination of IgM antibodies test with reflex of positive results to Line blot confirmation. Negative early testing does not rule out infection.</td></tr>
<tr><td>Lyme Disease, Line Blot</td><td>163600</td><td>Name (changed from Lyme Disease, Western Blot)
Test Includes Line blot analysis and interpretations for IgG- and IgM-specific antibodies
Container Red-top tube or gel-barrier tube or serum transfer tube
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>14 days</td></tr>
<tr><td>Refrigerated</td><td>14 days</td></tr>
<tr><td>Frozen</td><td>14 days</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x3</td></tr>
</table>
Methodology Line blot
Additional Information Provides both IgM and IgG Line blot results. Increased specificity reduces cross-reactivity from other spirochetes. Detect and analyze antibodies against specific B burgdorferi proteins. The sensitivity of a Line blot assay by itself is not sufficient to assess Lyme infection adequately. Both EIA and Line blot tests should be performed.</td></tr>
<tr><td>Lyme Disease/Syphilis Antibodies Differential Profile</td><td>161653</td><td>Test Includes Lyme disease antibodies; Lyme disease total antibodies, EIA; STS (serologic test for syphilis); supplementary Line blots for all positives from antibody test
Container Red-top tube or gel-barrier tube or serum transfer tube
Methodology Lyme disease: enzyme immunoassay (EIA)/Line blot; charcoal flocculation</td></tr>
</table>

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Malnutrition Cascade	**460500**	**Additional Information** Adults whose diets do not provide enough nutrients-including calories and protein-required for appropriate tissue repair and maintenance experience undernutrition, or malnutrition.[1] It was reported that "malnutrition is a major contributor to increased morbidity and mortality, decreased function and quality of life, increased frequency and length of hospital stay, and higher health care cost."[1] Parameters used to diagnose malnutrition reflect both nutrition intake and severity and duration of disease. Another proposal in diagnosing malnutrition in adults is based on etiology, which will integrate the present understanding of inflammatory responses to disease and trauma.[2] The Academy of Nutrition and Dietetics, along with the American Society for Parenteral and Enteral Nutrition (ASPEN), have adopted patient-specific definitions based on etiologies, including social and environmental circumstances and chronic and acute illness.[1] Diagnosis categories include: (1) starvation-related malnutrition, or chronic starvation without inflammation; (2) chronic disease-related malnutrition, highlighted by mild-to-moderate chronic inflammation; and (3) acute disease or injury-related malnutrition, where inflammation is acute and severe.[1] **Cascade Steps and Interpretation** 1. The cascade starts with testing for the levels of **Insulin-like Growth Factor-1 (IGF-1),** as it was reported to be a sensitive indicator of malnutrition independent of classical nutritional markers like serum proteins,[4] and renutrition is reported to be associated with an increase of serum IGF-1.[3-8] If the IGF-1 result is equal to or above its age-/gender-specific lower limit, testing will stop and the interpretive comment will read: **"Not suggestive of energy and/or protein deprivation."** 2. If the IGF-1 result is less than its age-/gender-specific lower limit, the cascade will reflex to Step 2 — testing for **Serum Albumin.** Serum albumin is reported to be a marker of long-term (more than two weeks) malnutrition due to its long biological half-life.[9,10] If the serum albumin result is equal to or above its age-/gender-specific lower limit, the cascade will reflex to Step 4 **(Serum Transferrin).** If the serum albumin result is below its age-/gender-specific lower limit, the cascade will reflex to Step 3 — testing for **C-Reactive Protein (CRP).** 3. Testing for **C-Reactive Protein (CRP)** will aid in assessment of the presence and degree of inflammation as outlined by ASPEN recommendations.[1] a. If the CRP result is greater than 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of long-term energy and/or protein deprivation (more than two weeks) due to acute disease or injury-related malnutrition (like major infection, burns, trauma, closed head (injury)."**[1,10] b. If the CRP result is between 10 mg/L and 100 mg/L,[11] testing will stop and the interpretive comment will read: "**Suggestive of long-term energy and/or protein deprivation (more than two weeks) due to chronic disease-related malnutrition (like organ failure, pancreatic cancer, rheumatoid arthritis, sarcopenic obesity)**."[1,10] c. If the CRP result is less than 10 mg/L, testing will stop and the interpretive comment will read: **"Suggestive of long-term energy and/or protein deprivation (more than two weeks) due to starvation-related malnutrition (like pure starvation, anorexia nervosa)**."[1,11] 4. Testing for **Serum Transferrin** will aid in further evaluation of the patient, as it is reported to be a marker of mid-term malnutrition due to its biological half-life.[9,10] If the transferrin result is greater than or equal to its age-/gender-specific lower limit, the cascade will reflex to Step 5 **(Serum Prealbumin).** If the transferrin result is below its age-/gender specific lower limit, the cascade will reflex to Step 3 — (CRP). a. If the CRP result is greater than 100 mg/L, testing will stop and the interpretive comment will read: **"Suggestive of mid-term energy and/or protein deprivation (more than eight days) due to acute disease or injury-related malnutrition (like major infection, burns, trauma, closed head injury)."**[1,9,10] b. If the CRP result is between 10 mg/L and 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of mid-term energy and/or protein deprivation (more than eight days) due to chronic disease-related malnutrition (like organ failure, pancreatic cancer, rheumatoid arthritis, sarcopenic obesity)."**[1,9,10] c. If the CRP result is less than 10 mg/L, testing will stop and the interpretive comment will read: **"Suggestive of mid-term energy and/or protein deprivation (more than eight days) due to starvation-related malnutrition (like pure starvation, anorexia nervosa)."**[1,9,10] 5. Testing for serum prealbumin will aid in the assessment of short-term malnutrition, as it is reported to be a marker for this condition.[10] If the prealbumin result is equal to or greater than its age-/gender-specific lower limit, the cascade will reflex to Step 6 — **(Serum Retinol-binding Protein[RBP]).** If the prealbumin result is less than its age-/gender-specific lower limit, the cascade will reflex to Step 3 — (CRP). a. If the CRP result is greater than 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of short-term energy and/or protein deprivation (more than two days) due to acute disease or injury-related malnutrition (like major infection, burns, trauma, closed head injury)."**[1,10] b. If the CRP result is between 10 mg/L and 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of short-term energy and/or protein deprivation (more than two days) due to chronic disease-related malnutrition (like organ failure, pancreatic cancer, rheumatoid arthritis, sarcopenic obesity.)"** [1,10] c. If the CRP result is less than 10 mg/L, testing will stop and the interpretive comment will read: **"Suggestive of short-term energy and/or protein deprivation (more than two days) due to starvation-related malnutrition (like pure starvation, anorexia nervosa)."**[1,10]

