CLIENT UPDATE

BioReference LABORATORIES | genpath | LABORATORIO Buena Salud

OPKO Health Companies

February 2019

TEST NAME	TEST CODE	EFFECTIVE DATE	DESCRIPTION
Multiple	Multiple	N/A	**Biotin**, also known as **vitamin B7**, is an essential coenzyme involved in carbon dioxide transfer in carboxylase reactions. Recently, biotin has been marketed as a beauty supplement for hair and skin. High doses of biotin (>5 mg/day) can interfere with a broad range of diagnostic immunoassay tests. Large amounts of biotin in the serum or plasma may potentially impact any assay that uses biotin-streptavidin binding. Susceptibility to biotin interference is variable depending on the assay design, and can skew results either falsely high or low. The list of tests potentially impacted include: thyroid function tests **(TSH, T3U,T3, FT3, T4, FT4)**, hormonal assays **(prolactin, progesterone, LH, estradiol, PTH, FSH, HCG, tPSA, fPSA**), and others **(CEA, AFP, HE4, proBNP, c-Telopeptide).** Please advise your patients to abstain from taking biotin supplements for at least 8 hours before getting their blood drawn, to safeguard against any potentials interference in their test results.
N/A	N/A	N/A	BioReference Laboratories is pleased to continue to be an in-network provider with most national health plans and hundreds of regional plans, including: • United Healthcare • Aetna • Cigna • Anthem • Medicare & Medicaid While some national plans have made changes in their network, these changes DO NOT AFFECT BioReference and its specialty labs, GenPath and GeneDx. BioReference looks forward to providing you and your patients with quality diagnostic services throughout 2019. For a complete list of health plans contracted with BioReference, please visit www.bioreference.com

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TEST NAME	TEST CODE	EFFECTIVE DATE	DESCRIPTION
Babesia/ Malaria/Other blood parasites Babesia Microti, Direct Smear Malaria blood smear	J897 3142 0831	Immediately	When ordering tests **Babesia/ Malaria/Other blood parasites** (J897), **Babesia Microti, Direct Smear** (3142) and/or **Malaria blood smear** (0831), please remember to provide the following information on the test requisition: • Patient's travel history including name of country and dates of last visit • Anti-malarial agents This information helps in the identification of blood parasites and is required by State Departments of Health when reporting positive blood parasites.
Culture, Chlamydia Trachomatis	0555	Immediately	Testing for **Chlamydia trachomatis testing on semen specimens** is no longer offered at our laboratory. Accordingly, the Semen Culture Panel (Code 4260) will be modified to remove test 0555. No alternate testing is available.
IGH/MAFB t(14;20) by FISH	B545-5 (Global) & TB61-7 (TC-only)	January 28	**IGH/MAFB t(14;20) by FISH for Multiple Myeloma** is now available for testing, global and TC-only. • Reciprocal chromosomal translocations involving IGH gene at 14q32 with MAFB gene at 20q12, IGH/MAFB t(14;20)(q32;q12), are rare primary cytogenetic alterations in multiple myeloma that are associated with poor prognosis. • In contrast, IGH/MAFB t(14;20) are thought to be associated with long-term stable disease in monoclonal gammopathies of undetermined significance (MGUS) and smoldering multiple myeloma (SMM); precancerous stages preceding multiple myeloma. Note, that due to the low cellularity of plasma cells in peripheral blood, GenPath performs multiple myeloma FISH testing on BM or non-decalcified FFPE specimens only. Please see next page for additional test details.

481 Edward H Ross Drive • Elmwood Park NJ 07407 • tel 800 229 5227 • fax 201 791 1941 • www.bioreference.com

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TEST NAME	TEST CODE	EFFECTIVE DATE	DESCRIPTION
IGH/MAFB t(14;20) by FISH	B545-5 (Global) & TB61-7 (TC-only)	January 28	**New/Alternate Test Information** **Specimen Requirements**: FFPE and Bone Marrow **Turn Around Time***: 3-5 days **Transportation Temperature**: Room temp. **Methodology**: Fluorescence In Situ Hybridization (FISH) **Reference Range**: The cut off values for IGH/MAFB t(14;20) by specimen type are: **Bone marrow:** 1.4% for dual fusions & 5.0% for single fusions **FFPE tissue:** 0.5% for dual fusions **CPT Code(s)****: 88374 x1
Various Referral Tests	Various	Immediately	Due to changes at our reference laboratory, test information for the below tests have been updated. Please refer to pages 4-6 for more information • **Bordetella pertussis ABS, IgA/IgG w/Reflex to Immunoblot** (Code 1113) – Effective Immediately • **Estrone Sulfate** (Code 0281) – Effective Immediately • **Homovanillic Acid, 24-Hour Urine** (Code 1399) – Effective Immediately • **Isotretinoin** (Qualitative), Serum/Plasma (Code 3652) – Effective February 25 • **Organic Acids, Plasma** (Code 3196) – Effective February 19 • **Methsuximide and Metabolite, Serum/Plasma** (Code 1180) – Effective February 25 • **Phenylethylmalonamide, Serum/Plasma** (Code 3863) – Effective February 25
Electronic Client Update	N/A	Reminder	Please be reminded that monthly client updates are also available to be received via email. **To subscribe to receive client updates via email instead of fax, please visit http://bit.ly/BRLIGoGreen**

