Client Update

BioReference® | GenPath®

Test Name	Test Code	Effective Date
CINtec® PLUS Cytology	**TP42-8**	**Immediately**

BioReference® and GenPath® Women's Health are pleased to enhance our cervical cancer screening options with the addition of **CINtec® Plus Cytology** (Test Code TP42-9), which serves as a triage from discrepant co-testing results (Pap normal and hrHPV positive) of women ages 30-65.

CINtec® PLUS Cytology is the only FDA approved triage test that uses multiplex immunohistochemistry to simultaneously detect p16 and Ki-67 in women 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 Cytology can ONLY be ordered out of a ThinPrep vial along with one of the following Pap and HPV test codes. Both test codes must be selected.

- B975-4 – Pap + Pap Dependent HPV
- P734-7- Pap + Pap Dependent HPV + CT/GC
- P079-7- Pap + HPV DNA non 16,18 Genotyping 16,18 (Roche cobas)
- P372-6- Pap + HPV DNA non 16,18 Genotyping 16,18 + CT/GC (Roche cobas)

Test details can be found in the table below. Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement.

	New Test Information
Test Code	TP42-9- Must be ordered along with one of the following Pap and cobas hrHPV test codes: B975, P734, P079, P372
Primary Container	ThinPrep
Turn Around Time*	3-5 days after the Pap is completed
Transportation Temp	Room temperature
Stability	No More than 21 days
Methodology	Immunohistochemistry
Reference Range	Not Detected
Collection Instructions	Collect ThinPrep samples as per manufacturer's guidelines
CPT Code(s)**	88344

ClariTest® Core Non Invasive Prenatal Screening	**TH18-5 and TH19-3**	**March 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 March 1, 2023, NIPS orders will require the following questions be provided upon order entry:

Patient received pretest counseling regarding screening options from:

- Board certified genetic counselor
- Physician
- Other healthcare professional
- Unknown

Please note that for clients that have non-global EMR compendiums, the client will need to open a ticket with their EMR vendor and add the additional AOE questions manually.

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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
Epstein-Barr virus (EBV), PCR Quant	**TN89-3**	**February 7, 2023**
BK Virus DNA (BK), PCR Quant	**TN90-1**	

BioReference will now complete testing for **Epstein-Barr virus (EBV), PCR Quant** (Test Code TN89-3) and **BK Virus DNA (BK), PCR Quant** (Test Code TN90-1) at our in-house laboratory, and these tests will no longer be sent to a reference laboratory.

Additional Profile codes are log calculated as follows: BKV by PCR (Test Code M331); BK Virus DNA (Test Code TN90); BKvirus DNA log (10)(Test Code TP30), EBV by PCR (Test Code M328); EBV (Test Code TN89); EBV log (10) (Test Code TP31). The purpose of a log result is to reduce the variability in the viral load and aid the healthcare provider in gauging whether an actionable increase or decrease has occurred.

Transplant recipients are at increased risk for many viral and bacterial infections that are more likely to cause severe adverse health outcomes in the transplant patient population compared to the general healthy population[1]. Laboratory testing of potential donors can help in preventing the transmission of infectious diseases to transplant patients. There is high inter-laboratory and inter-assay variability due to non-standardization of laboratory tests, and this is eliminated by having assays that are on the international standard.

FDA approved assays for EBV and BK that meet the International Standard and eliminate need to re-baseline patients. Test Information is as follows:

	Previous Test Information	New Test Information
Test Name	Epstein-Barr virus (EBV)	
Test Code	3206	TN89-3
Primary Container	Plasma only	
Reference Range	200 – 2,000,000 copies/mL	35 IU/mL – 4,000,000 IU/mL
Clinical Significance	In transplant recipients, EBV can cause disease either through reactivation of latent virus from memory B cells, or through a new primary infection, especially in EBV-negative transplant recipients who receive grafts from EBV-positive donors. For these patients, the most severe form of EBV-related disease is post-transplant lymphoproliferative disorder (PTLD), which results from uncontrolled proliferation of lymphocytes, typically B cells. Overall, > 70% of PTLD cases among transplant recipients are linked to EBV infection. The highest risk for PTLD occurs during the first year after transplant, and >90% of PTLD cases that occur during this period are linked to EBV. Up to 20% of PTLD cases that occur after the first year post-transplant are EBV-negative. Risk factors for early-onset PTLD include serostatus at transplantation (EBV sero-negative for solid organ transplant, EBV sero-positive for hematologic stem cell transplant), younger age, exposure to lymphocyte-depleting antibodies, and type of organ transplanted. Early identification of primary EBV infections and DNA level monitoring can support prompt therapeutic intervention to prevent progression to EBV-related disease.	