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Malnutrition Cascade (continued)	**460500**	6. Testing for serum RBP will aid in the assessment of acute malnutrition as it is reported to be a marker for this condition.[9] If the RBP result is equal to or greater than its age-/gender-specific lower limit, the cascade will reflex to Step 3 — (CRP). a. If the CRP result is greater than 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of acute disease or injury-related malnutrition (like major infection, burns, trauma, closed head injury)."**[1] b. If the CRP result is between 10 mg/L and 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of chronic disease-related malnutrition (like organ failure, pancreatic cancer, rheumatoid arthritis, sarcopenic obesity)."**[1] c. If the CRP result is less than 10 mg/L, testing will stop and the interpretive comment will read: **"Suggestive of starvation-related malnutrition(like pure starvation, anorexia nervosa)."**[1] 7. If the RBP result is less than its age/gender-specific lower limit, the cascade will reflex to Step 3 — (CRP). a. If the CRP result is greater than 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of acute energy and/or protein deprivation due to acute disease or injury-related malnutrition (like major infection, burns, trauma, closed head injury)."**[1,9] b. If the CRP result is between 10 mg/L and 100 mg/L,[11] testing will stop and the interpretive comment will read: **"Suggestive of acute energy and/or protein deprivation due to chronic disease-related malnutrition (like organ failure, pancreatic cancer, rheumatoid arthritis, sarcopenic obesity)."**[1] c. If the CRP result is less than 10 mg/L, testing will stop and the interpretative comment will read: **"Suggestive of acute energy and/or protein deprivation due to starvation-related malnutrition (like pure starvation, anorexia nervosa)."**[1,9]
Measles, Mumps, Rubella (MMR) Immunity Profile	**058495**	**Test Includes** Measles IgG antibodies; Mumps IgG antibodies; Rubella IgG antibodies **Use** Aid in the determination of serological status to measles, mumps, and rubella viruses. A positive result generally indicates exposure to virus or previous vaccination. A positive result is considered adequate laboratory evidence of immunity. **Additional Information** (removed "Presence of specific viral antibodies is presumptive evidence of immunity in the absence of clinical findings suggesting acute infection.") **References** Centers for Disease Control and Prevention. Manual for the Surveillance of Vaccine-Preventable Diseases. CDC web site. https://www.cdc.gov/vaccines/pubs/surv-manual/index.html. Accessed June 2019. Centers for DIsease Control and Prevention. Measles (Rubeola): For Healthcare Professionals. CDC web site. https://www.cdc.gov/measles/hcp/. Accessed June 2019. McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2013 Jun 14;62(RR-04):1-34. PubMed 23760231

