

Client Update

BioReference® | GenPath®

April 2024

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Test Name	Test Code	Effective Date
Kappa/Lambda Light Chains, Total, Random Urine	3848-9	Immediately

Kappa/Lambda Light Chains, Total, Random Urine (test code 3848-9) has been discontinued. The recommended alternative is Urine free Kappa + Lambda (test code L592-5).

	Previous Test Information	New Test Information
Primary Container	USC-Urine Cup, no preservative	USC-Urine Cup, no preservative
Minimum Volume	10.0 mL	10.0 mL
Turn Around Time*	1-3 days	3 days
Transportation Temp	Room Temperature	Refrigerate
Stability	12 days Room Temperature, 7 days Refrigerated, 14 days Frozen	
Methodology	Nephelometry	Immunoturbidimetric
Reference Range	Kappa Light Chain <2.00 mg/dL Lambda Light Chain <2.00 mg/dL	
Collection Instructions	Collect urine in cup, label with patient name. Submit urine specimen without preservatives.	Collect urine in cup, label with patient name. Submit urine specimen without preservatives.
Profile Components	Total Kappa Light Chains; Total Lambda Light Chains	Kappa/Lambda Urine Ratio; Free Kappa Urine; Free Lambda Urine
CPT Code(s)**	83883x2	83521x2, 99999x1
Clinical Utility (If applicable)	Useful in diagnosis of Plasma Cell Myeloma	The Measurement of free light chains is used in the diagnosis and monitoring of multiple myeloma, lymphocytic neoplasms, waldenstrom's macroglobulinemia, AL amyloidosis light chain deposition disease and connective tissue diseases such as systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings.

Test Name	Test Code	Effective Date
Discontinued Clinical Tests (Send-Outs)	Various (see below)	Immediately

Effective immediately, the following send-out tests have been discontinued.

Test Code	Test Name
1289	Complement (C5), Serum
1848	Complement C7
1850	Complement C9
TN17	Ku Autoantibodies
B878	Varicella-Zoster Antigen, DFA
T448	Rabies RFFOT Serology End Point Titer
0782	Chlamydia Direct Antigen

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Test Name	Test Code	Effective Date
HIV GenoSure Prime	B347-6	Immediately

HIV GenoSure Prime (test code B347) will be discontinued. The recommended alternative is HIV-1 Genotype (RTI, PI, Integrase Inhibitors) (test code TQ70-7).

	Previous Test Information	New Test Information
Primary Container	ALQE- Plasma from Lavender EDTA tube	ALQE- Plasma from Lavender EDTA tube
Minimum Volume	3 mL	4 mL
Turn Around Time*	14-21 days	7-10 days
Transportation Temp	Frozen	Frozen
Stability	2 years frozen	42 days frozen
Methodology	PCR Amplification, DNA Sequencing	Reverse Transcriptase PCR, Sequencing
Reference Range	Sensitive	No Resistance Predicted
Collection Instructions	Centrifuge lavender-top at high speed for 15 minutes. Transfer plasma into plastic transfer tube. Label with date/time collected, PLASMA and patient's name. Must be submitted frozen	Do not freeze whole blood or any samples stored in primary tube. Freshly drawn specimens (whole blood) may be stored at 2-25° C for up to 24 hours prior to centrifugation. Separate plasma from cells within 24 hours of collection by centrifugation. If shipping frozen, transfer plasma to a leak-proof transport tube, then freeze prior to shipment.
Profile Components	PI, NRTI, NNRTI, INI	PI, NRTI, NNRTI, Integrase Inhibitors
CPT Code(s)**	87900x1, 87901x1, 87906x1	87900x1, 87901x1, 87906x1
Clinical Utility (If applicable)	Detect resistance of HIV-1 to protease, reverse transcriptase, and integrase inhibitors.	Identify drug resistance mutations in HIV-1 patients failing antiretroviral regimens containing RT, PR or Integrase Inhibitors. Identify transmitted drug resistance mutations in the RT, PR or integrase genes in treatment-naïve patients prior to initiation of antiretroviral therapy.

Test Name	Test Code	Effective Date
HIV AG/AB 4 th generation	B688-3	Immediately

Effective immediately, red top tube is no longer an acceptable alternate sample type for HIV AB/AB 4th generation (test code B688-3).

