Client Update

BioReference LABORATORIES | genpath | LABORATORIO Buena Salud

OPKO Health Companies

October 2019

Test Name	Test Code	Effective Date
4Kscore® Test Requisition	**N/A**	**Immediately**

The **4Kscore® Test requisition form** has been modified to support updated coverage criteria from our Medicare carrier. A new proposed local coverage determination (LCD) was recently issued for the 4Kscore Test. This required a change to how we collect information from providers and patients prior to the 4Kscore Test being ordered.

Summary of Changes:

1. Documentation of shared decision making, including a detailed discussion about management options and patient preferences, is required prior to processing the test. **BOTH provider and patient signatures, legible names, and dates are required.**
2. **All questions** in the Prostate Cancer Risk Evaluation section **MUST BE COMPLETED**. This includes information related to the Medicare criteria for coverage and capturing clinical factors included in the 4Kscore Test algorithm.
3. A copy of the test requisition should be retained in the patient's medical record, as part of Medicare's requirement for documentation of Shared Decision Making prior to ordering the 4Kscore Test.

The updated 4Kscore Test requisition is now available for ordering. Going forward, this will be the only requisition form that can be used to place an order for the 4Kscore Test. **The supply order number for this new test requisition is 487**. Your Account Executive can provide you with additional details and information about the new test requisition. If you have any further questions, please call 4Kscore Customer Service at 833-4KSCORE (833-457-2673).

Comprehensive Respiratory Panel	**L740**	**Immediately**

We are pleased to announce that **The Comprehensive Respiratory Panel** is now available for testing. The panel provides comprehensive testing for upper respiratory infections, and simultaneously detects 17 viral and 4 bacterial infectious agents that present with similar symptoms. Please see below for test details.

	New Test Information
Primary Container	Swab-Viral Culturette
Turn Around Time*	2 Days
Transportation Temp	Refrigerate
Stability	3 Days
Methodology	Polymerase Chain Reaction
Collection Instructions	Collect sample, place in holder, label with patient name. NOT TO BE USED FOR BACTERIAL TRANSPORT.
Profile Components	**Viral:** Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H3, Influenza A/H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus. **Bacerial:** Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumonia, Mycoplasma pneumoniae
CPT Code(s)**	87486x1, 87581x1, 87633x1, 87798x1
Clinical Utility	Assess for various viral and bacterial infectious agents associated with symptomatic upper respiratory infections.

NOTE: When ordering tests, providers should only order tests that are medically necessary for the diagnosis or treatment of a patient, generally not for screening. Only a few screening tests are covered by most government and third party payers for certain conditions at specific intervals.

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Test Name	Test Code	Effective Date
Abnormal and Critical Calls	**Multiple**	**October 2**

Additional calls to clients for **abnormal lab results** will be modified. NOTE: These are additional tests that have been adjusted beyond the list that was provided in last month's client update. Please see the table on the next page for test codes/test names that will no longer be called for Abnormal Call Levels, however Critical levels will still remain the same.

Test Code	Test Name	Current Called Abnormal Level	Current Called Critical Level	New Call Level
0147 B171 A494	ALT	>500 U/L	>800 U/L	No Abnormal Critical Remains
0036 A144 B166	Amylase	>250 U/L	<10 >500 U/L	No Abnormal Critical Remains
0044	Direct Bilirubin	>5.0 mg/dL		None
0093	GGTP	>1500 U/L		None
0117	LDH	>1500 U/L		None
0128	Platelets	>800 x10(3)/uL	<20 >1000 x10(3)/uL	No Abnormal Critical Remains
J661	Citrated Platelets	>800 x10(3)/uL	<20 >1000 x10(3)/uL	No Abnormal Critical Remains
0157 B180	Uric Acid	>15.0 mg/dL		None

Absolute Basophil Count **3179** **September 11**

Due to findings during an in-house study, reference ranges have been updated for **Absolute Basophil Count,** a component of CBC w/Diff, Platelet Count (Test code 0053).

	Previous Test Information	New Test Information
Reference Range	Adult Male and Female 0.00-0.70 x10(3)/uL	Adult Male and Female 0.00-0.10 x10(3)/uL

Semen Liquefaction **0144** **September 23**

In addition to the new reference ranges for Sperm Analysis in last month's memo, reference range for **Semen Liquefaction,** a component of Sperm Analysis, Fertility (Test Code 0144) will also be updated to adhere to the World Health Organization 5th Edition Semen Analysis criteria reference. Please refer to the table below for updated normal reference ranges.

