

Client Update

BioReference® | GenPath®

September 2024

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| Test Name | Test Code | Effective Date |
|-------------------------|-----------|----------------|
| 250 New ICD-10-CM Codes | All | 10/1/2024 |

Being prepared for the fall season includes review of the ICD-10 diagnosis code updates effective October 1. The codes are required for outpatient encounters and hospital discharges occurring on or after October 1, 2024 through September 30, 2025. For laboratory testing, this update applies to specimen collections that occur on or after October 1.

Ordering providers solely determine which tests are reasonable and medically necessary for their patients. BioReference solely relies on providers to make that determination and expects providers to submit accurate information on their test requisitions using the correct ICD-10 diagnosis code(s) to the highest level of specificity. All payers, government and commercial, require ICD-10 codes for claim submission. BioReference may contact health care providers who do not provide the required diagnosis information via telephone, fax, or email.

The 2025 changes to diagnosis codes include 252 additions (including 63 new neoplasm codes), 13 revisions and 36 deletions across a wide range of diseases and conditions. Most of the deleted codes will be replaced with new, more specific coding options requiring use of more digits. Use of incorrect, invalid or outdated diagnosis codes can affect processing of laboratory requests. It is important to update your code files and references for diagnosis codes your practice uses most often.

Please download the ICD-10 guide from the CDC here: <https://stacks.cdc.gov/view/cdc/158747>, or refer to the on-line browser tool to search diagnosis codes here: <https://icd10cmtool.cdc.gov/?fy=FY2024>

| Test Name | Test Code | Effective Date |
|------------------------|----------------------|----------------|
| OnkoHRD™ (Non-NY Only) | TQ30-1 (With Interp) | Immediately |

BioReference®/GenPath® Oncology now offers OnkoHRD™ homologous recombination deficiency (HRD) assessment as an add-on test to select OnkoSight Advanced® NGS panels.

OnkoHRD can measure genomic scars, which are defined by large-scale genomic instability, such as loss of heterozygosity (LOH), telomeric allelic imbalance (TAI), and large-scale state transitions (LST), in addition to the sequencing of the critical genes involved in the homologous recombination repair (HRR) pathway (e.g., *BRCA1*, *BRCA2*).

IMPORTANT: OnkoHRD must be ordered concurrently with OnkoSight Advanced panel (listed below) or within 30 days of the sample receipt date at the laboratory.

- TH53-1: OnkoSight Advanced Gynecological Tumor Panel
- TP57-6: OnkoSight Advanced Breast Cancer Panel
- TK84-0: OnkoSight Advanced Pancreatic and Biliary Tract Tumor Panel
- TH48-2: OnkoSight Advanced Prostate Panel
- TJ16-5: OnkoSight Advanced General Solid Tumor Panel
- TM57-2: OnkoSight Advanced Complete Panel

Requisition forms with OnkoHRD code are now available at our warehouse. To request printed copies, please contact your Account Executive or call the GenPath Customer Service hotline at 800-627-1479.

OnkoHRD is currently available to non-NY clients only and is pending NYS approval.

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

**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.*

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

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| New Test Information | |
|-------------------------|---|
| Primary Container | BLK - Formalin-fixed, Paraffin-embedded Tissue |
| Turn Around Time* | -10 days |
| Transportation Temp | Room Temperature. Ship block with cold pack during warm weather |
| Methodology | Genotyping by Next-generation sequencing |
| Collection Instructions | BLK: This comes in block form from a client with a surgical number imprint |
| CPT Code(s)** | 81479x1 |
| Clinical Utility | Clinical indications for Homologous Recombination Deficiency (HRD) testing include patients with ovarian cancer, especially those with high-grade serous ovarian cancer who may benefit from poly (ADP-ribose) polymerase (PARP) inhibitor therapy and breast cancer patients, particularly those with triple-negative breast cancer (TNBC) or HER2-negative breast cancer, as well as pancreatic cancer, advanced prostate, endometrial, and pancreatic neuroendocrine tumors, where it can inform treatment choices. HRD testing may be used to determine eligibility for clinical trials investigating new therapies targeting HRD-related pathways in various cancer types. |

| Test Name | Test Code | Effective Date |
|-------------------------------|---------------------|----------------|
| Allergen Components (various) | Various (see below) | 9/9/2024 |