	New Test Information
Primary Container	SST
Minimum Volume	1mL
Turn Around Time*	1 day
Transportation Temp	Refrigerate
Stability	7 days
Collection Instructions	SST: 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

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Test Name	Test Code	Effective Date
Thyroid Stimulating Hormone (TSH)	0153-7, A518-3	4/15/2024

Due to an update in testing platform, the reference ranges for TSH (test code 0153-7, A518-3) have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information										
Primary Container	SST	SST										
Minimum Volume	1mL	1mL										
Turn Around Time*	1 day	1 day										
Transportation Temp	Refrigerate	Refrigerate										
Stability	7 days	7 days										
Methodology	Electrochemiluminescence Immunoassay	Electrochemiluminescence Immunoassay										
Reference Range	Age Range (uIU/mL) 0-30 days 0.347-11.257 31-60 days Not Established 2-23 mo 0.822-5.338 2-5 yrs 0.940-4.963 6-10 yrs 0.875-4.781 11-14 yrs 0.729-4.551 15-18 yrs 0.570-3.890 >18 yrs 0.282-4.000	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Age</th> <th style="width: 50%;">Reference Range</th> </tr> </thead> <tbody> <tr> <td>0 days - 13 days</td> <td>Not established</td> </tr> <tr> <td>2 weeks - 20 weeks</td> <td>1.700 - 9.100</td> </tr> <tr> <td>21 weeks - 18 years</td> <td>0.700 - 6.400</td> </tr> <tr> <td>19 years+</td> <td>0.270-4.200</td> </tr> </tbody> </table>	Age	Reference Range	0 days - 13 days	Not established	2 weeks - 20 weeks	1.700 - 9.100	21 weeks - 18 years	0.700 - 6.400	19 years+	0.270-4.200
Age	Reference Range											
0 days - 13 days	Not established											
2 weeks - 20 weeks	1.700 - 9.100											
21 weeks - 18 years	0.700 - 6.400											
19 years+	0.270-4.200											
Collection Instructions	SST: 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 min	SST: 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 min										
CPT Code(s)**	84443x1	84443x1										
Clinical Utility (If applicable)	Thyroid stimulating hormone (TSH) is produced by the anterior pituitary and promotes the uptake of iodide and the release of thyroid hormones T4 and T3. TSH levels are used to assess thyroid function regulated by the feedback mechanism of thyroid hormones. It is most commonly used as a screening test for hypothyroidism.	Thyroid stimulating hormone (TSH) is produced by the anterior pituitary and promotes the uptake of iodide and the release of thyroid hormones T4 and T3. TSH levels are used to assess thyroid function regulated by the feedback mechanism of thyroid hormones. It is most commonly used as a screening test for hypothyroidism.										

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Test Name	Test Code	Effective Date
Thyroxine, Free (FT4)	0091-9	4/15/2024

Due to an update in testing platform, the reference ranges for Thyroxine, Free (FT4) (test code 0091-9) have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information							
Primary Container	SST	SST							
Minimum Volume	1mL	1mL							
Turn Around Time*	1 day	1 day							
Transportation Temp	Refrigerate	Refrigerate							
Stability	7 days	7 days							
Methodology	Electrochemiluminescence Immunoassay	Electrochemiluminescence Immunoassay							
Reference Range	Age Range (ng/dL) 0-30 days 0.99-3.02 31-60 days Not Established 2-23 mo 1.00-1.70 2-5 yrs 1.04-1.64 6-10 yrs 1.01-1.58 11-14 yrs 0.88-1.52 15-18 yrs 0.92-1.61 >18 yrs 0.84-1.62	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">0 days - 13 days</td> <td style="width: 50%;">Not Established</td> </tr> <tr> <td>2 weeks - 20 years</td> <td>0.80 - 2.00</td> </tr> <tr> <td>21 years +</td> <td>0.92 - 1.68</td> </tr> </table>	0 days - 13 days	Not Established	2 weeks - 20 years	0.80 - 2.00	21 years +	0.92 - 1.68	
0 days - 13 days	Not Established								
2 weeks - 20 years	0.80 - 2.00								
21 years +	0.92 - 1.68								
Collection Instructions	SST: 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 min	SST: 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 min							
CPT Code(s)**	84439x1	84439x1							
Clinical Utility (If applicable)	Thyroxine (T4) and Triiodothyronine (T3) and thyroid stimulating hormone (TSH) are used to assess thyroid function. Most T4 and T3 circulate bound to protein but a small portion (free T4) circulates unbound and is the active form of thyroxine. Since free T4 is not affected by levels of protein it is not subject to fluctuations due to varying levels of protein.	Thyroxine (T4) and Triiodothyronine (T3) and thyroid stimulating hormone (TSH) are used to assess thyroid function. Most T4 and T3 circulate bound to protein but a small portion (free T4) circulates unbound and is the active form of thyroxine. Since free T4 is not affected by levels of protein it is not subject to fluctuations due to varying levels of protein.							

