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OPKO Health Companies

Client Update

MAY 2020

Test Name	Test Code	Effective Date
COVID-19 Antibody IgG	**TH99-5**	**Immediately**

As announced Monday, April 27, BioReference now offers **COVID-19 Antibody IgG,** a semi-quantitative immunoassay which measures SARS-CoV-2 specific IgG antibody levels, correlating with the patient's immune response after COVID-19 infection. An update has been made to test result categories and a correction was made on the self-pay price misprint. Please refer to the table below for details.

	Previously Provided Test Information	New Test Information
Test Results	< 0.90 AU/mL Negative 0.90-1.10 AU/mL Equivocal > 1.10 AU/mL Positive	Not Detected Equivocal Detected Numerical results will be provided as a semi-quantitative measure of antibody levels.
Price	Patient Price $50	Patient Price $55

COVID-19 RT-PCR Nasopharynx	**TH68-0**	**April 29**
COVID-19 RT-PCR Oropharynx	**TH69-8**	
COVID-19 RT-PCR Pooled N/NP/OP	**TH71-4**	

BioReference will not accept **MTM kits** as an alternate specimen collection type for **COVID-19 RT-PCR** due to the presence of guanidine thiocyanate. The FDA released new information about the compatibility with our testing platforms and has advised against use with the Hologic Panther or Panther Fusion Systems due to a disinfecting step involving bleach that is specific to the platform. When the bleach interacts with the guanidine thiocyanate in the transport media, it may produce dangerous cyanide gas. **If COVID-19 specimen is received utilizing these collection devices, the test will not be performed.** The following media are also not acceptable due to high likelihood of an Invalid Result: **PrimeStore, Ruhof, RNA later, RNA/DNA Shield, and Longhorn.**

Please also note that the specimen stability for COVID-19 RT-PCR has been extended from 2 days to 3 days when refrigerated. Frozen stability remains 30 days.

Catecholamines, Urine 24 Hour	**0164-4**	**June 22**

Due to changes at our reference laboratory, methodology for **Catecholamines, Urine 24 Hour** has been updated from Kinetic to High Performance Liquid Chromatography.

Culture, Chlamydia Trachomatis	**0555-3**	**Immediately**

Due to changes at our reference laboratory, collection instructions for **Culture, Chlamydia Trachomatis** will be updated. Please note that respiratory samples including nasal aspirate, nasopharyngeal and throat swabs will no longer be accepted, and refer to the table below for details.

	Previous Test Information	New Test Information
Collection Instructions	Place swab or nasal aspirate into VCM (Viral/Chlamydia/Mycoplasma) (equal volumes of fluid and VCM) or equivalent and transport the specimen to the laboratory as soon as possible. Best recovery is obtained when the specimens are refrigerated at 2-8° C prior to shipment. Specimens in VCM or equivalent should be frozen at -70° C or colder and transported on dry ice. Storage or transport at -20° C is not acceptable. Preferred Specimens: Endocervical, endourethral, eye (conjunctiva), nasopharyngeal, rectal mucosa (without feces), or throat swabs collected in VCM (green-top) or equivalent medium, or nasal aspirate added to equal volume VCM or equivalent transport medium (UTM or M4). Alternate: Vaginal swab on children <13 years.	Place swab into VCM (equal volumes of fluid and VCM) or equivalent and transport the specimen to the laboratory as soon as possible. Best recovery is obtained when the specimens are refrigerated at 2-8° C prior to shipment. Specimens in VCM or equivalent should be frozen at -70° C or colder and transported on dry ice. Storage or transport at -20° C is not acceptable. Preferred specimens: 1 swab (1 swab minimum) endocervical, endourethral, eye (conjunctival), or rectal mucosa (without feces) collected in a VCM or equivalent.

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MAY 2020

Test Name	Test Code	Effective Date
Culture, Virus, Body Fluids, Tissue	**0731-0**	**Immediately**

Due to changes at our reference laboratory, collection instructions for **Culture, Virus, Body Fluids, Tissue** will be updated. Please note that respiratory samples including nasal aspirate, nasopharyngeal and throat swabs will no longer be accepted, and refer to the table below for details.

