October 2025 Page 1 of 4

| Test Name | Test Code | Effective Date |
|-------------|-----------|----------------|
| ICD-10 Code | N/A | Immediately |

Being prepared for the fall season includes review of the ICD-10 diagnosis code updates effective October 1st. The codes are required for outpatient encounters and hospital discharges occurring on or after October 1, 2025, through September 30, 2026. For laboratory testing, this update applies to specimen collections that occur on or after October 1st.

Ordering providers solely decide which tests are reasonable and medically indicated for their patients. All payers, government and commercial, require ICD-10 codes for claim submission. The diagnosis combined with the test(s) ordered will determine if payer policy and medical necessity requirements have been met. BioReference relies on providers to submit correct information on test requisitions using the appropriate ICD-10 diagnosis code(s) to the highest level of specificity. When medical necessity requirements of the payer are not met, BioReference may contact health care providers for additional diagnosis information via telephone, fax, or email.

The October 1, 2025 changes to diagnosis codes 487 new codes, 28 deletions, and 38 revised codes. Deleted codes are replaced with new, more specific coding options requiring use of more digits. Use of incorrect, invalid or outdated diagnosis codes will affect processing of laboratory requests. It is important to update your code files and references for diagnosis codes your practice uses most often. Coordination between the ordering/referring provider and the reference laboratory for diagnostic tests is crucial to reducing billing errors and claim denials. BioReference relies on the referring provider to associate the reason (ICD-10-CM) that supports testing for each patient on that patient's date of service.

New, higher specificity codes for pelvic and perineal pain replace the previous general code R10.2 (e.g., R10.21 or R10.22). This changes the required level of clinical documentation.

Updates to diabetes coding mean that diagnoses of diabetes "in remission" or "resolved" that were previously reported under codes for unspecified (e.g., E11.9) or uncomplicated diabetes are no longer valid for billing. New, higher specificity codes for diabetes will be required.

Other changes include;

- Immunological findings in serum (e.g., R76.81 Anti-CCP antibody positive)
- Allergies, including detailed food allergy codes (e.g., Z91.011 Allergy to peanuts)

Please download the ICD-10 guide from the CMS here: https://www.cms.gov/files/document/fy-2026-icd-10-cm-coding-guidelines.pdf , or refer to the CDC online browser tool to search diagnosis codes here: https://icd10cmtool.cdc.gov/?fy=FY2026

October 2025 Page 2 of 4

| Test Name | Test Code | Effective Date |
|------------------------|-----------|----------------|
| Alpha-2- macroglobulin | 3882-8 | 10/27/2025 |

Test methodology and reference range changes (see below).

| | Previous Test Information | New Test Information |
|-----------------|---------------------------|--------------------------|
| Methodology | Nephelometry | immunoturbidimetric |
| Reference Range | 130-300 mg/dL | <18 years 2.25-5.25 g/L |
| | | >18 males 1.5-3.5g/L |
| | | >18 females 1.75-4.20g/L |

| Test Name | | Test Code | Effective Date |
|---------------------------|--|------------------|----------------|
| Vaginitis/Vaginosis w/o 1 | Trichomonas Trichomonas | M494-3 M495-0 | Immediately |
| | New Test Information | | |
| Primary Container | M494-3: ThinPrep vial, SurePath Tube, ThinPrep tube | | |
| | M495-0: Aptima tube | | |
| Turn Around Time* | 3 days | | |
| Transportation Temp | Room Temperature | | |
| Stability | Room Temperature | | |
| Methodology | Molecular Nucleic acid amplification testing (?) | | |
| Reference Range | Not Detected | | |
| Profile Components | Bacterial Vaginosis, Candida Vulvovaginitis | | |
| CPT Code(s)** | 87481, 81513 | | |
| Clinical Utility | This assay is intended to aid in the diagnosis of vaginitis or vaginosis caused by | | |
| | candida and bacterial vaginosis (BV). | | |

| Test Name | Test Code | Effective Date |
|---|-----------|----------------|
| Vaginitis/Vaginosis for TP, TPT, SP (Retired) | M435-6 | 10/20/2025 |
| B. fragilis by RT-PCR (Retired) | J216-3 | |

Test codes M435-6 and J216-6 will no longer be offered effective 10/20/2025. The suggested alternative for M435-6 is TR16-8 Bacterial Vaginosis (ThinPrep/SurePath) and TL79-8 Bacterial Vaginosis (Aptima Tube) (see below).

