Client Update

BioReference® | GenPath®

Test Name	Test Code	Effective Date
Tick-borne Panel by RT-PCR (non-NY)	**L580**	**Immediately**

Muliplex assay for the identification of: *Borrelia mayonii, Borrelia burgdoferi, and/or Babesia microti.*

The **Tick-Borne panel** is a multiplex PCR test to identify DNA from two Borrelia species and Babesia microti. These are the main causative agents of Lyme disease and babesiosis, both of which are tick borne diseases. Symptoms of Lyme disease and babesiosis are relatively nonspecific and range from asymptomatic to severe. DNA testing is typically used to confirm a primary infection at diagnosis.

Borrelia burgdorferi is a spirochete bacteria which is the main causative agent in Lyme disease or Lyme borreliosis in the US. Borrelia mayonii is a relatively newly discovered Borrelia species that also causes Lyme disease, and is found in the upper Midwestern US.

Babesia microti is a parasite that infects red blood cells. It is endemic to the Northeast and upper Midwestern US. Babesiosis is typically diagnosed on a peripheral blood smear; however, PCR testing is used for both confirmation of intra-erythrocyte inclusions and in patients with a high clinical index of suspicion without observable red cell abnormalities.

Test Information	
Primary Container	EDTA Whole Blood
Minimum Volume	1 mL
Turn Around Time*	7 days
Transportation Temp	Room temp (15-25 C),
Stability	7 days
Methodology	RT-PCR
Reference Range	Not Detected
CPT Code(s)**	87476 X 1 and 87798 x 2
List Price	$ 450.00
Clinical Utility	Diagnosis of Lyme disease and Babesiosis

OVA1Plus®	TN77	9/29/2022

Effective September 29, 2022, GenPath will offer **OVA1Plus**® to detect ovarian cancer risk in women diagnosed with a pelvic mass. OVA1plus is a reflex process, performed by Aspira Women's Health, Inc., which combines two FDA-cleared blood tests, OVA1® and OVERA®, to detect risk of ovarian malignancy in women with adnexal masses prior to surgery. OVA1® is performed first and if the OVA1 result is in the intermediate range, will reflex to OVERA®.

Test Information	
Primary Container	OVA1Plus Kit or 1 Full Serum Separator Tube
Minimum Volume	0.5mL serum or 1.5mL whole blood
Turn Around Time*	3-5 days
Transportation Temp	Refrigerated
Stability	8 days refrigerated
Methodology	IA- Immunoassay
Reference Range	0-10
Collection Instructions	
Profile Components	OVA1 and Overa
CPT Code(s)**	81503
List Price	$1,495

** 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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Test Name	Test Code	Effective Date
HSV by PCR	**J549**	**Immediately**

Due to changes at the reference laboratory, some changes to test information has changed. Please refer to the table below for updated information.

	Previous Test Information	New Test Information
Test Name	HSV by PCR	Herpes Simplex Virus (HSV-1/HSV-2) Subtype by PCR
Turn Around Time*	7 days	5 days
Collection Instructions		Collect: Lavender (EDTA), pink (K2EDTA), or serum separator tube. OR CSF, bronchoalveolar lavage (BAL), amniotic fluid, vesicle fluid, ocular fluid, tissue. OR endocervical specimen in ThinPrep Pap Test media. Collection Preparation: Separate plasma or serum from cells. Transfer 1 mL plasma, serum, CSF, BAL, amniotic fluid, ocular fluid or ThinPrep specimen to a sterile container. Tissue: Transfer to a sterile container and freeze immediately. Vesicle fluid: Transfer to viral transport media.
CPT Code(s)**	87529	87529 x2
List Price	$200.00	$333.75

Folate (Folic Acid)	**0090**	**9/23/2022**

Due to changes in instrumentation at the Elmwood Park, NJ laboratory, the Reference Range for Folic Acid testing has been revised. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	Units (ng/mL) Normal >5.38 Borderline deficient 3.38-5.38 Deficient 0.35-3.37 Excessive >24.00	> or = 4.00 ng/mL

Estradiol	**0516**	**9/22/2022**

Due to changes in instrumentation at the Elmwood Park, NJ and Melbourne, FL laboratories, the Reference Range for Estradiol testing has been revised. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	Range (pg/mL) Males (yrs) 1-11 5.00-10.00 12-14 5.00-30.00 15-17 5.00-45.00 Adult 7.02-49.06 Females (yrs) 1-5 5.00-10.00 6-9 5.00-60.00 10-11 5.00-300.00 12-17 24.00-410.00	Range (pg/mL) Males (yrs) 1-11 5.00-10.00 12-14 5.00-30.00 15-17 5.00-45.00 Adult 11.30-43.20 Females (yrs) 1-5 5.00-10.00 6-9 5.00-60.00 10-11 5.00-300.00 12-17 24.00-410.00

-Reference Range Continued on Next Page-

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Test Name	Test Code	Effective Date
	Phases Follicular 6.20-315.00 Ovulation 28.60-525.00 Luteal 7.69-752.00 Postmenopausal <5.00-51.60 Trimester 1st 127.00-4161.00 2nd 1137.00-25130.00 3rd 7398.00->30000.00	Phases Follicular 30.90-90.40 Ovulation 60.40-533.00 Luteal 60.40-232.00 Postmenopausal <5.00-138.00 Trimester 1st 127.00-4161.00 2nd 1137.00-25130.00 3rd 7398.00->30000.00

Progesterone **0335** **9/21/2022**

Due to changes in instrumentation at the Elmwood Park, NJ and Melbourne, FL laboratories, the Reference Range for Estradiol testing has been revised. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	PROGESTERONE EXPECTED VALUES Range (ng/mL) Female Follicular Phase 0.06-0.89 Ovulation Phase 0.12-12.00 Luteal Phase 1.83-23.90 Postmenopausal <0.14 Pregnancy (Trimester) 1st 11.00-44.30 2nd 25.40-83.30 3rd 58.70-214.00	PROGESTERONE EXPECTED VALUES Range (ng/mL) Female Follicular Phase <0.05-0.19 Ovulation Phase 0.06-4.14 Luteal Phase 4.11-14.50 Postmenopausal <0.05-0.12 Pregnancy (Trimester) 1st 11.00-44.30 2nd 25.40-83.40 3rd 58.70-214.00

REGIONAL UPDATE FOR MELBOURNE, FL LAB ONLY

Hepatitis C Antibody w/reflex RT PCR **B125** **9/26/2022**

Test code 0812 (Hepatitis C Antibody) has been retired. When this test code is ordered, the code will be replaced with B125 Hep C Ab w/ reflex to RT PCR in accordance with CDC recommendations.

The new test methodology has not been approved on patients < 18 months old.

If B125 is ordered on any patient < 18 months old, the test will be sent as a TNP message, Test Not Performed: The Hepatitis C Antibody test has been validated for patients aged >=18 months and an alternate test (TM01) will be performed.

	Previous Test Information	New Test Information
Primary Container	SST	SST
Minimum Volume	1.0 ml	1.0 ml
Turn Around Time*	1 day	1 day
Transportation Temp	Rm Temp	Rm Temp
Stability	4 days refrig	3 days @25, 7 days refrig, 30 days if serum frozen
Methodology	Immunoassay	ECLIA
Reference Range	Non-Reactive	Non-Reactive
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__	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__
Profile Components	Hep C Ab (B788) Hep C Ab S/CO Ratio (B787)	Hep C Ab (B788)
CPT Code(s)**	99999 x1 86803 x1	99999 x1 86803 x1

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