Test Name	Test Code	Effective Date
Toxoplasma Ab. IgG Toxoplasma Ab. IgG with Reflex	**0552-0** **2376-2**	**Immediately**

Update to the reference range for test codes 0552 and 2376 to qualitative.

	Previous Test Information	New Test Information
Primary Container	SST	SST
Minimum Volume	1 mL	1 mL
Turn Around Time*	1 day	1 day
Transportation Temp	Refrigerate	Refrigerate
Stability	7 days Refrigerated	7 days Refrigerated
Methodology	Chemiluminescence	Chemiluminescence
Reference Range	Neg=<6.4 [IU]/mL	Negative
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)**	86777x1	86777x1
Clinical Utility	To determine an acute, recent, or remote infection with toxoplasmosis. Acute and convalescent specimens are suggested at a 3-4 week interval.	To determine an acute, recent, or remote infection with toxoplasmosis. Acute and convalescent specimens are suggested at a 3-4 week interval.

Test Name	Test Code	Effective Date
Carbamazepine	**0154-5**	**4/14/2025**

Update reference range due to a new formulation of the reagent.

	Previous Test Information	New Test Information
Primary Container	Red	Red
Minimum Volume	1mL	1mL
Turn Around Time*	1 day	1 day
Transportation Temp	Refrigerate	Refrigerate
Stability	7 days Refrigerated	7 days Refrigerated
Methodology	Enzyme Immunoassay	Enzyme Immunoassay
Reference Range	8.0-12.0 ug/mL	4.0-12.0 ug/mL
Collection Instructions	RED: Fill tube, label with patient name	RED: Fill tube, label with patient name
CPT Code(s)**	80156x1	80156x1
Clinical Utility	Monitors level or carbamazepine, anticonvulsant and mood-stabilizing drug.	Monitors level or carbamazepine, anticonvulsant and mood-stabilizing drug.

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Test Name	Test Code	Effective Date
OvaWatch®	**TR61-4**	**Immediately**

OvaWatch is a multivariate index assay designed to assist clinicians in the initial clinical assessment of the risk of ovarian cancer in women with adnexal masses determined as either indeterminate or benign. OvaWatch utilizes a clinically validated proprietary machine learning algorithm that incorporates data from seven serum biomarkers, as well as age and menopausal status, to provide a personalized risk score.

Reports will include the OvaWatch score as well as CA-125 and HE4 values.

With a negative predictive value of over 99%, the use of OvaWatch could help clinicians more confidently conclude masses have a very low probability of malignancy, thus supporting a clinical course of treatment that minimizes unnecessary referrals to specialists and surgeries. Better resource management of specialist time potentially allows those who are at risk to see a specialist sooner and reduces the cost of care for those with benign masses.

	New Test Information
Primary Container	One(1) SST tube (please send one(1) separate SST if collecting blood for other tests) or one(1) OvaPlus® kit
Minimum Volume	1.1 mL
Turn Around Time*	3-5 days
Transportation Temp	Refrigerate
Stability	8 days Refrigerated
Methodology	Immunoassay
Reference Range	Indeterminate: ≥5 Low probability of malignancy: < 5
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
Profile Components	EER Malignancy Assessment, OvaWatch Malignancy Assessment, CA-125 II Malignancy Assessment, HE4 Malignancy Assessment, OvaWatch Score
CPT Code(s)**	PLA: 0375U
Clinical Utility	OvaWatch was optimized and validated in a real-world population that reflects the natural low prevalence of ovarian cancer, in which the majority of detected adnexal masses are considered benign or indeterminate by initial clinical assessment. The high negative predictive value (NPV)[1] could provide reassurance that patients with an OvaWatch "Low Probability of Malignancy" result can be appropriately managed and monitored by their clinician via the clinical management strategy in lieu of immediate surgical intervention.[2-6] A peer reviewed study indicates that using OvaWatch could have led to a potential 62% overall reduction in avoidable adnexal mass surgeries, the 59% reduction of surgical referrals among asymptomatic patients, and a 77% reduction of surgical girls among premenopausal patients.[7]

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References:

1. Reilly, G., Bullock, R. G., Greenwood, J., Ure, D. R., Stewart, E., Davidoff, P., ... & Northrop, L. E. (2022). Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer. JCO Clinical Cancer Informatics, 6, e2100192.
2. Taylor, et al. (2018). Disparities in treatment and survival among elderly ovarian cancer patients. Gynecologic oncology, 151(2), 269-274.
3. Multivariate index assay (MIA3G) to reduce preventive surgery for ovarian cancer. Srinka Ghosh, Todd C. Pappas, Gerard P Reilly, Ryan Phan. American Society of Clinical Oncology Abstract 2023
4. Multivariate index assay MIA3G vs other assessment tools for the ovarian cancer risk assessment of indeterminate masses. Srinka Ghosh, Todd C Pappas, Ryan Phan. American Society of Clinical Oncology Abstract 2023.
5. Burton S. Brodsky, MD, Gary M. Owens, MD, Dennis J. Scotti, PhD, MBA, Keith A. Needham, BS, and Christina L. Cool, MPH; Economic Impact of Increased Utilization of Multivariate Assay Testing to Guide the Treatment of Ovarian Cancer: Implications for Payers, Am Health Drug Benefits, 2017.
6. A real-world comparison of the clinical and economic utility of OVA1 and CA-125 in assessing ovarian tumor malignancy risk, Journal of Comparative Effectiveness Research.
7. Choudhury, M. Roy, Pappas, T. C., Twiggs, L. B., Caoili, E., Fritsche, H., & Phan, R. T. (2024). Ovarian Cancer surgical consideration is markedly improved by the neural network powered-MIA3G multivariate index assay. Frontiers in Medicine, 11, 1374836.

	Test Code	Effective Date
BD Vacutainer® K2E (EDTA) 5.4 mg Blood Collection Tube, 13x75mm, 3.0mL, Tan Closure	**N/A**	**Immediately**

BD has stopped manufacturing the tan top tube used for lead testing. **The recommended alternative is BD Vacutainer® Trace Element K2 EDTA (K2E) 5.4 mg Blood Collection Tube, 13X75mm, 3.0mL, Royal Blue Closure (*Lavender Line) - BioReference supply item #209.**

Test(s) affected by this change:

- 0398-8 Lead Blood (Child)
- 1438-1 Lead, Blood (Adult)

	Test Code	Effective Date
Chlamydia, Gonorrhea, and Trichomonas rRNA, TMA Aptima Urine	**H001-1**	**Immediately**

Please send the correct specimen type for H001 to help ensure test order processing and results. **The correct specimen to be submitted for this test is UGP – Urine Container, Genprobe-Aptima. UGP: First morning sample, collect in sterile cup, and transfer 2 ml into Aptima holder. The correct volume of urine has been added when the fluid level is between the black fill lines on the Aptima holder.**

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

**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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