	Previous Test Information	New Test Information
Test Name	BK Virus	
Test Code	**6208** *NOTE: Test Code A492 for BK Urine remains unchanged*	**TN90-1**
Primary Container	Plasma only. Serum no longer acceptable.	
Reference Range	Plasma 500-500,000,000 copies/mL	21.5 – 20,000,000 IU/mL
Clinical Significance	In EDTA plasma, cobas® BKV is intended for use as an aid in the management of BKV in transplant patients. In patients undergoing monitoring of BKV in EDTA plasma, serial DNA measurements can be used to indicate the need for potential treatment changes and to assess viral response to treatment. Regular monitoring for BKV in kidney transplant patients is recommended for up to 5 years post-transplant.	

1. *Roche cobas® EBV P/N: 08688206190. "Quantitative nucleic acid test for use on the cobas® 6800/8800 Systems". Page 4.*

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Test Name	Test Code	Effective Date
Glomerular Filtration Rate (GFR or e-GFR)	**Multiple**	**March 1, 2023**

Based on recommendation standards by the National Kidney Foundation, BioReference will adopt the new **CKD-EPI Creatinine equation (2021)**, effective March 1, 2023.

Glomerular filtration rate (GFR or e-GFR) is the best overall index of renal function. GFR varies with age, sex, and body size, and declines with age. This new equation, for the same creatinine value, will estimate a lower GFR for Black patients and a higher GFR for non-Black patients.

Test Name	Test Code	Effective Date
Hepatitis C Virus (HCV) FibroSure	**TN24-0**	**January 17, 2023**

Due to changes from the referring laboratory, specimen requirements have been updated for **Hepatitis C Virus (HCV) FibroSure** (Test Code TN24-0), and SST and RED Top are **no longer** acceptable. Please refer to the table below for changes.

	Previous Test Information	New Test Information
Primary Container	SST	Aliquot Serum from SST (ALQS) and Aliquot serum from Red (ALQRD)

Test Name	Test Code	Effective Date
OnkoClone™ CLL MRD	**TP05-5**	**February 14, 2023**

BioReference® and GenPath® Oncology now offers **OnkoClone™ CLL MRD** (Test code TP05-5). OnkoClone CLL MRD is a DNA-based next-generation sequencing (NGS) assay using EDTA blood that identifies unique sequences encoding B-cell receptors and can serve as molecular markers, or "barcodes". OnkoClone CLL MRD may serve as a follow-up testing/monitoring of high-risk CLL patients to evaluate therapy response and/or relapse and refractory disease. The test can also be used as a direct measure of disease in lymphoproliferative neoplasms including various types of lymphoma and leukemia.

Of note, CLL/MCL Prognosis: IGVH Mutation Analysis by NGS (Test code TM70-5) must be completed at GenPath prior to assessing MRD.

Test details can be found in the table below. Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement.

	New Test Information
Primary Container	Peripheral Blood - Lavender Top (5 ml) or Bone Marrow, Lavender Top
Minimum Volume	200uL PB or BM
Turn Around Time*	7 days
Transportation Temp	Ambient temperature. Ship with a cold pack during warm weather.
Stability	14 days
Methodology	Next-generation Sequencing
Collection Instructions	Extracted DNA is acceptable, providing that the isolation of nucleic acid occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS and/or the CAP.
CPT Code(s)**	81479

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Test Name	Test Code	Effective Date
REGIONAL UPDATE: Hackensack RCCA-LACTATE DEHYDROGENASE, LDH	**A920**	**January 23, 2023**

Due to new reagent, reference ranges for **RCCA-LACTATE DEHYDROGENASE, LDH (test Code A920) have been updated, when** performed at our Hackensack lab on the Vitros 4600. Please see table below for details.

	Previous Test Information	New Test Information
Reference Range	313-618 U/L	120-246 U/L
Reportable Range	125-43,000 U/L	60-20,000 U/L

Retired Test Codes **Multiple** **Immediately**

Due to changes at the reference laboratory, or low utilization, the following test codes and panels*** have been retired. No alternative codes are available at this time.

- 1253: Allergen Silk (k74), IgE Bombyx mori.
- L206: PANEL L206
- L233: PANEL L233
- L977: PANEL L977
- M054: PANEL M054
- M270: PANEL M270
- P950: PANEL P950
- Q003: PANEL Q003
- F675: PID/Infertility/Pregnancy Loss W/O PAP W/O HPV
- 0725: Raji Cell Immune Comp.
- 2098: Trypsin, Serum
- 6102: VEGF

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