Client Update

BioReference LABORATORIES | genpath | LABORATORIO Buena Salud

OPKO Health Companies

AUGUST 2019

Test Name	Test Code	Effective Date
Warm Weather Specimen Collection and Storage	**N/A**	**Immediately**

As we continue to experience high temperatures this summer, please be reminded of the below instructions when preparing a frozen sample for specimen pick-up.

- Collect specimen according to the specimen collection requirements and label tube.
- Place specimen inside specimen bag with requisition and affix Blue FROZEN specimen label.
- When ready for pick-up, call Customer Service to confirm you have a Frozen specimen.
- Keep specimen frozen until courier arrives. If utilizing a lock-box, place specimen bag inside pre-chilled Frozen Transport Container, and place full container inside the lock-box.

To order Frozen specimen supplies, please contact customer service and reference the following supply order numbers:

- Ice packs – Supply #904
- Frozen specimen labels – Supply #975
- Frozen transport container for specimen lock box – Supply #717

Abnormal and Critical Calls **Multiple** **September 3**

Calls to clients for abnormal lab results will be modified based on the changes outlined below:

Test Code	Test Name	Current Called Abnormal* Level	Current Called Critical* Level	New Call Level
0035	Ammonia	>60 umol/L	None	>150 umol/l as critical (no abnormal)
0049 A165 (Mineola) B257 (Park Ave)	BUN	None	>100 mg/dL	None
0058	Cholesterol	<50 or >1500 mg/dL	None	None
0070 A149 (Mineola) B176 (Park Ave)	Creatinine	> 5 mg/dL	None	>8 mg/dL as critical (no abnormal)
0019	Hematocrit	<21%	<18%	<18% critical (no abnormal)
5884	Influenza A	Detected	None	None
0127	Phosphorus	<2 or >9 mg/dL	None	<2 mg/dL critical (no abnormal or high)
0139 A167 (Mineola) B247 (Park Ave)	PTT	>50 sec	>90 sec	>90 sec critical (no abnormal)
0148 A140 (Mineola) B250 (Park Ave)	Sodium	>150 mmol/L	<120 or >160 mmol/L	<120 or >160 mmol/L critical (no abnormal)
0079	Strep A (DNA)	Positive	None	None
0155	Triglycerides	<20 or >1500 mg/dL	None	None
0542 B188 (Park Ave)	Valproic acid	>100 ug/mL	>125 ug/mL	>125 ug/mL as critical (no abnormal)

**Note: Abnormal values are called daily from 8:30am to 5pm seven days a week and are time zone dependent. Critical values are called 24/7 continuously throughout the day.*

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Test Name	Test Code	Effective Date
Customer Satisfaction Survey	**N/A**	**Immediately**

We invite you to participate in our 2019 customer satisfaction survey. As a token of our appreciation for completing this survey, you will be entered into a drawing for the chance to win one year membership to NETFLIX. The drawing will be on Monday, September 30, 2019. Your entry will remain separate from your survey responses to protect your anonymity. Completing this survey should take you approximately 5 minutes. Thank you for your time and we wish you luck in the drawing.

Please visit: https://www.bioreference.com/customersurvey to take the survey.

Note: Employees of BioReference and their relatives are not eligible to participate.

FGFR1 by FISH **B557-0 (Global)** **August 19**
TG46-8 (Tech Only)

FGFR1 by FISH is now available for testing. The assay detects rearrangements of FGFR1 gene at 8p11.2 to assist in the diagnosis of myeloid neoplasms with FGFR1 rearrangements.

Myeloid and lymphoid neoplasms with fibroblast growth factor receptor 1 (FGFR1) abnormalities, also known as 8p11 myeloproliferative syndrome (EMS), represent rare and aggressive disorders associated with chromosomal aberrations that lead to the fusion of FGFR1 to different partner genes. Myeloid/lymphoid neoplasms with FGFR1 rearrangement are hematologically and genetically heterogeneous. Eosinophilia, however, is a prominent feature, in that patients most frequently present with results suggestive of a myeloproliferative neoplasm (elevated white blood cell count) with unexplained/idiopathic eosinophilia. As in all myeloproliferative neoplasms, there is a risk of transformation to acute leukemia of either myeloid or lymphoid lineage, and therefore patients may also present with acute leukemia (myeloid or lymphoblastic).

Please refer to the table below for additional information.

