

Client Update

BioReference® | GenPath®

January 2023

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| Test Name | Test Code | Effective Date |
|-----------|-----------|----------------|
|-----------|-----------|----------------|

| | | |
|-----------------------------------|------------------|-------------------|
| ClariTest® Core NIPS Testing Kits | TH18-5 TH19-3 | December 31, 2022 |
|-----------------------------------|------------------|-------------------|

Please be advised that the **Cell-Free DNA white top tubes for ClariTest® Core (Test Codes TH18 and TH19)** have expired as of December 31, 2022 or will expire as of January 31, 2023. Please check your inventory and make sure to discard expired ClariTest® Core white top tubes, and order new ClariTest® Core NIPS kits to avoid any issues.

Please contact Customer Service to order new ClariTest® Core NIPS kits (Speedy #527).

| | | |
|-------------------------------|--------|-------------|
| COVID-19, Flu A/B, RSV by PCR | M322-6 | Immediately |
|-------------------------------|--------|-------------|

Due to continued reagent shortages for the **Comprehensive Respiratory Panel (Test Code M129)**, we continue to advise all clients to order our new triple test panel for **COVID-19, Flu A/B, RSV by PCR (Test Code M322)**. This test aids in providing definitive diagnosis, case management and treatment options for all three key analytes on a single swab, with a 1-2 day TAT.*

| | | |
|--|--------|------------------|
| Female High Risk Sexual Health Profile | F238-1 | February 2, 2023 |
| Male High Risk Sexual Health Profile | F239-9 | |

The **Female High Risk Sexual Health Profile (Test Code F238)** and **Male High Risk Sexual Health Profile (Test Code F239)** will be updated in accordance with screening guidelines with the following changes:

- HepBsAg (Test code 0106) and HepBcAb (Test code 0108) will be added to the panels.
- Mycoplasma/Ureaplasma will no longer be included in the panels (*Individual tests may be ordered if medically necessary*).

| | Previous Test Information | New Test Information |
|---------------------------|---|--|
| Primary Container | SST, SV- Viral culturette, Aptima-Urine Genprobe | SST, Aptima-Urine Genprobe |
| Profile Components | HBsAb, RPR, HCV Ab, HIV Ag/Ab 4 th gen, Mycoplasma/Ureaplasma, CT, GC, Trich.*** | HBsAb, HepBsAg, HepBcAb, RPR, HCV Ab, HIV Ag/Ab 4 th gen, CT, GC, Trich.*** |
| CPT Code(s)** | 86706, 86592, 86803, 87389, 87109, 87491, 87591, 87661 | 86706, 87340, 86704, 86592, 86803, 87389, 87491, 87591, 87661 |
| List Price | \$895.71 | \$860.30 |

Please contact your dedicated account representative or customer service for additional information, supply ordering and questions.

| | | |
|--|--------|------------------|
| IgH Gene Rearrangement by NGS | TN51-3 | October 20, 2022 |
| CLL/MCL Prognosis: IgVH Mutation Analysis by NGS | TM70-5 | |

Our Cancer Genomics and Molecular Pathology department is pleased to announce we have transitioned some of our **polymerase chain reaction (PCR) tests to next-generation sequencing (NGS)**.

- IGH gene rearrangements are the most widely applied targets for clonality assessment in B-cell lymphoid proliferations. NGS-based clonality assessment goes beyond detecting IGH gene rearrangements. NGS has distinct advantages over just length separation and includes the ability to determine the identity of the V, D, and J segments and the clonal relationship between histologically distinct lymphomas.
- Immunoglobulin heavy-chain variable region (IGVH) Somatic Hypermutation (SHM) status provides an important prognostic indicator for chronic lymphocytic leukemia (CLL). IgVH mutation analysis by NGS offers versatility in the detection and direct identification of clonal immunoglobulin gene rearrangements in neoplastic B-cell populations. It also enables unique clinical applications such as the determination of SHM status, minimal residual disease monitoring, clonal heterogeneity, and B cell receptor IG stereotypy.

-MEMO CONTINUED ON NEXT PAGE-

*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.

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Test Name

Test Code

Effective Date

With this announcement, the PCR codes included in the table below will be discontinued as of January 1, 2023. Please reach out to your Account Executive with any questions, and to assist with completing the necessary changes to your electronic interface to the NGS test codes available at our laboratory.