The Aptima® BV assay is an *in vitro* nucleic acid amplification test that utilizes real-time transcription-mediated amplification (TMA) for detection of ribosomal RNA from bacteria associated with bacterial vaginosis (BV). This includes *Lactobacillus* (*L. gasseri*, *L.crispatus*, and *L. jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*. The assay reports a single qualitative result (i.e., Detected, Not Detected, or Invalid) for BV and does <u>not</u> report results for individual organisms. The assay is intended to aid in the diagnosis of BV on Aptima vaginal swab specimens or ThinPrep or SurePath samples from females with a clinical presentation consistent with vaginitis and/or vaginosis.

October 2025 Page 3 of 4

| | New Test Information |
|-------------------------|---|
| Primary Container | Aptima Multitest Swabs or ThinPrep/SurePath |
| Turn Around Time* | 3 days |
| Transportation Temp | 15-30 degrees C (60-85 degrees F) |
| Stability | 21 days Room Temperature |
| Methodology | Real-time transcription-mediated amplification (TMA) |
| Reference Range | Not Detected |
| Collection Instructions | Using the Aptima Multitest swab: |
| | Physician Collection: Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab clockwise for 10 to 30 seconds. Make sure the swab touches the vaginal wall so that moisture is absorbed by the swab, and then withdraw the swab without touching the skin. The sample collection tube must be labeled with the Patient's First and Last Name, and Date of Birth (DOB). Patient Self Collection: The Aptima® Multitest Swab Specimen Collection Kit is validated and approved by the U.S. Food and Drug Administration (FDA) for self-collection of certain sexually transmitted infections and vaginal infections. IMPORTANT: It is required that the sample be collected within the healthcare facility (e.g., hospitals, clinics, doctors' offices, urgent care centers). The clinician or healthcare provider must review the collection instructions with the patient before the patient collects the sample in a healthcare facility setting. |
| CPT Code(s)** | 81513 |
| Clinical Utility | The assay is intended to aid in the diagnosis of Bacterial Vaginosis (BV) |

REMINDER:

| Test Name | | Test Code | Effective Date |
|-----------------------------|--------------------------|-----------|----------------|
| Breath Test for Detection | of Helicobacter Pylori | TS46-3 | Immediately |
| (H. pylori) | | | |
| New Test Information | | | |
| Primary Container | BBG - Breath Bag, Blue/0 | Gray | |
| Turn Around Time* | 2 Days | | |
| Transportation Temp | 15-30° C | | |
| Stability | 14 Days Room Temperati | ure | |

October 2025 Page 4 of 4

| Reference Range | Negative |
|-------------------------|--|
| Collection Instructions | This test can only be performed on specimens from patients greater than or equal to 3 years old collected in Meridian breath collection bags. Sampling begins with the collection of a baseline breath sample. The patient inflates the Baseline Breath Sample Bag (blue). The patient then ingests a test drink consisting of Curea tablet 75mg and 4.3g of Citrica Powder (4g citric acid). After 15 minutes a post-ingestion sample is collected by inflation of the Post Ingestion Breath Sample Bag (Gray). |
| Methodology | Molecular Correlation Spectrometry |
| CPT Code(s)** | 83013 |

Questions? Please contact your Account Executive or Customer Service directly at 800-229-5227.

Best regards, The BioReference® Team

Healthcare providers should only order panels if each 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.