	Previous Test Information	New Test Information
Reference Range	<60 Minutes	< or= 60 Minutes

Test Name	Test Code	Effective Date
ThinPrep and SurePath Cardboard Collection Kits	**N/A**	**November 4**

To continue our initiative to go-green, we will be discontinuing the use of cardboard-kits for **ThinPrep and SurePath** vials. This change will NOT impact the collection tools used. We will continue to accept ThinPrep and SurePath vials previously provided. Testing and turnaround time will not be impacted.

Units delivered will not change with this update, please refer to list below:

Supply Order #	Description	Units
313	SurePath Collection Vial	Pack of 25
325	SurePath Brush/Scraper	Pack of 25
368	SurePath Broom	Pack of 50
305	ThinPrep Collection Vial	Pack of 25
369	ThinPrep Brush/Spatula	Pack of 25
316	ThinPrep Broom	Pack of 50

REMINDER - Urine Specimen Collection **N/A** **September 6**

Effective September 6, multiple changes were made to enhance the usage of **Urine 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 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 (NOT FOR TRANSPORT)	272 and 415	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 cup with logo and lid (NOT FOR TRANSPORT) or 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) before being sent to the lab for testing.
Sterile Cup (Orange top)	401	BioReference paper cup with logo and lid (NOT FOR TRANSPORT)	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. (Please Note: the orange sterile specimen cup WILL NOT be discontinued.)

Test Name	Test Code	Effective Date
REGIONAL UPDATE - TSH and TSH with Reflex to Free T4	**0153, A518**	**September 16**

New Reference Ranges have been released based on new in house study, when testing is complete at **Elmwood Park, NJ, Melbourne, FL, Houston, TX** laboratory locations. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range	>18 years old 0.338-3.910 uIU/mL	>18 years old 0.234-4.020 uIU/mL

REGIONAL UPDATE - Cholinesterase, RBC and Plasma (Non-CA) 0484 **Effective immediately**

Due to changes at our reference laboratory, test information for **Cholinesterase, RBC and Plasma** has been update. Additionally, the test is no longer available to patients in California; A new test will be available to CA patients in the near future. Please refer to the table below for test changes applicable to **Non-CA testing**.

	Previous Test Information	New Test Information
Primary Container	Lavender Top	Whole blood (LAVENDER TOP or GREEN TOP) **AND** Plasma (LAVENDER TOP or WHITE TOP)
Minimum Volume	2 mL	5 mL and 1 mL
Turn Around Time*	8 days	10 days
Methodology	N/A	Kinetic Spectrophotometric
Reference Range	9572-15031 IU/L	Plasma (Male): 3334-7031 IU/L Plasma (Female): 2504-6297 IU/L RBC: 9572-15031 IU/L
Collection Instructions	LAV: Fill lavender-top (EDTA) tube completely, invert 8-10 times. DO NOT SHAKE TUBE!	Draw two lavender-top (EDTA) tubes of whole blood. Spin one tube to separate plasma. Pipette plasma into plastic aliquot tube (Label this vial as Plasma). Send one 5 mL refrigerated uncentrifuged whole blood (4 mL minimum) and 1 mL refrigerated plasma (0.5 mL minimum). Do not send packed cells. Do not send only one tube of whole blood. Plasma cholinesterase results, as well as the calculated RBC cholinesterase results, are not accurate if plasma sample is not separated from the RBC's in a timely manner. Hemolyzed plasma samples are not acceptable. Hemolysis can lead to apparent increases in plasma cholinesterase activity, and could mask an enzyme deficiency.
Profile Components	N/A	Cholinesterase, Plasma, Cholinesterase, RBC
CPT Code(s)**	82482	82482, 82480
Clinical Utility	N/A	True Cholinesterase (RBC and plasma) activity is decreased in individuals with exposure to organophosphorous insecticides. True Cholinesterase, found in erythrocytes and nerve tissue, is responsible for inactivating acetylcholinesterase at nerve endings. With decreased enzyme activity, patients may display a range of nervous system dysfunction. Analysis of RBC and serum or plasma activity is useful in monitoring exposure and recovery.

