Hologic Genius™ Digital Diagnostics System

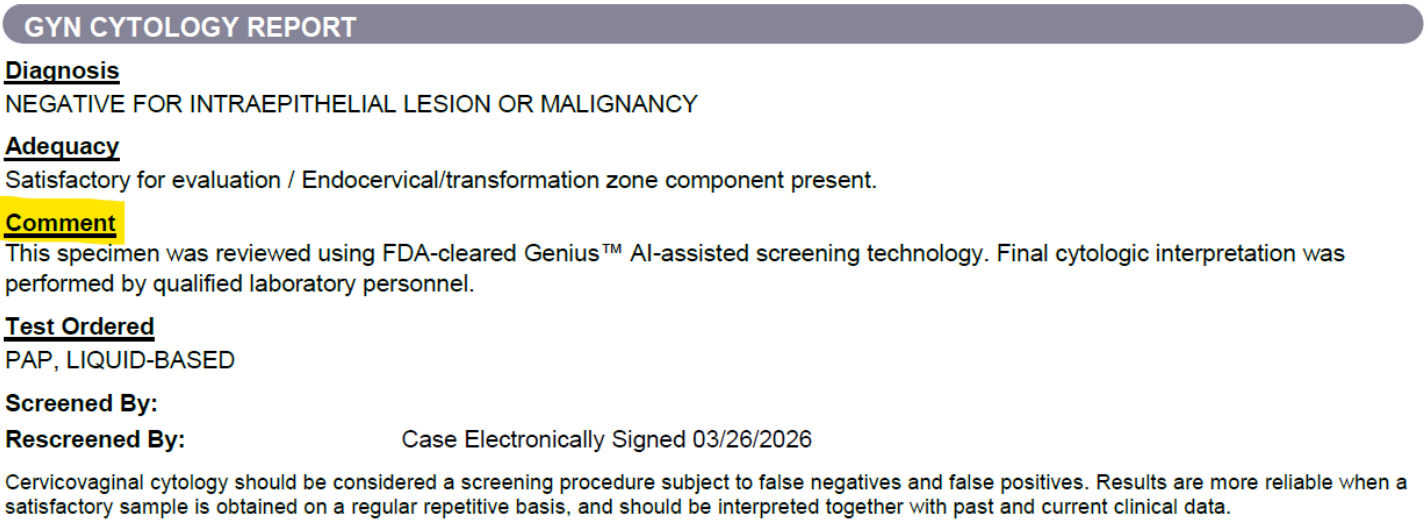
As part of BioReference® ongoing commitment to providing innovation and excellence in cervical cancer screening, our laboratory is adopting Hologic's newly FDA-cleared Genius™ Digital Diagnostics System to assist in AI-guided review of ThinPrep® Pap tests.

The Genius Digital Diagnostics System, powered by the Genius™ Cervical AI algorithm, combines digital imaging and artificial intelligence. This assistive technology supplements human review to help identify pre-cancerous lesions and cervical cancer cells on ThinPrep Pap test cases.

Currently, the patient's cervical cells are collected and sent to the lab, where they are transferred to a glass slide for cytological review by a cytologist/pathologist. With Genius Digital Diagnostics, the glass slides are digitally imaged, and an artificial intelligence algorithm curates a gallery of clinically relevant cells for cytologist and pathologist review.

The multi-site clinical study that supported FDA clearance found that review using Genius Digital Diagnostics **increased HSIL+ sensitivity** by 3.6% compared with the ThinPrep Imaging System.[1] It also found that the **detection of endocervical component increased** by 6.2% compared to the ThinPrep Imaging System.[1]

IMPORTANT: Starting April 10, 2026, some ThinPrep Pap tests sent to the lab will be reviewed using the Genius Digital Diagnostics System. A comment indicating the use of Genius AI-assisted screening technology will be added to the clinical test results if the sample sent to the lab was reviewed using the new Genius Digital Diagnostics System.



GYN CYTOLOGY REPORT

Diagnosis
NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY

Adequacy
Satisfactory for evaluation / Endocervical/transformation zone component present.

Comment
This specimen was reviewed using FDA-cleared Genius™ AI-assisted screening technology. Final cytologic interpretation was performed by qualified laboratory personnel.

Test Ordered
PAP, LIQUID-BASED

Screened By:

Rescreened By: Case Electronically Signed 03/26/2026

Cervicovaginal cytology should be considered a screening procedure subject to false negatives and false positives. Results are more reliable when a satisfactory sample is obtained on a regular repetitive basis, and should be interpreted together with past and current clinical data.

Reference: 1. Genius Digital Diagnostics System with the Genius Cervical AI Algorithm, Instructions for Use. AW-23890-001. Hologic, Inc.; 2024

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Test Name	Test Code	Effective Date
Phopho-Tau (181P) for Alzheimer's Disease	**TU65-8**	**Immediately**

BioReference® is pleased to offer the FDA-cleared Roche Elecsys® Phopho-Tau (181P) Plasma to rule out Alzheimer's-associated amyloid pathology.

- The pTau181 test measures phosphorylated Tau (pTau) 181 protein in human plasma, a key biomarker for Alzheimer's pathology, including amyloid plaque and tau aggregate pathology.
- The pTau181 test is intended for patients aged 55 and older who present with signs, symptoms, or complaints of cognitive decline.
- The pTau181 test is not recommended for patients with signs, symptoms, or complaints of cognitive decline who are already referred to a specialist.

Source: https://diagnostics.roche.com/us/en/products/lab/elecsys-phospho-tau-181p-plasma-pid00001042.html

	New Test Information
Primary Container	EDTA – Lavender Top *Alternate container:* ALQE- Aliquot Plasma
Minimum Volume	1.0 mL
Turn Around Time*	1 day
Transportation Temp	Refrigerated
Stability	7 days Refrigerated
Methodology	Electrochemiluminescence Immunoassay
Reference Range	< or = 0.722 pg/mL
Collection Instructions	LAV: Fill lavender-top (EDTA) tube completely, invert 8-10 times. DO NOT SHAKE TUBE. Label the tube with the patient's name, date of birth (DOB), and specimen collection date.
CPT Code(s)**	84393x1

Test Name	Test Code	Effective Date
PTH, Intact	**0598-3**	**Immediately**

Update to reference range.

	Previous Test Information	New Test Information
Reference Range	17.9-58.6 pg/mL	15.0-65.0 pg/mL

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

Best regards,
The BioReference® Team

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*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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