Client Update

BioReference® | GenPath®

August 2023

Test Name	Test Code	Effective Date
Anti-Thyroglobulin Ab. (ATG)	0041-4	August 29, 2023

Due to an update in testing platform, the specimen stability, methodology and reference range for **Anti-Thyroglobulin Ab. (ATG)** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Stability	Stability: 7 days / Frozen stability: 14 days	Stability: 4 days / Frozen stability: 2 months
Methodology	Chemiluminescence	Electrochemiluminescence
Reference Range	<40 IU/mL (Gender: both)	<116 IU/mL

Beta-2 Microglobulin Serum 0262-6 August 29, 2023

Due to an update in testing platform, the specimen stability, methodology and reference range for **Beta-2 Microglobulin Serum** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Stability	7 days, frozen 14 days	3 days, frozen 6 months
Methodology	Chemiluminescent	Immunoturbidimetric
Reference Range	<2.16 mg/L	<60 years 0.8-2.4mg/L >60 years <=3.0mg/L

Conventional Pap Slides 1100-7 and 1960-4 October 1, 2023

Cervical cytology for uterine cervical cancer screening has transitioned from conventional smears to liquid based cytology. Advantages of this include significantly lower rates of unsatisfactory pap smear results, HPV testing from the same specimen and the ability to utilize digital imaging platforms. Due to this, BioReference will no longer be offering the conventional pap smear as part of our test menu.

Effective October 1, **Conventional Pap Slide(s) (test code 1100-7)** and **Pap Smear Manual Screen (test code 1960-4)** will be retired. A liquid based Pap using ThinPrep or SurePath can be ordered in place of a conventional Pap with test code 1962-0

	Previous Test Information	Previous Test Information	Alternate Test Information
Test Name	Conventional Pap Slides	Pap Smear Manual Screen	Liquid Based Pap
Test Code	1100-7	1960-4	1962-0
Primary Container	Slide GYN	N/A	ThinPrep or SurePath
Turn Around Time*	5 days	5 days	5 days
Transportation Temp	Room Temperature	Room Temperature	Room Temperature
CPT Code(s)**	88148	88164	88175
List Price	$80.00	$80.00	$95.00

DHEA, Sulfate 0406-9 August 23, 2023

Due to an update in testing platform, the specimen stability, methodology and reference range for **DHEA, Sulfate** have been updated. Please refer to the table and the next page below for details.

	Previous Test Information	New Test Information
Stability	Stability: 2 days / Frozen stability: 60 days	Stability: 5 days / Frozen stability: 12 months
Methodology	Chemiluminescence	Electrochemiluminescence

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Test Name	Test Code	Effective Date

	Previous Test Information	New Test Information
Reference Range	Age Female (µg/dL) Male (µg/dL) 1-5 days <200 <220 1 mo-5 yrs <60 <58 6-9 yrs <95 <92 10-11 yrs <260 <220 12-17 yrs 51-455 44-531 Age Female (µg/dL) Male (µg/dL) 18-30 59-432 96-571 31-50 26-287 45-419 51-60 * 22-321 61-83 * 15-254 * post-menopausal range 15-195 ug/dL	Age Children (µg/dL) < 1 week 108-607 1-4 weeks 31.6-431 1-12 months 3.4-124 1-4 years 0.47-19.4 5-9 years 2.8-85.2 Age Female(µg/dL) Male (µg/dL) 10-14 33.9-280 24.4-247 15-19 65.1-368 70.2-492 20-24 148-407 211-492 25-34 98.8-340 160-449 35-44* 60.9-337 88.9-427 45-54* 35.4-256 44.3-331 55-64 18.9-205 51.7-295 65-74 9.40-246 33.6-249 ≥ 75 12.0-154 16.2-123

Insulin, Fasting 1648-5 August 24, 2023

Due to an update in testing platform, the specimen stability, methodology and reference range for **Insulin, Fasting** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Stability	Stability: 7 days / Frozen stability: 90 days	Stability: 2 days / Frozen stability: 6 months
Methodology	Indirect Fluorescence Assay	Electrochemiluminescence
Reference Range	3.0-25.0 uIU/mL (Gender: Both)	2.6-24.9 uU/mL

Insulin-Like Growth Factor I 1072-8 September 6, 2023

Due to an update in testing platform, the specimen stability methodology and reference range for **Insulin Like Growth Factor I** have been updated. Please refer to the table below and the following pages for details.