Orders received after January 1 for the retired test codes will be automatically converted to the new test codes.

| Retired PCR Test Code | Alternate NGS Test Code |
|--|---|
| 5278-7 Lymphoma B-Cell - IgH by PCR | TN51-3 IgH Gene Rearrangement by NGS |
| 5223-3 CLL Prognosis - IgVH Mutation Analysis by PCR | TM70-5 CLL/MCL Prognosis: IgVH Mutation Analysis by NGS |

References:

- Gupta SK, ViswanathaDS, Patel KP. Evaluation of Somatic Hypermutation Status in Chronic Lymphocytic Leukemia (CLL) in the Era of Next Generation Sequencing. *Front Cell Dev Biol.* 2020;8:357. Published 2020 May 19. doi:10.3389/fcell.2020.00357.
- Kadkol SS, Bland J, KavanaughA, Ni H, Nehru V, Peace D. NGS Analysis of Clonality and Minimal ResidualDisease in a Patient with Concurrent Richter's Transformation and CLL/SLL. *Case Rep Hematol.* 2021;2021:9740281. Published 2021 Dec 28. doi:10.1155/2021/9740281.
- Arcila ME, Yu W, Syed M, Kim H, MaciagL, Yao J, Ho C, PetrovaK, MounG, Salazar P, Rijol, BaldiT, ZehirA, LandgrenO, Park J, RoshalM, DoganA, NafaK. Establishment of Immunoglobulin Heavy (IGH) Chain Clonality Testing by Next-Generation Sequencing for Routine Characterization of B-Cell and Plasma Cell Neoplasms. *J MolDiagn.* 2019 Mar;21(2):330-342. doi: 10.1016/j.jmoldx.2018.10.008. Epub2018 Dec 25. PMID: 30590126; PMCID: PMC6436112

Influenza A

TK41, when ordered as part of panel M123-8

Immediately

We have received a notification from Roche that there have been rare instances of false negative Influenza A cases (Test Code TK41, when ordered as part of panel M123) when performed on the Cobas instrumentation that are low positive (minimal virus present for testing) that are specific to recently circulating mutations. The detection of SARS-CoV-2 and Influenza B targets is not affected. Currently the affected strain is not prevalent in the US.

Please monitor patients with negative influenza A results that are inconsistent with the clinical presentation or other clinical and epidemiological information. Medical decisions should be made based on the patient's complete clinical presentation with repeat testing considered if index of suspicion is high.

Myeloid NGS Testing

Multiple

January 15, 2023

Effective January 15, 2023, our laboratory be retiring the OnkoSight® NGS, as indicated in the table below. Please reach out to your dedicated account representative with any questions, and to assist with completing the necessary changes to your electronic interface to the alternate OnkoSight Advanced™ test codes available at our laboratory.

Orders received after January 15 for the retired test codes will be automatically converted to the new test codes.

| Retired Test Codes | Alternate Test Code |
|--|--|
| B894-7 OnkoSight® AML Panel Sequencing | TL94-7 OnkoSight Advanced™ NGS Rapid AML Panel |
| B823-6 OnkoSight® Myeloid Disorder Panel | TL95-4 OnkoSight Advanced™ NGS Myeloid Panel |
| B818-6 OnkoSight® MPN Panel Sequencing | TL96-2 OnkoSight Advanced™ NGS MPN Panel |
| TH39-1 NGS MPN Cascade Sequencing | TL97-0 OnkoSight Advanced™ NGS MPN Cascade Panel |
| B893-9 OnkoSight® MDS Panel Sequencing | TL98-8 OnkoSight Advanced™ NGS MDS Panel |
| J633-9 MPN: JAK2/MPL/CALR by NGS | TL99-6 OnkoSight Advanced™ NGS JAK2, MPL, and CALR if negative reflex to OnkoSight Advanced™ NGS Myeloid Panel |

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

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Non-gynecologic Cytology Tests

Multiple

Immediately

Please be reminded that any samples for the **non-gynecologic cytology tests** listed below must be submitted in a ThinPrep vial or 50% alcohol solution to preserve the specimen's stability. Any specimens submitted in a collection type without a fixative will no longer be accepted due to degenerative cell changes.