	Test Information
Specimen Requirements	Peripheral Blood (PB)/ Bone Marrow (BM)
Minimum Volume	PB Specimen (1.0mL); BM Specimen (0.5mL)
Turn Around Time*	3 days
Transportation Temperature	Room Temperature
Stability	Less than or equal to 72 hours
Methodology	Fluorescent In-Situ Hybridization (FISH)
Reference Range	Cut-off for PB: 1.0%; Cut-off for BM: 0.5%
Collection Instructions	Green top tube in sodium heparin or lavender top tube in EDTA
CPT Code(s)**	88374

OnkoSight Reports **N/A** **Immediately**

GenPath has updated its OnkoSight reporting to include pertinent negative genes. Previously, all genes that were analyzed were listed, and only those where genomic alterations were found were specifically called out. The new format clearly states which genes were analyzed, which were negative, and which genes had genomic alterations found. Additionally, the new report more clearly states that OnkoSight does not detect gene fusions.

For example, while GenPath offers PIK3CA by NGS for breast cancer, it does not cover a very rare PIK3CA C420R mutation. If testing is requested for solid tumor B821, and no mutation is detected, the following language will be included in the report:

> *"PIK3CA primary mutational hotspots involving codons 545 and 542 are targeted for analysis. Remaining NGS assay coverage of PIK3CA includes >90% of other exonic positions known to be very rarely altered or potentially actionable."*

Please contact your dedicated account executive with questions or to request a sample report.

Test Name	Test Code	Effective Date
Reference Laboratory Tests	**Multiple**	**Varies**

Due to changes at our reference laboratories, test information for the below tests has been updated. Please refer to pages 5-7 for full listing of test updates.

Test Name	Test Code	Effective
Autoimmune Dysautonomia Eval, S	B606	Immediately
EBV (Epstein-Barr Virus)DNA/PCR	3206	09/30/2019
HIV-2 DNA/RNA Qual. RT PCR	6207	09/30/2019
Histoplasma Antigen By EIA, Serum	3568	08/19/2019
Very Long Chain Fatty Acids	B658	Immediately

TSH and TSH with Reflex to Free T4 **0153, A518** **July 10**

Following an in-house study, reference ranges for **TSH and TSH with Reflex to Free T4** have been updated when testing is performed at the Elmwood Park (NJ), Melbourne (FL), and Houston (TX) laboratory locations.

	Previous Test Information	New Test Information
Reference Range	> 18 years old 0.178-4.530 uIU/mL	>18 years old 0.338-3.910 uIU/mL

Urinalysis (UA) Specimen Collection **N/A** **September 6**

Effective September 6, multiple changes will be made to enhance the usage of Urinalysis (UA) containers, as well as reduce the number/types of supplies needed for collection. Please refer to the changes below for specific details, and contact customer service at 800-229-5227 (Press 1) to begin ordering new items. After September 6, supply orders placed for old containers will automatically be replaced with the new items.

Old Container	SKU	New Container	SKU	Reason for Collection Change
Boricult Cup with Pill (White top)	410	BioReference paper cup with logo and lid	272	Use of the Boricult Cup with pill has caused safety concerns, as patients have accidentally ingested the pill. The laboratory is replacing this collection device to improve safety standards and for ease of use by patients. Upon collection, specimen should be poured off into a Vacutainer urine tube (grey top) (415) before being sent to the lab for testing.
Urine Collection cup with temperature strip	422	BioReference paper cups with logo and lid or the Sterile Cup (Orange top)	272 or 401	Use of the Urine Collection Cup with temperature strip for non-Chain of Custody specimen collection is effective, but not environmentally optimal. The laboratory is replacing this collection device to improve environmental standards. Specimen collection instructions remain the same.
UA Preservative Tube 8ml (Red/Yellow top)	417	Urinalysis tube (Yellow top)	409	UA Preservative Tube is not an environmentally optimal choice. The laboratory is replacing this collection device to improve environmental standards. The new tube will have 'Urinalysis' inscribed at top of the tube, and a Max line below it. Specimen collection instructions remain the same.
Urine C & S Kit with Large Cup	405	Straw and tube kit	402	Urine C & S Kit with Large Cup has caused safety concerns, as the cup comes with a long needle and patients have accidentally pricked their fingers and/or genitalia with the needle. The laboratory is replacing this collection device to improve safety standards and for ease of use by patients. Upon collection, specimen should be poured off into a Vacutainer urine tube (grey top) (415) before being sent to the lab for testing.
Sterile Cup (Orange top)	401	BioReference paper cup with logo and lid	272	Sterile Cup (Orange top) is used for several specimen tests. The laboratory is encouraging use of the alternate BioReference paper cup to improve environmental standards. Specimen collection instructions remain the same.