	Previous Test Information	New Test Information
Collection Instructions	CUSTOM COLLECTION INSTRUCTIONS: Fluid specimen in equal volume of VCM (Viral/Chlamydia/Mycoplasma) transport medium or equivalent. Swab or tissue in VCM or equivalent. Fluids in sterile container acceptable. To maintain optimum viability, place swab or fluid into VCM (equal volumes of fluid and VCM) or equivalent and transport the specimen to the laboratory as soon as possible. Best recovery is obtained when the specimens are refrigerated at 2-8°C or kept on wet ice following collection and while in transit. If there will be a long delay before processing, specimens in VCM or equivalent should be frozen at -70° or colder and transported on dry ice storage or transport at -20°C is not acceptable. Raw samples should only be refrigerated and not frozen. MINIMUM VOLUME: 1mL Fluid; 2mm tissue; 1 swab. Acceptable Sources: 3 mL bronchial aspirates/washes, tracheal aspirates/ washes, newborn urine, sterile body fluids, tissue/lung biopsy or conjunctival swab in VCM medium (green-cap) tube or equivalent Alternative Specimen(s) 3 mL body fluid, CSF, bronchial lavage/wash, tracheal aspirate, tissue biopsy, lung biopsy or newborn urine in sterile screw-cap container 3 mL CSF in VCM medium (green-cap) tube or equivalent Bone marrow collected in sodium heparin (green-top) tube or lithium heparin (green-top) tube	Instructions: Body fluids: For all body fluids add an equal volume of specimen to transport medium (VCM or equivalent). Newborn urine: Random urine, random clean catch urine, catheterized urine, or first void catch urine in sterile screw-capped container. Tissue and biopsy material: Sterile screw-capped container with small amount of saline, no fixative or preservative. Requested volume is as much as possible. Conjunctiva: Conjunctival swabs in VCM or equivalent transport media. Respiratory samples will no longer be accepted

Test Name	Test Code	Effective Date
Cytokine Panel, TH1 By MAFD	**B119-0**	**May 18**

Due to changes at our reference laboratory, reference ranges for **Cytokine Panel, TH1 By MAFD** will be updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range	• **Interleukin 2:** 12 pg/mL or less • **Interleukin 2 Receptor (CD25), Soluble:** 1033 pg/mL or less • **Interleukin 12:** 6 pg/mL or less • **Interferon gamma**: 5 pg/mL or less	• **Interleukin 2:** 2.1 pg/mL or less • **Interleukin 2 Receptor (CD25), Soluble:** 175.3 pg/mL – 858.2 pg/mL • **Interleukin 12:** 1.9 pg/mL or less • **Interferon gamma:** 4.2 pg/mL or less

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MAY 2020

Test Name	Test Code	Effective Date
Cytokine Panel, TH2 By MAFD	**B122-3**	**May 18**

Due to changes at our reference laboratory, reference ranges for **Cytokine Panel, TH2 By MAFD** will be updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range	• **Interleukin 4:** 5 pg/mL or less • **Interleukin 5:** 5 pg/mL or less • **Interleukin 10:** 18 pg/mL or less • **Interleukin 13:** 5 pg/mL or less	• **Interleukin 4:** 2.2 pg/mL or less • **Interleukin 5:** 2.1 pg/mL or less • **Interleukin 10:** 2.8 pg/mL or less • **Interleukin 13: 2**.3 pg/mL or less

Fatty Acid Profile (Non-NY)	**3596-4**	**Immediately**

Due to COVID-19, testing for **Fatty Acid Profile (Non-NY)** is temporarily unavailable until further notice. Our reference laboratory will hold specimens for 11-14 days, but testing will not be performed. An update will be provided when testing resumes.

Pancreatic Polypeptide	**2414-1**	**Immediately**

Due to changes at our reference laboratory, test information for **Pancreatic Polypeptide** will be updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Primary Container	2 mL ALQE	0.5 mL ALQE
Minimum Volume	0.6 mL	0.3 mL
Turnaround Time*	14 Days	12 Days
Stability	Ambient: N/A Refrigerated: 7 Days Frozen: 28 Days	Ambient: 5 Days Refrigerated: 7 Days Frozen: 365 Days
Methodology	Radio Immuno Assay	Electrochemiluminescence
Reference Range	• **18-29 years:** < or = 274 pg/mL • **30-39 years:** < or = 594 pg/mL • **40-49 years:** 61-1192 pg/mL • **50-64 years:** < or = 1823 pg/mL • **>64 years:** Not Established	• **< 4 years:** Not Established • **4-17 years:** 92-752 pg/mL • **>or = 18 years:** 56-480 pg/mL
CPT Code(s)**	83519	82397