Test Name	Test Code	Effective Date
REGIONAL UPDATE – California Reference Ranges	**Multiple (See Below)**	**September 16**

New reference ranges and stabilities have been implemented due to a change in instrumentation when testing is complete at the **Campbell, CA** laboratory location. All tests will now be performed on the Roche e602 analyzer. Please refer to the table below and on pages 6-8 for details.

Test Name	Test Code	Old Reference Ranges	New Reference Ranges	Old Stability	New Stability
Estradiol	0516	Male <39.81 pg/mL Females Range (pg/mL) Follicular Phase 19.50-144.20 Midcycle Peak 63.90-356.70 Luteal Phase 55.80-214.20 Post-menopausal (untreated) <32.21	Male (yrs) Range (pg/mL) 1-11 5.00-10.00 12-14 5.00-30.00 15-17 5.00-45.00 Adult 7.02-49.06 Female (yrs) Range (pg/mL) 1-5 5.00-10.00 6-9 5.00-60.00 10-11 5.00-300.00 12-17 24.00-410.00 Phases Follicular 6.20-315.00 Ovulation 28.60-525.00 Luteal 7.69-752.00 Postmenopausal <5.00-51.60 Pregnant (Trimeter) 1st 127.00-4161.00 2nd 1137.00-25130.00 3rd 7398.00->30000.00	2 Days	7 Days
Luteinizing Hormone (LH)	0342	Male 1.5-9.3 mIU/mL Female Range (mIU/mL) Follicular Phase 1.9-12.5 Midcycle Peak 8.7-76.3 Luteal Phase 0.5-16.9 Post-menopausal 15.9-54.0 Pregnant <0.1-1.5 Contraceptives 0.7-5.6	Male 1.7-8.6 mIU/mL Female Range (mIU/mL) Follicular Phase 2.4-12.6 Ovulation Phase 14.0-95.6 Luteal Phase 1.0-11.4 Postmenopausal 7.7-58.5	2 Days	7 Days
Prolactin	0134	Male 2.1-17.7 ng/mL Female Range (ng/mL) Non-pregnant 2.8-29.2 Pregnant 9.7-208.5 Post-menopausal 1.8-20.3	Male 4.0-15.2 ng/mL Female Range (ng/mL) Non-Pregnant 4.8-23.3 Pregnant 3rd Trimester 95.0-473.0	2 Days	7 Days

Test Name	Test Code	Old Reference Ranges	New Reference Ranges	Old Stability	New Stability
Progesterone	0335	Male 0.28-1.22 ng/mL Female Range (ng/mL) Follicular Phase <1.41 Luteal Phase 3.34-25.56 Mid Luteal Phase 4.44-28.03 Post-menopausal <0.74 Pregnant (Trimester) 1st 11.22-90.00 2nd 25.55-89.40 3rd 48.40-422.50	Male <0.16 ng/mL Female Range (ng/mL) Follicular Phase 0.06-0.89 Ovulation Phase 0.12-12.00 Luteal Phase 1.83-23.90 Postmenopausal <0.14 Pregnant (Trimester) 1st 11.00-44.30 2nd 25.40-83.30 3rd 58.70-214.00	2 Days	5 Day
FSH (Follicle Stimulating Hormone)	0092	Male 1.4-18.1 mIU/mL Female Range (mIU/mL) Follicular Phase 2.5-10.2 Midcycle Peak 3.4-33.4 Luteal Phase 1.5-9.1 Post-menopausal 23.0-116.3 Pregnant <0.3	Male 1.5-12.4 mIU/mL Female Range (mIU/mL) Follicular Phase 3.5-12.5 Midcycle Peak 4.7-21.5 Luteal Phase 1.7-7.7 Postmenopausal 25.8-134.8	2 Days	7 Days
Testosterone	0379	Male (yrs) Range(ng/dL) <50 123.1-813.9 > or=50 87.0-780.1 Female Range(ng/dL) Premenopause 9.0-47.9 Postmenopause <7.0-45.6	Male (yrs) Range (ng/dL) 7-18 <2.5-1048.0 19-49 249.0-836.0 > or=50 193.0-740.0 Female (yrs) Range(ng/dL) 8-18 <2.5-39.8 19-49 8.4-48.1 > or=50 2.9-40.8	2 Days	7 Days
SHBG	0658	Male (yrs) Range (nmol/L) <50 15-95 >or=50 22-113 Female Range (nmol/L) Premenopause 11->180 Postmenopause 23-159	Male (yrs) Range(nmol/L) <20 Not Estab. 20-49 17-56 >49 19-76 Female (yrs) Range (nmol/L) <21 Not Estab. 21-49 25-122 >49 17-125	2 Days	3 Days
HCG Quant Tumor Marker	1201	Male <10.0 mIU/mL Female <10.0 mIU/mL	Male <2.0 mIU/mL Female (mIU/mL) Non-Pregnant < or=5.2 Post Menopausal < or=7.0	2 Days	7 Days