New allergen components are now available. Please refer to the table below for details.

| Test Code | Test Name | Test Code | Test Name |
|-----------|--------------------------------------|-----------|--|
| TQ56-6 | Allergen component Wheat (Gliadin) | TQ41-8 | Allergen Cat component IgE (rFel d1) |
| TQ57-4 | Allergen component rTri a 14 | TQ42-6 | Allergen Cat component IgE (nFel d2) |
| TQ58-2 | Allergen component rTri a 19 | TQ43-4 | Allergen Cat component IgE (rFel d4) |
| TQ59-0 | Allergen component ngly m 5 | TQ44-2 | Allergen Cat component IgE (rFel d7) |
| TQ60-8 | Allergen component ngly m 6 | TQ45-9 | Allergen Hazelnut component IgE (rCor a8) |
| TQ61-6 | Allergen component rses l 1 | TQ46-7 | Allergen Hazelnut component IgE (rCor a1) |
| TQ35-0 | Allergen dog component IgE (rCan f1) | TQ47-5 | Allergen Hazelnut component IgE (rCor a14) |
| TQ36-8 | Allergen dog component IgE (rCan f2) | TQ48-3 | Allergen Hazelnut component IgE (rCor a9) |
| TQ37-6 | Allergen dog component IgE (nCan f3) | TQ49-1 | Allergen Brazilnut component IgE rBer e1) |
| TQ38-4 | Allergen dog component IgE (rCan f4) | TQ50-9 | Allergen walnut component IgE (rJug r1) |
| TQ39-2 | Allergen dog component IgE (rCan f5) | TQ51-7 | Allergen walnut component IgE (rJug r3) |
| TQ40-0 | Allergen dog component IgE (rCan f6) | TQ52-5 | Allergen Cashewnut component IgE rANA o3) |
| | | TQ53-3 | Allergen Horse component IgE (rEqu c1) |

| New Test Information | |
|----------------------|-------------|
| Primary Container | SST |
| Minimum Volume | 1.0mL |
| Turn Around Time* | 4 days |
| Transportation Temp | Refrigerate |

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| Stability | 14 days |
| Methodology | Immunocap |
| Reference Range | <0.10 kUA/L |
| 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 |
| CPT Code(s)** | 86008 |

| Test Name | Test Code | Effective Date |
|------------------------------|-----------|----------------|
| Allergen Garlic IgG (Non-NY) | B428-4 | Immediately |

Test code B428-4 Allergen Garlic IgG (NON-NY) will no longer be offered as a Send Out. The suggested alternate test is in house test code 0965-4 Allergen Garlic (f47), IgE.

| | Previous Test Information | New Test Information |
|-------------------------|---|---|
| Primary Container | SST | SST |
| Minimum Volume | 0.3mL | 3mL |
| Turn Around Time* | 7 days | 2 days |
| Transportation Temp | Refrigerate | Refrigerate |
| Stability | 14 days Refrigerate, 30 days Frozen | 14 days Refrigerate |
| Methodology | Immunoassay | Immunocap |
| Reference Range | <2.0 | <0.10 |
| 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. |
| CPT Code(s)** | 86001 | 86003 |

| Test Name | Test Code | Effective Date |
|----------------------------|-----------|----------------|
| Reducing Substances, Stool | 0187-5 | Immediately |

Due to an update in quality metrics, Reducing Substances, Stool will be required to be submitted frozen.

| Test Name | Test Code | Effective Date |
|-------------------|-----------|----------------|
| IG Absolute Count | TQ94-7 | Immediately |

In an effort to standardize laboratory practices, we are implementing a new component of CBC.

