

Client Update

BioReference® | GenPath®

September 2023

Page 1 of 8

Test Name	Test Code	Effective Date
CINtec® PLUS Cytology Reflex from Aptima® mRNA HPV	TP75-8	September 12, 2023

We are pleased to share that we have expanded our CINtec® PLUS offering to reflex from Aptima® HPV in addition to Roche cobas® HPV. It can be ONLY be ordered for women ages 30-65 from a ThinPrep vial using test code TP75-8 along with one of the Pap and Aptima® HPV test codes listed below (two codes must be ordered). CINtec PLUS will only be performed when the Pap is normal (NILM) and any hrHPV is positive. Please refer to the table below for ordering details.

Test Code	Test Name
A250-3	Pap + HPV mRNA Screen, if pos., Rfx 16,18/45
A252-9	Pap + HPV mRNA Screen, if pos., Rfx 16, 18/45 + CT/GC
M280-6	PAP + HPV MRNA (NO GENOTYPING)
M281-4	PAP + HPV MRNA (NO GENOTYPING) + CT/GC
Q723-9	Stormpath PAP + HPV HR W/Rfx to HPV 16 and 18/45
Q724-7	Stormpath PAP+CT/GC+HPV HR w/RFX to HPV 16 and 18/45

CINtec PLUS Cytology is a triage test that uses dual biomarker technology to simultaneously detect p16 and Ki-67 in women ages 30-65 with HPV-positive results. The presence of both biomarkers, p16 and Ki-67, within the same cell is a strong indicator that an HPV infection is undergoing oncogenic transformation.

CINtec PLUS as a reflex from Roche cobas HPV remains available to order using test code TP42-8. Please refer to the table below for test information.

Test Information	
Primary Container	ThinPrep
Turn Around Time*	3-5 days after the Pap is completed
Transportation Temp	Room temperature
Stability	21 days
Methodology	Immunohistochemistry
Reference Range	Not Detected
Collection Instructions	Collect ThinPrep samples as per manufacturer's guidelines
CPT Code(s)**	88344
List Price	\$711.45

OnkoSight Advanced™ Breast Cancer NGS Panel	TH48-2	Immediately
OnkoSight Advanced GYN Tumor NGS Panel	TH53-2	
OnkoSight Advanced Pancreaticobiliary Tumor NGS Panel	TK84-0	
OnkoSight Advanced Prostate Cancer NGS Panel	TH48-2	
Select OnkoSight Advanced Solid Tumor NGS Panel	TJ16-5	

BioReference® and GenPath® Oncology are pleased to enhance our OnkoSight Advanced NGS panels for breast, GYN, prostate, and pancreatic and biliary tract tumors, general solid tumor by incorporating copy number alterations (CNAs) assessment into these panels. CNAs 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 single-nucleotide variant (SNV) analysis enables the detection of chromosomal gains and losses that enhance diagnostic accuracy, prognostic assessments, and therapeutic stratification.

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.
- If a client orders OnkoSight Advanced Solid Tumor NGS Panel (TJ16-5), CNA assessment will be performed on samples/cases with indication for tumor subtypes with HRD-associated therapy including HGSO (high grade serous ovarian, Fallopian tube and mesenteric), prostate, breast, pancreaticobiliary.

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

* TAT is based upon receipt of the specimen at the laboratory.

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Client Update

BioReference® | GenPath®

September 2023

Page 2 of 8

Test Name	Test Code	Effective Date
Beta-2-Microglobulin, Urine, Random	1754-1	October 2023