Test Name	Test Code	Effective Date
REMINDER - Patient Portal	**N/A**	**July 1**

Please be reminded that the new BioReference Patient Portal launched on July 1. This HIPAA compliant and secure test results and billing system gives your patients access to their important laboratory information at the tip of their fingers. With this portal, patients will be able to:

- Access their laboratory reports
- Keep track of trends in their health
- Pay their laboratory bills
- Update or add their insurance information

By providing your patients with access to this portal, you should experience fewer calls to your office for test results and laboratory billing questions. Patients can register themselves in the portal by going to https://www.bioreference.com/patient-portal and will have access to their results 5-10 business days after the report is final.

Your Account Executive can provide you with additional information about the new portal. If you or your patients have any additional questions, please call us at 833-4MYLABS (833-469-5227) Monday through Friday from 8AM to 8PM ET or email us anytime at PatientPortal@bioreference.com.

NOTES:

Client updates are also available to be received via email instead of fax. To subscribe to receive client updates via email, please visit http://bioreferencelabs.bioreference.com/go-green

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

***CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.*

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	Old Test Information	New Test Information
Autoimmune Dysautonomia Eval, S (B606) - Effective Immediately		
Profile Components	Dysautonomia, Interpretation, S ACh Receptor (Muscle) Binding Ab AChR Ganglionic Neuronal Ab, S ANNA-1, S Reflex Added GAD65 Ab Assay, S Neuronal (V-G) K+ Channel Ab, S N-Type Calcium Channel Ab P/Q-Type Calcium Channel Ab Striational (Striated Muscle) Ab, S	Dysautonomia, Interpretation, S ACh Receptor (Muscle) Binding Ab AChR Ganglionic Neuronal Ab, S ANNA-1, S Reflex Added DPPX Ab IFA, S GAD65 Ab Assay, S Neuronal (V-G) K+ Channel Ab, S N-Type Calcium Channel Ab P/Q-Type Calcium Channel Ab Striational (Striated Muscle) Ab, S
Reflex Options	ACh Receptor (Muscle) Modulating Ab AMPA-R Ab CBA, S AMPA-R Ab IF Titer Assay, S Amphiphysin Ab, S Amphiphysin Western Blot, S Anti-Neuronal Nuclear Ab, Type 2 Anti-Neuronal Nuclear Ab, Type 3 CASPR2-IgG CBA, S CRMP-5-IgG Western Blot, S CRMP-5-IgG, S NMO/AQP4 FACS, S NMO/AQP4 FACS TITER, S GABA-B-R Ab CBA, S GABA-B-R Ab IF Titer Assay, S LGI1-IgG CBA, S NMDA-R Ab CBA, S NMDA-R Ab IF Titer Assay, S Paraneoplastic Autoantibody WBlot,S Purkinje Cell Cytoplasmic Ab Type 1 Purkinje Cell Cytoplasmic Ab Type 2 Purkinje Cell Cytoplasmic Ab Type Tr	ACh Receptor (Muscle) Modulating Ab AMPA-R Ab CBA, S AMPA-R Ab IF Titer Assay, S Amphiphysin Ab, S Amphiphysin Western Blot, S Anti-Neuronal Nuclear Ab, Type 2 Anti-Neuronal Nuclear Ab, Type 3 CASPR2-IgG CBA, S CRMP-5-IgG Western Blot, S CRMP-5-IgG, S DPPX Ab CBA, S DPPX Ab IFA Titer, S GABA-B-R Ab CBA, S GABA-B-R Ab IF Titer Assay, S LGI1-IgG CBA, S NMDA-R Ab CBA, S NMDA-R Ab IF Titer Assay, S Paraneoplastic Autoantibody WBlot,S Purkinje Cell Cytoplasmic Ab Type 1 Purkinje Cell Cytoplasmic Ab Type 2 Purkinje Cell Cytoplasmic Ab Type Tr
EBV (Epstein-Barr Virus)DNA/PCR (3206) – Effective 09/30/2019		
Minimum Volume	0.3mL	0.5mL
Reference Range	EBV DNA, QN PCR - <200 copies/mL	EBV DNA, QN PCR - <200 copies/mL EBV DNA, QN PCR - <2.30 log copies/mL *(Note: The same component is reporting with 2 units of measure.)*
HIV-2 DNA/RNA Qual. RT PCR (6207) – Effective 09/30/2019		
Primary Container	Whole blood (LAVENDER or YELLOW TOP)	Whole blood (LAVENDER TOP)
Histoplasma Antigen By EIA, Serum (3568) – Effective 08/19/2019		
Reference Range	Negative – Less than 2.0 U/mL Weak Positive – 2.0-4.0 U/mL Positive – Greater than 4.0 U/mL	Not Detected – Less than 0.19 ng/mL Detected – 0.19-60.0 ng/mL Detected (Above the limit of quantification) – Greater than 60.0 ng/mL