pH, Feces	**1656-8**	**Immediately**

Due to changes at our reference laboratory, reference ranges for **pH, Feces** will be updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range	5.92-8.00 pH units	• **Newborns (Neonates), Birth through 28 days: 5**.0-7.0 • **Infants, >1 month through 2 years:** Bottle fed; Neutral or slightly alkaline: >=7.0; Breast Fed; Slightly acidic: <7.0 • **>2 years:** 7.0-7.5

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MAY 2020

Test Name	Test Code	Effective Date
Solid Tumor NTRK Gene Fusion Assay by Next-Generation Sequencing (NGS)	**J355-9**	**April 23**

NTRK Gene Fusions are now recognized as an important pan-cancer, histology agnostic biomarker relevant to routine clinical oncology practice. The detection of NTRK gene fusion can assist in selecting patients that may benefit from TRK inhibitor therapies. Starting April 23, 2020, all cases for **Solid Tumor NTRK Gene Fusion Assay by Next-Generation Sequencing (NGS)** will be performed at GenPath Diagnostics. This positive change will provide significant improvement in turnaround time as you will start to receive patient results within 7-10 days instead of ~30 days. Solid Tumor and Personalized Medicine Test Requisition Forms have been updated with in-house test code.

Genes included in Solid Tumor NTRK Gene Fusion Panel (18 genes): ALK, AXL, BRAF, CCND1, EGFR, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, PPARG, RAF1, RET, ROS1, THADA.

Please prefer to the table below for details, and contact our GenPath Customer Service department with any questions: GenPathCustomerService@genpathdiagnostics.com or 1-800-627-1479.

	Previous Test Information	New Test Information
Test Names	MGH Solid Fusion Assay	Solid Tumor NTRK Gene Fusion Assay
Test Codes	TF80-9	J355-9
Specimen Requirements	FFPE: Specimen block preferred. Slides: 15 unstained slides cut at 5 microns containing adequate amounts of tumor to be analyzed with corresponding H&E slides from the top and bottom of the sample and a pathology report.	FFPE: Specimen block preferred. Slides: 15 unstained slides cut at 5 microns containing a minimum 10% tumor cellularity Alternative specimen: Extracted Total Nucleic Acid (TNA) or RNA is acceptable, providing that the isolation of nucleic acid occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS and/or the CAP.
Turnaround Time*	~30 days (7 days at GenPath for DNA isolation; ~14-20 days at MGH for NGS testing)	7-10 days
Transportation Temperature	Room Temperature	Specimen can be sent in either room temperature or refrigerated.
Collection Instructions	BLK: This comes in block form from client with surgical number imprint.	BLK: This comes in block form from client with surgical number imprint.
Clinical Utility	Assess biomarker status of fusion genes for precision medicine eligibility	Assess biomarker status of fusion genes for precision medicine eligibility
CPT Code(s)**	81445x1	81445x1

Test Name	Test Code	Effective Date
Stone Analysis	**0527-2**	**June 1**

Due to changes at our reference laboratory, methodology and components for **Stone Analysis** will be updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Methodology	Infrared Spectrum Analysis, Gravimetric	Infrared Spectroscopy (Fourier Transform Infrared Spectroscopy), Gravimetric
Profile Components	Specimen Source Nidus Component 1 Component 2 Stone Weight	Specimen Source Component 1 Component 2 Stone Weight

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Test Name	Test Code	Effective Date
Supersaturation Profile, 24 Hour Urine	**J350-0**	**Immediately**

Due to changes at our reference laboratory, components for **Supersaturation Profile, 24 Hour Urine** will be updated. The proile will now include Patient Surface Area, Height (cm), and Weight (kg).

REGIONAL UPDATE - INR **B246-0** **March 5**

Due to reagent changes, the reference range for Normal Non-Medicated Patients for **INR** has been updated when performed at our **Park Avenue, New York** laboratory location.

	Previous Test Information	New Test Information
Reference Range	0.89-1.14	0.88-1.13

NOTES:
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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