Client Update

BioReference® | GenPath®

July 2023

Test Name	Test Code	Effective Date
Patient Portal	N/A	July 24, 2023

As part of our continuous efforts to keep patient data safe and secure, we have implemented enhanced security measures within our HIPAA-compliant secure Patient Portal. A portal update will take place on July 24, and while we expect it to be a seamless transition for patients, they will be asked to reset their passwords upon their next login. Should patients have any questions or experience issues, they can reach out to our Patient Support Group at 888-279-0967, available M-F 9AM-5PM ET.

ClariTest® Core Non Invasive Prenatal Screening	TH18-5 and TH19-3	July 1, 2023

Due to changes in the internal claims processes implemented by many insurance companies, BioReference and GenPath Women's Health are implementing an update to clinical information before ordering Claritest® Core NIPS (Test Codes TH18-5 and TH19-3). Effective July 1, 2023, NIPS orders will require the following questions be provided upon order entry:

Clinical indications

- Routine Screening
- Advanced Maternal Age
- Abnormal Antenatal Screen for: _____
- Family History: _____
- Ultrasound Finding(s):_____
- Previous Pregnancy History: _____

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

Hepatitis B	Multiple	September 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

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****Healthcare providers should only order panels if each test in the panel is medically necessary.*

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Test Name	Test Code	Effective Date
Hep B Surf Ag w/ confirm, Rfx to DNA, Quant, Prenatal	TP85-7	September 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
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	September 2023

BioReference and GenPath strive to ensure that you have the most up to date and guideline driven testing options. Coming in September, 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.

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Test Name	Test Code	Effective Date

	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)**

	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.

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Test Name	Test Code	Effective Date
Rubella IgG		June 29, 2023

Rubella IgG is moving to a different testing platform and will no longer be reported quantitatively. It will now be reported as "Immune" or "Non-Immune". The following information in a table format will be added to the patient report:

> "The Analyzer automatically calculates Rubella Virus IgG antibody concentrations expressed as Index value and grades the results. The cutoff value (Index=1) has been set at 10IU/mL based on calibration traceability to the WHO 1st International Standard for anti-Rubella Immunoglobulin, Human (1997). This is in accordance to CLSI Guideline (I/LA6-A) that recommends 10 IU/mL as indicator of immune status. Sample results are interpreted as follows:
> < 0.90 Index = Negative. Sample is considered negative for IgG antibodies to rubella virus. A negative result presumes that immunity has not been acquired. If exposure to rubella virus is suspected despite negative finding, a second specimen should be collected and tested one or two weeks later. Seroconversion from a negative specimen to a positive specimen is evidence of either recent infection, response to vaccination, or administration of immunoglobulins.
> > = 0.90 Index and <1.00 Index = Equivocal. The equivocal specimen should be re-tested. In case the result remains in this range after repeat testing, a second specimen should be collected.
> > = 1.00 Index = Positive. Sample is considered positive for IgG antibodies to rubella virus."

If you remain in need of quantitative results, please contact your dedicated account representative to discuss alternate test options.

END

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