Due to a change in performing laboratory location, test information for Beta-2-Microglobulin Urine, Random (Test code 1754) has been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Primary Container	USC-Urine Cup	Quest Diagnostics Beta-2 Microglobulin Transport –OR– Urine (pH of the specimen must be adjusted to between 6 and 8 using 1N NaOH)
Minimum Volume	4 mL	10 mL
Turn Around Time*	2 days	5 days
Stability	7 days, 60 days frozen	5 days Ambient, 15 days Refrigerated, 30 days Frozen
Methodology	Chemiluminescence	Immunoturbidimetric
Reference Range	<0.300 mg/L	≤0.20 mg/L
Collection Instructions	USC: Collect urine in cup, label with patients name. Specimen Comments: use NaOH to adjust PH to 6-8 (ship cold).	<ol style="list-style-type: none"> 1. Patient should void bladder, then drink at least 500 mL (approximately 17 oz) of water. 2. A urine sample should be collected within 1 hour. 3. Pour exactly 10 mL of random urine into a Quest Diagnostics Beta-2 Microglobulin Transport Tube. 4. Alternatively, if the collection tubes are not available, pH of the specimen must be adjusted to between 6 and 8 using 1N NaOH prior to shipping. Beta-2 Microglobulin in urine is unstable in acidic urine (less than pH 6). <p><i>Please note: Exactly 10 mL of urine in the Quest Diagnostics Beta-2 Microglobulin Transport Tube is required to achieve the required pH of between 6 and 8. Any volume above or below 10 mL will result in a pH that is outside the acceptable range.</i></p>
List Price	\$85.30	\$156.35
Clinical Utility	Evaluate the severity and prognosis of multiple myeloma, chronic lymphocytic leukemia, or non-Hodgkin's lymphoma; detect kidney damage and distinguish between glomerular and tubular kidney disorders.	Beta-2-Microglobulin, Urine - Beta-2-Microglobulin (B2M) is a low molecular weight protein that forms the light chain component of the histocompatibility antigen. It is synthesized by all nucleated cell types. It is an integral part of the class I MHC antigens and is present in all body fluids. B2M is filtered through the glomeruli of the kidney and is then reabsorbed and catabolised by the proximal tubular cells. In normal patients only trace amounts of B2M appear in the urine. Elevated urine B2M is seen in tubulo-interstitial disorders. Increased urine B2M is seen in cadmium exposure, diatrizoate, exercise, fever, nephrectomy, semen. There is evidence that monitoring B2M levels in HIV-infected individuals offers an independent predictor of progression to AIDS, leukemia and lymphoma.

Calcitonin, Serum	0196-6	October 2023
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Due to a change in performing laboratory location, test information for Calcitonin, Serum (Test code 0196) has been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Turn Around Time*	2 Days	4 days
Stability	15 days Frozen	7 days Refrigerated, 90 days Frozen
Methodology	Chemiluminescence	Quantitative Chemiluminescent Immunoassay
Reference Range	Male: <8.8 pg/mL Female: <5.8 pg/mL	Male, 3 years and older: 0.0-7.5 pg/mL Female, 3 years and older: 0.0-5.1 pg/mL
Collection Instructions	ALQS: Place 1-3 mL of serum in transport tube. Label as serum; freeze as required.	Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to a Standard Transport Tube. Label as serum; freeze as required.
List Price	\$171.00	\$80.00

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Client Update

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September 2023

Page 3 of 8

Test Name	Test Code	Effective Date
Human Growth Hormone, Multiple	0510-8, 3303-5, 3304-3, 3305-0, 3306-8, 3307-6	October 2023

Due to a change in performing laboratory location, test information for Human Growth Hormone (Test code 0510) has been updated. Please refer to the table below for details.

Please also note that Growth Hormone Test codes 3303-5, 3304-3, 3305-0, 3306-8 & 3307-6 have been retired. If ordered, the tests will not be performed.

Previous Test Information	New Test Information																					
Turn Around Time*	2 days																					
Methodology	Chemiluminescence																					
Reference Range	Quantitative Chemiluminescent Immunoassay																					
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Age</th> <th>Male</th> <th>Female</th> </tr> </thead> <tbody> <tr> <td>0-6 years</td> <td>0.10-6.20 ng/mL</td> <td>0.10-6.20 ng/mL</td> </tr> <tr> <td>7-17 years</td> <td>0.05-11.00 ng/mL</td> <td>0.05-17.30 ng/mL</td> </tr> <tr> <td>> 18 years</td> <td>0.05-3.00 ng/mL</td> <td>0.05-8.00 ng/mL</td> </tr> </tbody> </table>	Age	Male	Female	0-6 years	0.10-6.20 ng/mL	0.10-6.20 ng/mL	7-17 years	0.05-11.00 ng/mL	0.05-17.30 ng/mL	> 18 years	0.05-3.00 ng/mL	0.05-8.00 ng/mL									
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Both	15-18 Y	<13.5 ng/mL																				
Collection Instructions	Allow specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP or within 2 hours of collection.																					
List Price	\$92.20																					

IGF Binding Protein-3 1316-9 October 2023

Due to a change in performing laboratory location, test information for IGF Binding Protein-3 (Test code 1316) has been updated. Please refer to the table below for details.

