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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 will be available for ordering by mid-September. 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).

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.*

Peanut Components, IgE H993 September 16

Peanut allergies are a growing concern and the number one cause of death related to food-induced anaphylaxis. BioReference offers **Peanut Component Panel**, **IgE** (**Test Code H993**), which includes components Ara h1,2,3,8 and 9. Effective September 16, the panel will be modified to also include Ara h6. In addition, **Peanut Allergen w/reflex** (**Test Code K361**) which automatically reflexes to the peanut components panel when positive, will reflex to the modified H993 panel. **NOTE: Peanut Allergen (Test Code 0674) does NOT include the components and does NOT reflex.**

- Ara h1, 2 and 3 are peanut proteins associated with higher risk of systemic reactions including anaphylaxis. Peanut allergic adults are mainly sensitive to Ara h1 and H2.
- Ara h8 sensitivity is associated with more mild, localized symptoms, i.e. itching/tingling of the lips, mouth and oropharynx. Cross reactivity with pollens (e.g. birch) has been noted. 2
- Ara h9 is associated with variable risk of systemic reactions and is often associated with sensitivity to other peanut proteins. Cross reactivity with some fruits and pits (e.g. peaches) has been noted. 2
- Ara h6 exhibits reactivity similar to Ara h2. Both proteins are associated with potential severe reactions in children whose IgE antibody
 levels can vary over time indicating the risk of a more dynamic reactivity to peanuts. 2

Knowing specific peanut protein sensitivities can assist physicians by understanding the risk(s) associated with each component. Over 77% of children with sensitive to peanuts may not be at risk for systemic reactions. Peanuts are mainly consumed as peanut butter but are used as cooking oil (refined or crude) and can be converted to hydrogenated oil, peanut acid (used as a surfactant or cleansing agent) and peanut glycerides used in cosmetics or peanut flour used in baking and health food products. Peanut oil has been used in many products including infant food resulting in sensitization in some children.

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Test Name	Test Code	Effective Date
Sperm Analysis	0144	September 23

Reference Ranges for Sperm Analysis will be update to adhere to the World Health Organization 5th Edition Semen Analysis criteria reference ranges, and existing World Health Organization 3rd Edition Semen Analysis criteria reference ranges will be retired. Please refer to the table below for updated normal reference ranges.

	Previous Test Information	Updated Test Information	
Reference Ranges	Semen Concentration: >20 million	Semen Concentration: ≥15 mil/ml	
	Total Sperm Count: >40 million	Total Sperm Count: >39 mil/ml	
	Percent Motility: >50 %	Percent Motility: >40 %	
	Ph: ≥7.2	Ph: 7.2 – 8.0	
	Sperm Morphology: <u>></u> 29%	Sperm Morphology: <u>></u> 4%	
	Sperm Agglutination: None Seen	Sperm Agglutination: Negative	

REMINDER - 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	BUN	None	>100 mg/dL	None	
A165 (Mineola)					
B257 (Park Ave)					
0058	Cholesterol	<50 or >1500 mg/dL	None	None	
0070	Creatinine	> 5 mg/dL	None	>8 mg/dL as critical (no abnormal)	
A149 (Mineola)					
B176 (Park Ave)					
0019	Hematocrit	<21%	<18%	<18% critical (no abnormal)	
5901	Influenza A	Detected	None	None	
0127	Phosphorus	<2 or >9 mg/dL	None	<2 mg/dL critical (no abnormal or high)	
0139	PTT	>50 sec	>90 sec	>90 sec critical (no abnormal)	
A167 (Mineola)					
B247 (Park Ave)					
1498	RBC	<1.00 or >7.50 x10(6)/uL	None	None	
0148	Sodium	>150 mmol/L	<120 or >160 mmol/L	<120 or >160 mmol/L critical	
A140 (Mineola)				(no abnormal)	
B250 (Park Ave)					
0079	Strep A (DNA)	Positive	None	None	
0152	T3 Uptake	<10 or >90%	None	None	
0151	T4 Total	<1.5 >40.0 ug/dL	None	None	
0155	Triglycerides			None	
0542	Valproic acid	>100 ug/mL	>125 ug/mL	>125 ug/mL as critical (no abnormal)	
B188 (Park Ave)	·			,	

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
REMINDER - Urine Specimen Collection	N/A	September 6

Effective September 6, multiple changes will be 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	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 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.

REMINDER - Patient Portal N/A

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, and 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

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^{*} 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.