	Previous Test Information	New Test Information
Stability	Stability: 7 days Frozen stability: 365 days	Stability: 2 days Frozen stability: 28 days
Methodology	Chemiluminescence	Electrochemiluminescence
Reference Range	Age Male (ng/mL) Female(ng/mL) 0-3 <15-189 <15-272 4-6 47-231 55-248 7-9 55-222 80-233 10-11 95-315 96-545 12-13 95-460 147-549 14-15 211-512 208-444 16-18 57-426 176-429	Age Male(ng/mL) Female (ng/mL) 0.25 12.0-94.1 13.8-86.4 0.5 11.8-94.6 15.4-92.0 1 11.8-96.4 18.7-104.0 2 13.9-104.0 26.1-128.0 3 18.9-116.0 34.2-155.0 4 26.8-134.0 43.2-185.0 5 36.6-156.0 53.0-216.0 6 47.1-184.0 63.6-250.0 7 57.5-216.0 75.0-286.0 8 67.5-254.0 87.3-324.0

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Test Name	Test Code	Effective Date

Age (Years)	Both (ng/mL)
19-21	105-346
22-24	107-367
25-29	88-537
30-34	41-246
35-39	57-241
40-44	43-209
45-49	74-196
50-54	55-248
55-59	36-200
60-64	51-187
65-69	37-219
70-79	24-200
80-90	17-323

9	76.9-296.0	99.9-363.0
10	85.7-343.0	112.0-398.0
11	93.9-392.0	123.0-427.0
12	101.0-434.0	132.0-451.0
13	108.0-467.0	140.0-468.0
14	115.0-489.0	146.0-480.0
15	120.0-501.0	151.0-485.0
16	125.0-503.0	154.0-485.0
17	129.0-495.0	156.0-479.0
18	132.0-476.0	156.0-466.0
19	134.0-450.0	155.0-449.0
20	136.0-421.0	152.0-429.0
21	137.0-394.0	148.0-410.0
22	137.0-370.0	143.0-392.0
23	136.0-348.0	138.0-375.0
24	135.0-328.0	134.0-359.0
25	132.0-310.0	130.0-343.0
26	130.0-295.0	126.0-329.0
27	128.0-282.0	122.0-315.0
28	125.0-271.0	118.0-303.0
29	123.0-263.0	115.0-292.0
30	120.0-257.0	112.0-281.0
31	118.0-253.0	109.0-271.0
32	116.0-250.0	107.0-263.0
33	114.0-247.0	104.0-255.0
34	111.0-244.0	102.0-248.0
35	109.0-242.0	100.0-242.0
36	107.0-239.0	98.3-238.0
37	105.0-236.0	96.5-234.0
38	103.0-234.0	94.8-231.0
39	101.0-231.0	93.1-228.0
40	98.5-229.0	91.4-227.0
41	96.4-226.0	89.8-225.0
42	94.4-223.0	88.1-224.0
43	92.4-221.0	86.5-222.0
44	90.5-218.0	84.9-221.0
45	88.5-216.0	83.3-220.0
46	86.5-214.0	81.8-219.0
47	84.6-211.0	80.2-218.0
48	82.6-209.0	78.7-218.0
49	80.6-207.0	77.2-217.0
50	78.7-205.0	75.7-215.0
51	76.7-203.0	74.3-214.0
52	74.8-201.0	72.8-212.0
53	72.8-200.0	71.4-210.0
54	70.9-198.0	70.0-207.0
55	68.9-196.0	68.6-204.0
56	67.0-195.0	67.3-201.0
57	65.3-194.0	65.9-198.0
58	63.7-193.0	64.6-194.0