Previous Test Information	New Test Information																																																																																																																													
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Client Update

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September 2023

Page 4 of 8

Test Name	Test Code	Effective Date
Collection Instructions	ALQS: Place 1-3 mL of serum in transport tube. Label as serum; freeze as required.	Separate serum or plasma from cells. Transfer 1.00 mL serum or plasma to a Standard Transport Tube. Label as serum; freeze as required.
List Price	\$87.30	\$70.00

Insulin Tolerance Tests Multiple – See Below Immediately

Due to an update in testing platform, test information for multiple **Insulin Tolerance Tests** has been updated. Please refer to the table below for details.

Previous Test Information	New Test Information
Stability	7 days / Frozen stability: 90 days
Methodology	Indirect Fluorescence Assay
Reference Range	See Table On Next Page

Test Code	Test Name	Current Reference Range	New Ref Range
2258	Insulin, 1/2 Hr.	Not Estab.	Not Estab.
1649	Insulin, 1 Hr.	18.0-276.0	Not Estab.
3366	Insulin, 90 Min.	Not Estab.	Not Estab.
1650	Insulin, 2 Hr	16.0-166.0	Not Estab.
6264	Insulin, 2 1/2 Hr.	Not Estab.	Not Estab.
1651	Insulin, 3 Hr.	3.0-25.0	Not Estab.
3373	Insulin, 3 1/2hrs.	Not Estab.	Not Estab.
1652	Insulin, 4 Hr.	3.0-25.0	Not Estab.
1653	Insulin, 5 Hr.	3.0-25.0	Not Estab.
1654	Insulin, 6 Hr.	3.0-25.0	Not Estab.

MYD88 Sequencing J130-6 and TN95-0 Immediately

Please be advised that we are retiring test code **J130-6 OnkoSight MYD88 Sequencing (Non-NY)** as it was replaced with test code **TN95-0 OnkoSight Advanced MYD88 Sequencing**. There will be no changes to the specimen requirement, CPT code, etc.

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

Multiple – See Below Multiple – See Below Immediately

Please be advised that reference ranges for multiple test codes, listed below, have been updated.

Test	Test Code	Current Reference Range	New Reference Range
Ionized calcium	0051	4.5-5.3 mg/dL	4.4-5.2 mg/dL
Beta-2-glycoprotein IgG	3904	<20 G units	<7 G units
beta-2-glycoprotein IgA	3905	<20 A units	< 7 A units
beta-2-glycoprotein IgM	3906	<20 M units	<7 M units
Cardiolipin IgG	0881	neg= <23 low pos=23-35 mod. Pos=36-50 high pos= >50	<10 GPL - U/mL
Cardiolipin IgA	1425	neg= <22 low pos=22-35 mod.pos=36-45 high pos= >45	<14 APL - U/mL
Cardiolipin IgM	0882	neg= <11 low pos= 11-20 mod. pos= 21-30 high pos= >30	<10 MPL - U/mL
INR	1112	range: 0.92-1.12	0.80-1.07

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Client Update

BioReference® | GenPath®

September 2023

Page 5 of 8

Test Name	Test Code	Effective Date
Toxoplasma IgG & reflex, when performed at our Florida laboratory Location	0552 & 2376 neg= <6.4 IU/mL equivocal=6.4-9.9 IU/mL pos= >9.9 IU/mL	Negative

Prostate Specific Acid Phos (P.A.P.) 0030-7 September 14, 2023

Due to a change in performing laboratory location, test information for Prostate Specific Acid Phos (P.A.P.) (Test code 0030) has been updated. Please refer to the table below for details.

Previous Test Information	New Test Information
Primary Container	SST - SST Tube
Turn Around Time*	2 Days
Transportation Temp	Refrigerate
Stability	7 Days
Methodology	Chemiluminescence
Reference Range	<3.5 ng/mL
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__
List Price	\$65.00

QuantiFERON® T814-3 N/A

Please be reminded that testing for tuberculosis, **QuantiFERON® TB Gold Plus (Test Code T814)** requires accurate and timely specimen management. Pre-analytical factors can have an impact on QuantiFERON® test results potentially causing an indeterminate report. Proper collection and storage of filled blood collection tubes is crucial. Please refer to the specimen management and handling requirements below.