| New Test Information | |
|----------------------|-------------|
| Primary Container | Lav |
| Turn Around Time* | 1 day |
| Transportation Temp | Refrigerate |
| Stability | 2 days |

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| Methodology | Flow cytometry |
| Reference Range | 0-2 d 0.00-0.28 3-13d 0.00-0.27 2-3W 0.00-0.22 4-12W 0.00-0.09 13-25W 0.00-0.06 6-23M 0.00-0.14 2-5Y 0.00-0.06 6-11Y 0.00-0.04 12-17Y 0.00-0.03 >/=18Y 0.00-0.09 |
| Collection Instructions | LAV: Fill lavender-top (EDTA) tube completely, invert 8-10 times. DO NOT SHAKE TUBE! |
| CPT Code(s)** | 85048x1 |

| Test Name | Test Code | Effective Date |
|-----------|---------------------|----------------|
| Insulin | Various (see below) | Immediately |

Due to an update in test platform, the reference ranges for Insulin have been updated. Please refer to the table below for details.

| Test Code | Test Name | Ref Range Current | Ref Range New |
|-----------|-----------------------|-------------------|---------------|
| 1648-5 | Insulin, Fasting | 2.6-24.9 | <25.0 |
| 0113-1 | Insulin, Total/Random | Not Estab. | Not Estab. |
| 2258-2 | Insulin, 1/2 HR. | Not Estab. | 30.0-230.0 |
| 1649-3 | Insulin, 1 HR. | Not Estab. | 18.0-276.0 |
| 3366-2 | Insulin, 90 MIN. | Not Estab. | Not Estab. |
| 1650-1 | Insulin, 2 HR | Not Estab. | 16.0-166.0 |
| 6264-6 | Insulin, 2 1/2 HR. | Not Estab. | Not Estab. |
| 1651-9 | Insulin, 3 HR. | Not Estab. | <25.0 |
| 3373-8 | Insulin, 3 1/2HRS. | Not Estab. | <25.0 |
| 1652-7 | Insulin, 4 HR. | Not Estab. | <25.0 |
| 1653-5 | Insulin, 5 HR. | Not Estab. | <25.0 |
| 1654-3 | Insulin, 6 HR. | Not Estab. | <25.0 |

| | Previous Test Information | New Test Information |
|---------------------|--------------------------------------|--------------------------------------|
| Primary Container | SST | SST |
| Minimum Volume | 1.0mL | 1.0mL |
| Turn Around Time* | 4 days | 4 days |
| Transportation Temp | Refrigerate | Refrigerate |
| Stability | 7 days | 7 days |
| Methodology | Electrochemiluminescence Immunoassay | Electrochemiluminescence Immunoassay |
| Reference Range | See above | See above |

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|-------------------------|--|--|
| 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 |
| CPT Code(s)** | 83525x1 | 83525x1 |

| Test Name | Test Code | Effective Date |
|-----------------------------|-----------|----------------|
| Partial Thromboplastin Time | 0139 | Immediately |

Due to an update in test platform in Elmwood Park, NJ, the reference ranges for Partial Thromboplastin Time have been updated. Please refer to the table below for details.

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|----------------------|
| Reference Range | 23.6-31.6 | 23.3-36.2 |

| Test Name | Test Code | Effective Date |
|------------------------------|-----------|----------------|
| INR (Int'l Normalized Ratio) | 1112 | Immediately |

Due to an update in test platform in Elmwood Park, NJ, the reference ranges for INR have been updated. Please refer to the table below for details.

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|----------------------|
| Reference Range | 0.80-1.07 | 0.90-1.10 |

| Test Name | Test Code | Effective Date |
|------------------|-----------|----------------|
| Prothrombin Time | 0137 | Immediately |

Due to an update in test platform in Elmwood Park, NJ, the reference ranges for INR have been updated. Please refer to the table below for details.

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|----------------------|
| Reference Range | 9.1-11.9 | 10.0-12.5 |

Questions? Please contact your Account Executive or Customer Service directly.

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