**** TAT is based upon receipt of the specimen at the laboratory***

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FEBRUARY 2019 CLIENT UPDATE TEST ADDENDUM

	Previous Test Information	New Test Information
Bordetella pertussis ABS, IgA/IgG w/Reflex to Immunoblot (Code 1113) – Effective immediately		
Turn Around Time*	6 days	10 days
Stability	Ambient: N/A Refrig: 7 days Frozen: N/A	Ambient: N/A Refrig: 2 weeks Frozen: 1 year
Methodology	Multi-Analyte Immunodetection	Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot
Reference Range	• PT IgG <45 IU/mL • PT IgA <10 IU/mL • FHA IgG <90 IU/mL • FHA IgA <50 IU/mL	Bordetella pertussis Antibody, IgA by ELISA • 0.9 IV or less: Negative - No significant level of detectable Bordetella pertussis IgA antibody. • 1.0-1.1 IV: Equivocal - Repeat testing in 10-14 days may be helpful. • 1.2 IV or greater: Positive - IgA antibody to Bordetella pertussis detected, which may indicate a current or past exposure/immunization to B. pertussis. Bordetella pertussis Antibody, IgA by Immunoblot • Negative Bordetella pertussis Antibody IgG by ELISA • 0.94 IV or less: Negative - No significant level of detectable B. pertussis IgG antibody. • 0.95-1.04 IV: Equivocal - Repeat testing in 10-14 days may be helpful. • 1.05 IV or greater: Positive - IgG antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis. Bordetella pertussis Antibody, IgG by Immunoblot • Refer to report
Collection Instructions	Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes.	Separate from cells ASAP or within 2 hours of collection. Transfer serum to a standard transport tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens.
Profile Components	PT IgG PT IgA FHA IgG FHA IgA	B. pertussis Ab, IgA by ELISA B. pertussis Ab, IgG by ELISA
CPT Code(s)**	86615x4	86615x2
Estrone Sulfate (Code 0281) – Effective Immediately		
Specimen Requirements	Serum	Serum
Minimum Volume	2 mL	1 mL
Turn Around Time*	15 days	10 days
Transportation Temperature	Refrig	Frozen
Stability	Ambient: N/A Refrig: 30 days Froze: N/A	Ambient: 2 days Refrig: 2 days Frozen: 2 years