Test Name	Test Code	Effective Date
Chromogranin A	TA34-6	4/1/2024

Chromogranin A (test code TA34-6) will be discontinued. Recommended alternative is Chromogranin A, Serum (test code 2411-7).

	Previous Test Information	New Test Information	
Primary Container	ALQS	ALQS	
Minimum Volume		1mL	
Turn Around Time*	4 days	3-7 days	
Transportation Temp	Strict frozen	Strict frozen	

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Stability	14 days	120 days
Methodology	Enzyme linked Immunoassay	Indirect Fluorescence Assay
Reference Range	21-106 ng/mL	
Collection Instructions	ALQS: Place 1-3 mL of serum in transport tube. Label as serum; refrigerate or freeze as required.	ALQS: Place 1-3 mL of serum in transport tube. Label as serum; refrigerate or freeze as required.
CPT Code(s)**	86316x1	86316x1
Clinical Utility (If applicable)	To help in the diagnosis of other neuroendocrine tumors, including pheochromocytomas, medullary thyroid carcinomas, functioning and nonfunctioning islet cell and gastrointestinal amine precursor uptake and decarboxylation tumors, and pituitary adenomas	Aids in monitoring but is not recommended for diagnosis of carcinoid tumors. May be useful in monitoring nonsecretory sympathetic and parasympathetic neuroendocrine tumors. Nontumor-related elevations of Chromogranin A can be observed in gastrointestinal, cardiovascular, and renal disorders, as well as with proton pump inhibitor (PPI) therapy. It is recommended to stop PPI treatment for at least two weeks prior to testing. Moderate H2-receptor antagonist therapy does not lead to significant elevations of Chromogranin A.

Test Name	Test Code	Effective Date
Prenatal Targeted Chromosomal Microarray	A583-7, A592-8, B222-1	Immediately

The reference lab that performs our microarray testing is consolidating their prenatal microarray options and will no longer offer Prenatal Targeted Microarray. They will continue to offer Prenatal Whole Genome Microarray. We have updated our prenatal microarray options accordingly with the following changes:

- A583-7 and A592-8 will be retired and will flip to A591-0 and B158-7 respectively (see below).
- B222-1 Reflex to Prenatal Microarray from FISH will now reflex to the Prenatal Whole Genome Microarray in place of the Prenatal Targeted Microarray. Sample collection, specimen requirements, report format, turnaround time, and CPT codes will remain unchanged.

The Prenatal Whole Genome Chromosomal Microarray has a higher resolution than the Prenatal Targeted Chromosomal Microarray; therefore, it will detect everything that the targeted array detects plus additional smaller clinically relevant copy number variants. The higher resolution will also lead to a higher rate of detecting variants of uncertain significance (VUS). If you would like to discuss these changes further, please call customer service and ask to speak to a prenatal genetic counselor.

Test code	Test name	Change	Client Action
A583-7	Prenatal Targeted Chromosomal Microarray	Retired and will auto flip to A591-0	A591-0- Prenatal Whole Genome Chromosomal Microarray should be ordered in place of A583-7 to avoid any reporting issues.
A592-8	Reflex to Prenatal Targeted Chromosomal Microarray from Chromosomes	Retired and will auto flip to B158-7	B158-7- Reflex to Prenatal Whole Genome Chromosomal Microarray from Chromosomes should be ordered in place of A592-8 to avoid any reporting issues.
B222-1	Reflex to Microarray from normal FISH (chromosomes if FISH abnl)	Will now reflex to Whole Genome Chromosomal Microarray instead of Targeted Chromosomal Microarray	No action

Questions? Please contact your Account Executive or Customer Service directly.

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