	Old Test Information	New Test Information
Interpretive Data	This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis.	The quantitative range of this assay is 0.19-60.0 ng/mL. Antigen concentrations greater than 60.0 ng/mL fall outside the linear range of the assay and cannot be accurately quantified. This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histological examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis. Crossreactivity with *Blastomyces dermatiditis, Coccidioides immitis*, and possibly *Talaromyces marneffei* have been observed with this EIA. Other clinically and geographically relevant endemic mycoses should be considered in the case of a positive test result. Test developed and characteristics determined by ARUP Laboratories.
Very Long Chain Fatty Acids (B658) - Effective Immediately		
Methodology	LC/MS	Gas Chromatography/ Tandem Mass Spectrometer
Components and Reference Ranges	**Phytanic Acid** Adult 0.48-3.13 umol/L Pediatric 5-17 Years 0.37-3.46 umol/L **Pristanic Acid** Adult ≤ 0.35 umol/L Pediatric 5-17 Years ≤0.28 umol/L **Docosanoic Acid, C22** Adult 39.18-99.20 umol/L Pediatric 5-17 Years 32.04-84.33 umol/L **Tetracosanoic Acid, C24** Adult 31.26-84.11 umol/L Pediatric 5-17 Years 25.27-64.05 umol/L **Hexacosanoic Acid, C26** Adult ≤ 0.94 umol/L Pediatric 5-17 Years ≤0.68 umol/L **Ratio C24/C22** Adult 0.64-0.99 Pediatric 5-17 Years 0.67-0.87 **Ratio C26/C22** Adult 0.002-0.010 Pediatric 5-17 Years 0.002-0.010 **Ratio Pristanic/Phytanic** Adult 0.01-0.16 Pediatric 5-17 Years 0.02-0.15 **Discriminant Function** Males ≤ 7.5 Females ≤5.0	**Phytanic Acid** 1-31 days 0.14-1.28 umol/L 1-11.9 months 0.14-1.92 umol/L 1-17 years 0.38-5.04 umol/L > or = 18 years 0.58-2.54 umol/L **Pristanic Acid** 1-31 days 0.11-0.16 umol/L 1-11.9 months 0.11-0.31 umol/L 1-17 years 0.11-0.43 umol/L > or = 18 0.11-0.41 umol/L **Docosanoic, C22:0** 1-31 days 26.2-95.1 umol/L 1-11.9 months 35.1-101.8 umol/L 1-17 years 36.9-82.6 umol/L > or = 18 years 42.9-112.7 umol/L **Tetracosanoic, C24:0** 1-31 days 25-84.6 umol/L 1-11.9 months 26.9-82.9 umol/L 1-17 years 32.1-71.9 umol/L > or = 18 years 35.6-101.6 umol/L **Hexacosanoic, C26:0** 1-31 days 0.38-1.27 umol/L 1-11.9 months 0.33-0.86 umol/L 1-17 years 0.35-1.22 umol/L > or = 18 years 0.31-0.81 umol/L **Ratio C24/C22** 1-31 days 0.75-1.05 umol/L 1-11.9 months 0.69-1.11 umol/L 1-17 years 0.74-1.02 umol/L > or = 18 years 0.726-0.988 umol/L

	Old Test Information	New Test Information
		Ratio C26/C22 1-31 days 0.008-0.028 umol/L 1-11.9 months 0.007-0.016 umol/L 1-17 years 0.006-0.02 umol/L > or = 18 years 0.0049-0.0118 umol/L **Ratio Pristanic/Phytanic** 1-31 days 0.076-3.592 umol/L 1-11.9 months 0.054-0.52 umol/L 1-17 years 0.071-0.311 umol/L > or = 18 years 0.093-0.254 umol/L