Test Name	Test Code	Old Reference Ranges	New Reference Ranges	Old Stability	New Stability
HCG-BETA	0327	Weeks of Gestation Range (mIU/mL) 2-4 39.1-8,388.0 5-6 861.0-88,769.0 6-8 8,636.0-218,085.0 8-10 18,700.0-244,467.0 10-12 23,143.0-181,899.0 13-27 6,303.0-97,171.0 28-40 4,360.0-74,883.0 Non-pregnant <6.0 Post-menopausal <10.0	Weeks of Gestation Range (mIU/mL) 3 5.8-71.2 4 9.5-750.0 5 217.0-7,138.0 6 158.0-31,795.0 7 3,697.0-163,563.0 8 32,065.0-149,571.0 9 63,803.0-151,410.0 10 46,509.0-186,977.0 12 27,832.0-210,612.0 14 13,950.0-62,530.0 15 12,039.0-70,971.0 16 9,040.0-56,451.0 17 8,175.0-55,868.0 18 8,099.0-58,176.0 Non-Pregnant < or=5.2 Postmenopausal < or=7.0	2 Days	7 Days
TPSA	0190	<4.10 ng/mL	<4.00 ng/mL	2 Days	3 Days
Screening PSA	3268	<4.10 ng/mL	<4.00 ng/mL	2 Days	3 Days
PSA w/reflex to Free PSA	J034	<4.10 ng/mL	<4.00 ng/mL	2 Days	3 Days
T3	0150	60-181 ng/mL	Age Range (ng/dL) 0-30 days 75-205 2-23 mo 65-260 2-5 yrs 103-236 6-10 yrs 114-222 11-14 yrs 105-211 15-18 yrs 89-191 >18 yrs 72-180	2 Days	7 Days
T4	0151	4.5-10.9 ug/dL	Age Range (ug/dL) 0-30 days 4.5-14.4 2-23 mo 4.5-14.0 2-5 yrs 5.8-12.5 6-10 yrs 5.7-11.9 11-14 yrs 4.8-11.3 15-18 yrs 4.7-11.6 >18 yrs 4.9-12.9	2 Days	7 Days
FT3	0271	2.3-4.2 pg/mL	Age Range (pg/mL) 0-30 days 1.7-5.4 2-23 mo 1.1-6.3 2-5 yrs 2.5-5.5 6-10 yrs 3.0-5.4 11-14 yrs 2.8-5.2 15-18 yrs 2.5-4.7 >18 yrs 2.0-4.7	2 Days	7 Days

Test Name	Test Code	Old Reference Ranges	New Reference Ranges	Old Stability	New Stability
FT4	0091	0.89-1.76 ng/dL	Age Range (ng/dL) 0-30 days 0.81-2.01 2-23 mo 0.87-1.83 2-5 yrs 0.98-1.66 6-10 yrs 0.97-1.61 11-14 yrs 0.86-1.53 15-18 yrs 0.86-1.58 >18 yrs 0.80-1.73	2 Days	7 Days
Free T4 Index	0666	1.4-3.1	1.5-3.8	2 Days	7 Days
TSH and TSH w/rflex to Free T4	0153 A518	0.550-4.780 uIU/mL	Age Range (uIU/mL) 0-30 days 0.064-4.570 2-23 mo 0.246-4.849 2-5 yrs 0.688-4.750 6-10 yrs 0.782-4.730 11-14 yrs 0.634-4.610 15-18 yrs 0.478-4.380 >18 yrs 0.234-4.020	2 Days	7 Days
T-UP	0152	22.5-37.0 %	24.3-39.0 %	2 Days	7 Days

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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