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Test Name	Test Code	Effective Date		
		59	62.3-192.0	63.3-190.0
		60	61.1-191.0	62.0-186.0
		61	60.0-190.0	60.7-182.0
		62	59.2-189.0	59.5-179.0
		63	58.5-188.0	58.3-176.0
		64	57.9-188.0	57.3-173.0
		65	57.4-187.0	56.3-170.0
		66	56.8-186.0	55.5-168.0
		67	56.3-186.0	54.8-166.0
		68	55.8-185.0	54.2-164.0
		69	55.2-185.0	53.8-163.0
		70	54.7-185.0	53.5-162.0
		71	54.1-184.0	53.3-161.0
		72	53.6-184.0	53.2-160.0
		73	53.0-184.0	53.2-160.0
		74	52.4-184.0	53.3-160.0
		75	51.9-184.0	53.5-160.0
		76	51.3-184.0	53.7-161.0
		77	50.7-184.0	54.0-162.0
		78	50.2-184.0	54.3-163.0
		79	49.6-184.0	54.7-164.0
		80		55.1-166.0
Multiple (See Below)	Multiple (See Below)	August 28, 2023		

Due to an update in testing platform, the methodology and reference range for **Multiple ENA Tests** have been updated. Please refer to the table below for details.

Test code	Test name	Previous Reference Range		New Reference Range			Previous Units	New Units
0587	CENP	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
0364	DsDNA	<27 (Negative)	27-35 (Inter); >35 (Pos)	<10.0 (Negative)	10.0-15.0 (Equivocal)	>15.0 (Positive)	[IU]/mL	IU/mL
T974	Jo-1	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
0868	La	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
TA10	Ro52	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
TA11	Ro60	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
0315	Scl-70	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
0851	SmD^P-S	<20 (Negative)	≥20 (Positive)	<7.0 (Negative)	7.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL
0852	U1RNP	<20 (Negative)	≥20 (Positive)	<5.0 (Negative)	5.0-10.0 (Equivocal)	>10.0 (Positive)	{CU}	EliA U/mL

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Test Name	Test Code	Effective Date
OnkoSight Advanced™ Chronic Lymphoid Neoplasm NGS Panel	TH55-7 (PB/M); TJ93-4 (FFPE)	Immediately
OnkoSight Advanced™ Plasma Cell Myeloma NGS Panel	TL67-3 (PB/BM); TL68-1 (FFPE)	

BioReference® and GenPath® Oncology are pleased to enhance our OnkoSight Advanced NGS panels for Chronic Lymphoid Neoplasms and Multiple Myeloma by incorporating virtual karyotyping into these panels. Copy number alterations (**CNAs) are now included in the new section of the OnkoSight Advanced NGS reports for CLL and Multiple Myeloma along with SNVs (single nucleotide variants).** This important feature can inform the presence of large-scale, whole chromosome, chromosome arm, large deletion, or large gain in a sample. Traditionally, such analysis has been restricted to fluorescent *in-situ* hybridization (FISH), chromosomal metaphase karyotyping, and microarray.

Adding CNA information alongside SNV analysis enables the detection of chromosomal gains and losses that enhance diagnostic accuracy, prognostic assessments, and therapeutic stratification in CLL and MM cases.

This application may be considered an adjunct or substitute for routine cytogenetic karyotyping, providing the sample tumor burden is >50%. Balanced translocations can be detected by fluorescent *in-situ* hybridization (FISH) and/or by routine karyotyping.

PLEASE NOTE: **The Cancer Genomics Laboratory at GenPath will require samples with >50% tumor burden to run the copy number alteration algorithm.** Normal findings will not be reported. The Genome-wide Distribution of CNV and SNV section in CLL and Multiple Myeloma reports will appear only when an alteration is detected.

Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement.