If submitting urine for both clinical testing and cytology testing, two separate samples must be submitted. The cytology sample must be in a ThinPrep vial or 50% alcohol solution.

| Test Code | Test Name |
|-----------|--|
| 5242 | Cytology, ThinPrep FNA |
| 5244 | Cytology, Thinprep Fluids |
| 5254 | Cytopathology, Urine (Thinprep) |
| 6626 | Anal Cytopathology, ThinPrep |
| J534 | Cytology, Bladder Washing (ThinPrep) |
| 2100 | Cytology, Urine With Interpretation |
| 5112 | Cerebrospinal Fluid (CSF) Cytology |
| 5243 | Cytology, Alcohol-Based FNA |
| 5245 | Cytology, Alcohol-Based Fluids |
| J529 | Cytology, Bladder Washing (50% Alcohol) |
| B415 | Urine Cytology Reflex Atypical or above to Urovysion |
| 5324 | Comprehensive Urine Pathology |

PD-L1 22C3 by IHC for Keytruda (other tumor types, including gastric)

TK85-7

Immediately

GenPath® Oncology is pleased to offer **DAKO PD-L1 22C3 by IHC (Test Code TK85)** as complimentary diagnostics for Keytruda. Healthcare providers who wish to assess the patient's PD-L1 status for tumors other than NSCLC, cervical cancer, HNSCC, and esophageal cancer may order test code TK85.

Please reach out to your dedicated account representative or email if you have any questions about the test.

Visit www.keytruda.com to view full prescribing information for Keytruda.

Potassium, Serum

0129-7

Immediately

With the arrival of colder weather, the handling of blood specimens to avoid any adverse effects associated with exposure to cold temperatures, is once again a concern that could affect patient care.

Serum potassium is one example of a test that is highly sensitive to extremes in temperature. Spurious elevations to serum potassium will be seen when RBCs rupture due to exposure to cold temperatures. An increase in serum potassium above the normal range of 5.5 mmol/L can easily occur when RBCs, which contain almost 20 times the amount of potassium found in serum, rupture when exposed to severe drops in the ambient temperature.

Proper collection of blood specimens is essential for accurate assessment of various analytes in serum, plasma and whole blood. In particular, serum separator tubes (i.e. SSTs), must be allowed to clot thoroughly followed by adequate centrifugation.

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VITB1,THIAMINE,Total **0293-1** **January 4, 2023**

Due to changes in instrumentation, methodology and reference range for VITB1,THIAMINE, Total (Test Code 0293) have been updated. Please refer to the table below for details.

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|----------------------|
| Methodology | HPLC | LCMSMS |
| Reference Range | 2.7-13.3 ng/mL | 2.7-10.1 ng/mL |

VIT.B2,RIBOFLAVIN **3325-8** **January 4, 2023**

Due to changes in instrumentation, methodology and reference range for VIT.B2,RIBOFLAVIN (Test Code 3325) have been updated. Please refer to the table below for details.

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|----------------------|
| Methodology | HPLC | LCMSMS |
| Reference Range | 3.0-15.0 ng/mL | 2.5-9.5 ng/mL |

VIT.B6,PYRIDOX.PHOS **0296-4** **January 4, 2023**

Due to changes in instrumentation, methodology and reference range for VIT.B6,PYRIDOX.PHOS (Test Code 0296) have been updated. Please refer to the table below for details.

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|----------------------|
| Methodology | HPLC | LCMSMS |
| Reference Range | 5.0-50.0 ng/mL | 4.9-30.9 ng/mL |

REGIONAL UPDATE (NEW JERSEY): Hepatitis C Antibody w/reflex RT PCR **B125-6** **December 1, 2022**

Due to changes in instrumentation, test components for Hepatitis C Antibody (Test Code B125) have been updated, when performed at our Elmwood Park, NJ laboratory.

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 |
|--------------------|--|----------------------|
| Profile Components | Hep C Ab (B788) Hep C Ab S/CO Ratio (B787) | Hep C Ab (B788) |

REGIONAL UPDATE (FLORIDA): RBC Folate **M329** **January 3, 2023**

A new profile for RBC Folate (Test Code M329) has been created for testing performed at our Melbourne, FL laboratory. The lab will be moving to a new platform and will no longer be able to perform the current RBC Folate Profile (Test Code 0873). The components are the same and will report Hematocrit and RBC Folate.

RBC Folate Profile (Test Code 0873) will continue to be accessioned in Elmwood Park, Burbank and Houston.

| | Previous Test Information | New Test Information |
|--------------------|------------------------------------|------------------------------------|
| Methodology | Chemiluminescence | Electrochemiluminescence |
| Reference Range | 280-791 ng/mL | 499-1504 ng/mL |
| Profile Components | A976 RBC Folate 0019 Hematocrit | TP10 RBC Folate 0019 Hematocrit |

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