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Measles (Rubeola) Antibodies, IgG</td><td>096560</td><td>
Name (changed from Rubeola Antibodies, IgG)
Synonyms Measles
Storage Instructions Room temperature
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>14 days</td></tr>
<tr><td>Refrigerated</td><td>14 days</td></tr>
<tr><td>Frozen</td><td>14 days</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x4</td></tr>
</table>
Use Aid in the determination of serological status to measles virus. A positive result generally indicates exposure to measles virus or previous vaccination. A positive result is considered adequate laboratory evidence of measles immunity. Persons with an equivocal serologic test result do not have adequate presumptive evidence of immunity and should be considered sesceptible unless they have other evidence of measles immunity.
Documented age-appropriate vaccination supersedes the results of subsequent serologic testing. If a person who has two documented doses of measles-containing vaccine is tested serologically and is determined to have negative or equivocal measles results, it is not recommended that they receive an additional dose of vaccine. These individuals should be considered to have presumptive evidence of immunity.
Additional Information Measles virus (rubeola) is a member of the Paramyxoviidae family of viruses which includes the parainfluenza viruses, mumps, and respiratory syncytial virus. Measles is a highly contagious rash illness that is transmitted from person to person by direct contact with respiratory droplets generated through coughing and sneezing. Ninety percent of susceptible persons exposed to measles infected individuals will go on to develop measles. Although vaccination is highly effective against measles virus and the United States was declared free from endemic measles in 2000, travel-associated cases and spread among unvaccinated individuals continues to occur resulting in local measles epidemics.
Acceptable presumptive evidence of Measles Immunity:
Per the Centers for Disease Control and Prevention (CDC), acceptable presumptive evidence of immunity against measles virus includes at least one of the following:
• Documentation of age-appropriate vaccination against measles virus.
• Laboratory evidence of immunity (IgG in serum; equivocal results should be considered negative).
• Laboratory confirmation of measles.
• Birth before 1957.
References
Centers for Disease Control and Prevention. Manual for the Surveillance of Vaccine-Preventable Diseases. CDC web site. https://www.cdc.gov/vaccines/pubs/surv-manual/index.html. Accessed June 2019.
Centers for DIsease Control and Prevention. Measles (Rubeola): For Healthcare Professionals. CDC web site. https://www.cdc.gov/measles/hcp/. Accessed June 2019.
McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2013 Jun 14;62(RR-04):1-34. PubMed 23760231
</td></tr>
<tr><td>Microarray-Products of Conception (POC) Reveal® FFPE</td><td>511997</td><td rowspan="3">Special Instructions (removed "This assay is not approved for patients of New York State physicians.")</td></tr>
<tr><td>Microarray-Products of Conception (POC) Reveal® FFPE, Data Transfer</td><td>512029</td></tr>
<tr><td>Microarray-Tumor Reveal® FFPE</td><td>512014</td></tr>
<tr><td>Mumps Antibodies, IgG</td><td>096552</td><td rowspan="2">
Storage Instructions Room temperature
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>14 days</td></tr>
<tr><td>Refrigerated</td><td>14 days</td></tr>
<tr><td>Frozen</td><td>14 days</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x4</td></tr>
</table>
</td></tr>
<tr><td>Mumps Antibodies, IgM</td><td>160499</td></tr>
<tr><td>NPM1 Mutation Analysis</td><td>489140</td><td>Limitations (removed "The FDA has determined that such clearance or approval is not necessary.")</td></tr>
<tr><td>Rubeola Antibodies, IgM</td><td>160218</td><td>
Storage Instructions Room temperature
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>14 days</td></tr>
<tr><td>Refrigerated</td><td>14 days</td></tr>
<tr><td>Frozen</td><td>14 days</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x4</td></tr>
</table>
</td></tr>
<tr><td>von Willebrand Disease Profile (Esoterix)</td><td>500247</td><td>Minimum Volume One 1 mL tube</td></tr>
<tr><td colspan="3">Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.</td></tr>
</table>

CPT Code Updates

Test Name	Test No.	CPT(s)
Carbamazepine Sensitivity HLA Associations	**167443**	81381(x2)
Gene Sequencing, aHUS	**825178**	81404; 81405; 81479

Deleted Procedures

Deleted Tests	Test No.	LabCorp Offers	Test No.
PD-L1, IHC (Nivolumab), Melanoma	**480603**	Please contact your LabCorp representative for testing options	

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 the individual LabCorp published assays is updated on a regular basis at www.labcorp.com.

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