

BioReference® | GenPath® Client Update

November 2024

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Please note, in order to mitigate any disruption, clients that rely on InsightDx should no longer use the CareEvolve.com URLs and to migrate to the InsightDx versions (as noted below). Should any client need assistance with this change, our Tech Support team is able to help.

Website URLs no longer supported:

brli.careevolve.com
genpath.careevolve.com
genpathwh.careevolve.com

InsightDx URLs for all future access:

<https://brli.insightdx.com>
<https://genpath.insightdx.com>
<https://genpathwh.insightdx.com>

Test Name	Test Code	Effective Date
OnkoRisk BRCA Panel (Non-NYS only)	TP68-3	Immediately
OnkoRisk Hereditary Oncology Management Panel (Non-NYS only)	TP65-9	
OnkoRisk Hereditary Urology Panel (Non-NYS only)	TP66-7	
OnkoRisk Women's Hereditary Cancer Panel (Non-NYS only)	TP67-5	
OnkoRisk Hereditary Oncology Guideline Panel (Non-NYS only)	TP70-9	
OnkoRisk Hereditary Oncology Plus Panel (Non-NYS only)	TP69-1	

We are pleased to announce that OnkoRisk™ Hereditary Cancer testing (NON-NYS ONLY) is now available for order using buccal swab as a sample type. Buccal swab can be useful for patient sample collection when collecting blood is not feasible.

Please contact your account executive, customer service, or order new supplies through InsightDx. For clinical questions please contact OnkoRisk@BioReference.com

	New Test Information
Primary Container	Lavender Top
Secondary Container	Buccal Swab (Oragene)
Minimum Volume	5-6 mL whole blood or 2 buccal swab tubes
Turn Around Time*	14 days
Transportation Temp	Room Temperature
Methodology	NGS
Profile Components	See specific test codes for genes at https://www.genpathdiagnostics.com/hcp/oncology/hereditary-cancer-testing/hereditary-cancer-testing-options/
CPT Code(s)**	81432x1 or 81435x1

Test Name	Test Code	Effective Date
Hepatitis C Virus (HCV) FibroSure	TN24-0	Immediately

*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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Test TN24-0, Hepatitis C Virus (HCV) FibroSure, will no longer be offered. The recommended alternate is test H510-1, Fibrotest/Actitest.

	Previous Test Information	New Test Information
Test Name	Hepatitis C Virus (HCV) FibroSure	FibroTest/Actitest
Test Code	TN24-0	H510-1
Performing Location	Send Out	BioReference
Turn Around Time	9 days	2 days
Sample Type	Frozen Serum from Red Top Tube	Serum from Red Top Tube
Sample Volume	2.0 mL	5.0 mL
Sample Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: 30 days	Room Temperature: N/A Refrigerated: 7 days Frozen: N/A
Transport Temperature	Frozen	Refrigerated
Test Components	Fibrosis Score Fibrosis Stage Necroinflammation Activity Score Necroinflammation Activity Grade Fibrosis Scoring Necroinflammation Activity Scoring Alpha-2 Macroglobulins Haptoglobin Apolipoprotein A-1 Bilirubin, Total GGTP ALT (SGPT) Interpretations	Fibrosis Score Fibrosis Stage Necroinflammation Activity Score Necroinflammation Activity Grade Fibrosis Scoring Necroinflammation Activity Scoring Alpha-2 Macroglobulins Haptoglobin Apolipoprotein A-1 Bilirubin, Total GGTP ALT (SGPT) Interpretations
CPT Code(s)**	81596	81596

Test Name	Test Code	Effective Date
HLA B1502 Typing - RETIRED	B807-9	Immediately
Test B807-9 HLA B1502 Typing will be retired with no recommended alternative.		

Test Name	Test Code	Effective Date
Fibrinogen Antigen, Quantitative, Nephelometry	5732-3	11/25/2024
Please see below for changes in reference range.		
	Previous Test Information	New Test Information
Reference Range	<350 mg/dL	180-350 mg/dL

Test Name	Test Code	Effective Date
Anti-Sperm Antibody (DIRECT) - RETIRED	3454-6	Immediately
Due to reagent unavailability, test 3454-6 Anti-Sperm Antibody (DIRECT) will be retired with no alternate available.		

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Test Name	Test Code	Effective Date
New HPV Assays	Various	Immediately

In addition to our PAP and HPV offerings, BioReference Health is expanding our existing Women’s Health test menu:

Co-Testing Test Codes (currently offered):

- P079-7 - PAP + HPV DNA High Risk 16, 18, and non 16/18
- P372-6 - PAP + HPV DNA High Risk 16, 18, and non 16/18 + CT/GC
- A250-3 - PAP and mRNA Genotyping 16, 18/45
- A252-9 - PAP and mRNA Genotyping 16, 18/45 + CT/GC
- B975-4 - PAP + PAP Dependent HPV
- P734-2 - PAP + PAP Dependent HPV + CT/GC

If NILM, and non 16/18 positive for Roche HPV or NILM and HPV positive for Aptima HPV mRNA Screen, may add CINtec PLUS to current PAP and HPV menu with Hologic ThinPrep Collected Samples:

- **TP42-8:** CINtec PLUS Cytology Reflex from NILM PAP and Roche non 16/18 HPV DNA positive result with negative type 16 and 18.
- **TP63-4:** CINtec PLUS Cytology Reflex from NILM PAP and Aptima HPV mRNA screen positive result

Additional Assays with Hologic ThinPrep Collected Samples:

- **M408-3:** PAP Dependent HPV + CINtec Plus: Pap Dependent algorithm and PAP will reflex to CINtec Plus when NILM and non 16/18 positive only.

Note:

According to ACOG, ASCCP, and SG guidelines, primary high-risk HPV testing demonstrated value in individuals aged 25 years and older. The basic algorithm for HPV Primary Screening is to perform the FDA approved Roche High Risk HPV assay. If the result is negative, repeat HPV assay in 3-5 years. If the result of the HPV is positive, reflex to a PAP smear.

New ASCCP cervical cancer management guidelines now include the Roche CINtec PLUS (dual-stain triage assay) with Roche Primary screening. The classical Primary Screening is if Roche HPV is positive for type 16 or 18, refer to colposcopy. Type non 16/18, reflex to PAP if ASCUS or greater reflex to colposcopy. IF NILM, follow-up in one year. At BioReference we adjusted the classical Primary Screening to reflex to PAP when any Roche HPV was positive.

We introduce CINtec Plus with various offerings:

- **M412-5:** Primary Screening HPV DNA. If HPV non 16/18 is only positive, will reflex to PAP. If PAP is NILM, will reflex to CINtec Plus (>/= 25 years old)
- **M411-7:** Primary Screening HPV DNA. If any HPV is positive, will reflex to PAP. If PAP is NILM, will reflex to CINtec Plus(>/= 25 years old)
- **H852-7:** HPV Primary Screening, if HPV is positive, reflex to PAP (>/=25 years old). CINtec Plus (TP29-5) may be added onto this assay only if PAP is NILM.
- **TK87-3:** Primary Screening HPV DNA. If HPV non 16/18 only positive, will reflex to CINtec Plus (>/=25 years old). No PAP.
- **TP77-4:** Primary Screening HPV DNA. If any HPV positive, will reflex to CINtec Plus (>/=25 years old). No PAP.

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

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