Ribosomal-P	TQ11	August 28, 2023

Testing has been validated to be completed in-house at our facility, therefore test information for **Ribosomal-P** has been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Primary Container	SST	SST
Minimum Volume	0.5 mL	40ul per test
Turn Around Time*	5 Days	4 Days
Transportation Temp	Refrigerated	Refrigerated
Stability	7 Days Refrigerated	7 Days Refrigerated
Methodology	Immunoassay	EliA G
Reference Range	<1.0 Neg	<7.0 ELU/mL
Collection Instructions	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	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
CPT Code(s)**	83516	83516
List Price	$95.00	$40

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Test Name	Test Code	Effective Date
Sex-Hormone Binding Globulin	0658-5	August 22, 2023

Due to an updated in testing platform, the methodology and reference range for **Sex-Hormone Binding Globulin** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Methodology	Chemiluminescence	electrochemiluminescence
Reference Range	Male 10-57 nmol/L Female 18-144 nmol/L	Age (yrs) Male (nmol/L) <20 Not Estab. 20-49 16.5-55.9 >or=50 19.3-76.4 Age (yrs) Female (nmol/L) <21 Not Estab. 21-49 24.6-122.0 >or=50 17.3-125.0

REMINDERS

Hepatitis B	Multiple	October 2023

Due to state requirements to report pregnancy status for all positive Hepatitis B Virus results, BioReference and GenPath Women's Health will soon require pregnancy status to be indicated upon order entry for the following Hepatitis B test codes:

- 0106-5 Hepatitis B Surface Antigen
- 0197-4 Hepatitis B Panel
- 3389-4 Hepatitis B Virus, DNA, Quantitative, RT-PCR

Order Entry Question	Is the patient pregnant?
Answer Options	Pregnant, Not Pregnant, Not Applicable

Please note that clients with a non-global EMR compendium will need to open a ticket with their EMR vendors to add the additional Ask on Order Entry (AOE) questions manually.

Hep B Surf Ag w/ confirm, Rfx to DNA, Quant, Prenatal	TP85-7	October 2023

We are pleased to share that we will soon be offering **Hepatitis B Surface Antigen (with confirmation), if positive, reflex to DNA, Quant for prenatal patients (Test code: TP85-7).**

The Centers for Disease Control and Prevention (CDC) recommends that all HBsAg-positive pregnant women should be tested for HBV DNA to guide the use of maternal antiviral therapy during pregnancy for the reduction of HBV transmission to the newborn. Antiviral therapy has been studied as an intervention to reduce perinatal HBV transmission among pregnant women with high HBV DNA levels (e.g., average HBV DNA levels >200,000). Maternal antiviral therapy started at 28–32 weeks' gestation, as an adjunct to HepB vaccine and HBIG administered to the infant shortly after delivery, has been associated with significantly reduced rates of perinatal HBV transmission.

This new test code (TP85) will replace 0106- Hepatitis B Surface Antigen in the standard OB Panels to align with the CDC's recommendations.

	New Test Information
Primary Container	Serum Separator Tube (SST)
Turn Around Time*	1-4 days
Transportation Temp	Refrigerate

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Test Name	Test Code	Effective Date

Stability	7 days
Methodology	Electrochemiluminescence Immunoassay
Reference Range	Non-reactive
Collection Instructions	Fill tube. Invert 5 times. Label with patient name, must stand for a minimum of 30 minutes, maximum of 1 hour. Spin for 10-15 minutes.
Profile Components	Hepatitis B Surface Antigen Hepatitis B Virus, DNA, Quantitative, RT-PCR
CPT Code(s)**	87340 87517 (if reflex is performed)
List Price	$52.50 $350 (if reflex is performed)
Clinical Utility (If applicable)	Detect acute or chronic hepatitis in pregnant women and ensure proper health department notification of pregnancy and reflexively measure viral load of hepatitis B in pregnancy and determine if antiviral therapy is needed to decrease transmission of Hepatitis B to the fetus when HBsAg is positive.