Proper Specimen Management:

- Collect 6mL (minimum 5mL) Blood into single Lithium-heparin (green top) tube. Blood collection tubes should be room temperature, 17–25°C, at the time of blood collection.
- Gently mix well by inverting the tube several times to dissolve the heparin.
- Label specimen with patient name immediately after draw.
- Blood drawn into lithium-heparin tube may be held at room temperature (17–25°C) up to 3 hours after blood collection.
- Prepare the lithium-heparin tube for transfer to the testing laboratory by placing in the designated QuantiFeron® specimen bag.
- Specimen must be stored at 2–8°C in refrigerator.
- If placed in specimen box, ensure a cold pack is used to maintain refrigerated state. A barrier should be placed between the specimen bag and cold pack (cardboard or batting).

Note: For offices using an outside specimen box, we recommend keeping your specimen box inside during very warm or cold days. Place the box outside once you have placed your specimens for pickup inside the box. This assists in maintaining the proper temperature and specimen integrity. We can provide Styrofoam box inserts and cold packs for your specimen box.

Ribosomal-P TQ11 and 1811-9 Immediately

Due to a change in performing laboratory location, test information for **Ribosomal-P (Test code TQ11)** has been updated. Please refer to the table below for details.

Please also note that previous test code **1811-9** will be retired, and if ordered, the test will automatically be ordered using the new test code.

Previous Test Information	New Test Information
Minimum Volume	0.5 mL
Turn Around Time*	5 Days
Methodology	Immunoassay
Reference Range	<1.0 Neg
List Price	\$95.00

* TAT is based upon receipt of the specimen at the laboratory.

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

Client Update

BioReference® | GenPath®

September 2023

Page 6 of 8

Test Name	Test Code	Effective Date
Surgical Pathology	N/A	N/A

In order for BioReference® to provide your patients with the highest quality care, and to avoid unnecessary delays in test processing and results, we want to remind you to please remember to include biopsy source and site (for example not just polyp- but sigmoid colon polyp, or not just skin- but skin right leg), pertinent clinical history and diagnosis codes on the requisition. For consults (Test codes 5111 and 5207), please include reason for consult (for example cancer vs. atypia) as well as gross description and preliminary diagnosis if available. Having this information is vital to arriving at the correct diagnosis and is also a regulatory and compliance requirement. Effective 30 days following this client update, if cases are submitted without the required information, the client will be called to obtain. Please note that this additional step for required information may cause a delay in processing.

Reminder that HER2 Fish cannot be performed on decalcified specimens.

When sending in breast cases for HER2/ER/PR analysis if the invasive focus is small or difficult to identify please send in accompanying IHC slides if performed and available which highlight area of invasion. This will expedite review and ensure correct interpretation.

Thyroid Stimulating Immunoglobulin	J510-9	September 11, 2023
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Due to a change in performing laboratory location, test information for **Thyroid Stimulating Immunoglobulin (Test code J510)** has been updated. Please refer to the table on the next page for details.

	Previous Test Information	New Test Information
Primary Container	SST - SST Tube	ALQS - Aliquot Tube-Serum
Turn Around Time*	1 day	3 days
Stability	7 days	7 days Refrigerated. 1 year Frozen
Methodology	Chemiluminescence	Semi-Quantitative Chemiluminescent Immunoassay
Reference Range	<0.56 IU/L	Consistent with healthy thyroid 0.54 IU/L or less Consistent with Graves disease 0.55 IU/L or greater
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.	Allow specimen to clot completely at room temperature. Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum or plasma to a Standard Transport Tube.
List Price	\$260.00	\$230.00
Clinical Utility (If applicable)	N/A	This assay specifically detects thyroid stimulating autoantibodies.

REMINDERS

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

* TAT is based upon receipt of the specimen at the laboratory.

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Client Update

BioReference® | GenPath®

September 2023

Page 7 of 8

Test Name	Test Code	Effective Date
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
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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. Please see the table below and on the next page for more information

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	November 2023
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BioReference® and GenPath® strive to ensure that you have the most up to date and guideline driven testing options. Coming in November, 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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