Methodology	Extraction	High-Pressure Liquid Chromatography/Tandem Mass Spectrometry
Reference Range	• Adult Males: 230-2200 pg/mL • Premenopausal Females, Follicular Phase: 300-2600 pg/mL • Premenopausal Females, Luteal Phase : 100-3200 pg/mL • Postmenopausal Females: 100-1300pg/mL	• <18 years: no reference range established • Adult Males: <10-138ng/dL • Premenopausal Females, Early (days 0-6) Follicular Phase: <10-154 ng/dL • Premenopausal Females, Late (days 7-luteal) Follicular Phase: 15-390 ng/dL • Premenopausal Females, Luteal Phase: <10-373 ng/dL • Postmenopausal Females :<10-69 ng/dL
Collection Instructions	Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes.	Serum must be separated from cells within 45 minutes of venipuncture. Send serum in plastic transport tube.
Homovanillic Acid, 24-Hour Urine (Code 1399) – Effective Immediately		
Specimen Requirements	24 hour urine	24 hour urine
Minimum Volume	4 mL	10 mL
Turn Around Time*	7 Days	12 Days
Stability	Ambient: N/A Refrig: 7 days Frozen: 14 days	Ambient: 10 days Refrig: 14 days Frozen: 90 days
Methodology	High Pressure Liquid Chromatography/Tandem Mass Spectrometry	High Pressure Liquid Chromatography
Reference Range	Homovanillic Acid - per 24h • 18 years and older: 0.0-15.0 mg/d Homovanillic Acid - ratio to CRT • (The HVA-to-creatinine ratio will be reported when the patient is under 18 years, the urine collection is random or other than 24 hours, or the urine volume is less than 400 mL/24 hours.) • 0-2 years: 0-42 mg/g CRT • 3-5 years: 0-22 mg/g CRT • 6-17 years: 0-15 mg/g CRT • 18 years and older: 0-8 mg/g CRT • Creatinine, Urine - per 24h (Male) • 3-8 years: 140-700 mg/d • 9-12 years: 300-1300 mg/d • 13-17 years: 500-2300 mg/d • 18-50 years: 1000-2500 mg/d • 51-80 years: 800-2100 mg/d • 81 years and older: 600-2000 mg/d Creatinine, Urine - per 24h (Female) • 3-8 years: 140-700 mg/d • 9-12 years: 300-1300 mg/d • 13-17 years: 400-1600 mg/d • 18-50 years: 700-1600 mg/d • 51-80 years: 500-1400 mg/d • 81 years and older: 400-1300 mg/d	Homovanillic Acid, 24-Hour Urine • 3-8 years: 0.5-6.7 mg/24 hours • 9-12 years: 1.1-6.8 mg/24 hours • 13-17 years: 1.4-7.2 mg/24 hours • Adults: 1.6-7.5 mg/24 hours

FEBRUARY 2019 CLIENT UPDATE TEST ADDENDUM

Collection Instructions	Abstain from medications for 72 hours prior to collection. Transfer aliquot from a well-mixed 24 hour collection to a standard transport tube.	It is preferable for the patient to be off medications for three days prior to collection. Common antihypertensives (diuretics, ACE inhibitors, calcium channel blockers, alpha and beta blockers) may cause minimal or no interference. Patient should avoid alcohol, coffee, tea, tobacco and strenuous exercise prior to collection. Collect urine urine preserved with 25 mL 6N HCl collected in a 24-hour urine container. ph adjusted to <3.0 using 6N HCl.
Profile Components	Creatinine, Urine - per volume Creatinine, Urine - per 24h Homovanillic Acid - per 24h Homovanillic Acid Interpretation Homovanillic Acid - per volume Homovanillic Acid - ratio to CRT Total Volume Hours Collected	Creatinine, 24-Hour Urine HVA, 24-Hour Urine Total Volume
CPT Code(s)**	83150	83150, 82570
Isotretinoin (Qualitative), Serum/Plasma (Code 3652) – Effective February 25		
Stability	Ambient N/A Refrig 9 days Frozen 150 days	Ambient 14 days Refrig 14 days Frozen 14 days
Methodology	High-performance liquid chromatography	Liquid chromatography-tandem mass spectrometry
Reference Range	None Detected Units: ng/mL Reporting limit: 20	Patients taking 30 to 50 mg daily oral isotretinoin for 3 months had steady state plasma isotretinoin concentrations ranging from 91 to 291 ng/mL and an elimination half-life ranging from 10 to 37 hours. Compounds known to interfere with this substance: 9-cis, 13-cis-retinoic acid. Units: ng/mL Reporting limit: 10
Methsuximide and Metabolite, Serum/Plasma (Code 1180) – Effective February 25		
Methodology	High-performance liquid chromatography	Liquid chromatography-tandem mass spectrometry
Organic Acids, Plasma (Code 3196) – Effective February 19		
Profile Components	Organic Acids, Interpretation Lactic Acid Pyruvic Acid Succinic Acid 3-OH-Butyric Acid Acetoacetic Acid 2-Keto-3-methylvaleric Acid 2-Ketoisocaproic Acid 2-Ketoisovaleric Acid Citric Acid	Organic Acids, Interpretation Lactic Acid Pyruvic Acid Succinic Acid 3-OH-Butyric Acid Acetoacetic Acid 2-Keto-3-methylvaleric Acid 2-Ketoisocaproic Acid 2-Ketoisovaleric Acid Glutaric Acid
Phenylethylmalonamide, Serum/Plasma (Code 3863) – Effective February 25		
Methodology	High-performance liquid chromatography	Liquid chromatography-tandem mass spectrometry
Reference Range Comment	Following a 1000 mg primidone daily regimen: 7 - 10 mcg PEMA/mL.	Following a single oral dose of 400 mg Primidone to elderly men: 12+/- 3 mcg PEMA/Ml SERUM.

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