Obstetric Panels **Multiple** **October 2023**

BioReference and GenPath strive to ensure that you have the most up to date and guideline driven testing options. Coming in October, we will be making updates to our **Obstetric/Prenatal Panel (Test Code 0008), Obstetric AMA Panel (test code 0010),** and **Obstetric Panel (Test Code 7307)** to reflect current ACOG and CDC recommendations. Please see the tables on the next page for the anticipated test names changes and test components updates.

	Test Code 0008 - Previous Test Information		Test Code 0008 - New Test Information	
Test Name	**Obstetric/Prenatal I**		**Obstetric ACOG Panel w/HIV**	
Test Components	0039	ANTIBODY SCREEN	0039	ANTIBODY SCREEN
	0053	CBC WITH DIFF	0053	CBC WITH DIFF
	0142	RPR	0142	RPR
	0156	ABO/Rh BLOOD TYPE	0156	ABO/Rh BLOOD TYPE
	0973	RUBELLA, IGG	0973	RUBELLA, IGG
			B688	**HIV**
			B125	**HEP C ANTIBODY W/RFX RT PCR**
			0080	**URINE CULTURE**
			TP85	**HEP B SURF AG W/CONF, IF POS, RFX to DNA, QUANT, PRENATAL**

	Test Code 0010 - Previous Test Information		Test Code 0010 - New Test Information	
Test Name	**Obstetric AMA Panel**		**Obstetric ACOG Panel w/HIV/CT/GC/Trich**	
Test Components	0039	ANTIBODY SCREEN	0039	ANTIBODY SCREEN
	0053	CBC WITH DIFF	0053	CBC WITH DIFF
	0142	RPR	0142	RPR
	0156	ABO/Rh BLOOD TYPE	0156	ABO/Rh BLOOD TYPE
	0973	RUBELLA, IGG	0973	RUBELLA, IGG
	0106	HEP B SURFACE ANTIGEN	**TP85** †	**HEP B SURF AG W/CONF, IF POS, RFX to DNA, QUANT, PRENATAL**
			B688	**HIV**
			B125	**HEP C ANTIBODY W/RFX RT PCR**
			0080 ††	**URINE CULTURE**
			A861 ††	**TRICH (URINE, RNA)**
			6368 ††	**CT (URINE, RNA)**
			6369 ††	**GC (URINE RNA)**

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	Test Code 7307 - Previous Test Information		Test Code 7307- New Test Information	
Test Name	Obstetric/Prenatal I		Obstetric ACOG Panel w/out HIV	
Test Components	0039	ANTIBODY SCREEN	0039	ANTIBODY SCREEN
	0053	CBC WITH DIFF	0053	CBC WITH DIFF
	0142	RPR	0142	RPR
	0156	ABO/Rh BLOOD TYPE	0156	ABO/Rh BLOOD TYPE
	0973	RUBELLA, IGG	0973	RUBELLA, IGG
	0080	URINE CULTURE	0080	URINE CULTURE
	0106	HEP B SURFACE ANTIGEN	TP85 †	HEP B SURF AG W/CONF, IF POS, RFX to DNA, QUANT, PRENATAL
			B125	HEP C ANTIBODY W/RFX RT PCR

†Hepatitis B Surface Antigen (with confirmation), if positive, reflex to DNA, Quant for prenatal patients (Test code: TP85-7) will replace 0106- Hepatitis B Surface Antigen in the standard OB Panels to align with the Centers for Disease Control and Prevention (CDC) recommendation that all HBsAg-positive pregnant women should be tested for HBV DNA to guide the use of maternal antiviral therapy during pregnancy for the reduction of HBV transmission to the newborn.
††When collecting urine culture, please pour off urine into GenProbe Aptima urine tube for CT, GC, Trich

Please refer to the test compendium or online test search for specimen requirements, collection instructions and CPT codes. If you have a favorites or profile currently created within your EMR, test components will need to be updated in September accordingly, in order to *avoid* test not performed (TNP's) due to duplicate orders. If you have any additional questions or need more information, please contact customer service or reach out to your dedicated sales representative.

END

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