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TEST UPDATE
CERVICAL FISH

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OVERVIEW AND CLINICAL UTILITY:

Effective April 4, **2016**, PathGroup is pleased to inform you that we will now perform Cervical FISH testing via new methodology utilizing state-of-the-art FISH-based technology. Cervical FISH testing identifies high risk HPV positive women with low grade or undetermined lesions (ASCUS/LSIL) who are most at risk to progress to more advanced cervical disease, including cancer. Utilization of this testing allows for additional triage of your patients with Pap and HPV results in these categories and assists in determining who will most benefit from colposcopy. This methodology identifies clonal chromosomal aberrations commonly detected in cervical cancer and observed with higher frequencies in cervical lesions of increasing severity.

This new methodology utilizes 4 DNA probes in comparison to the 3 DNA probe methodology previously used, providing the highest sensitivity among tests in this category. The 4 biomarkers utilized in this methodology were derived from data obtained from collaboration with the National Cancer Institute as published in *Gynecologic Oncology* (Luhn *et al.* 2013). These biomarkers have a sensitivity of 89.5% compared to the sensitivity of the highest performing single biomarker (79%), based on The Cancer Genome Atlas Database.

As a result of this change in methodology, turnaround time for this test will be shortened to 3-5 days, versus the previous 5-7 days. A new test code and updated CPT code structure will be introduced. All EMR/EHR, LIS and PathConnect ordering systems will be updated with new orderable codes effective April 4, providing a seamless transition for clients.

TEST METHODOLOGY:

Fluorescence in situ hybridization (FISH) analysis is performed on interphase nuclei derived from liquid-based Pap specimens using the FISH-based HPV-Associated Cancer Test (FHACT®) DNA probes specific for chromosome regions 3q26 (TERC), 5p15 (TERT), CEP7 (centromere 7), and 20q13 (D20S911) (Cancer Genetics, Inc., Rutherford, NJ). The assay has been optimized to identify copy number gains of each of these loci. A probe pattern of 3 or more signals is considered a gain of that probed locus if the number of cells within the abnormal signal pattern exceeds the established cutoff value for that probe, and is reported as a positive result. A negative result does not preclude the presence of an abnormal clone.

ORDERING: EFFECTIVE APRIL 4, 2016

TEST NAME	TEST CODE	CPT CODES
CERVICAL FISH (FHACT®)	0CERF	88271*4 88275*4 88291*1

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IMPORTANT NOTES:

- The previous Cervical FISH Test Code **0Dtex** will no longer be available for order effective April 4, 2016.
- All standing reflex orders will remain in effect. The new methodology will be performed on reflex tests effective April 4, 2016.
- Specimen collection and transportation requirements remain the same.
- For clients with EMR/EHR interfaces, you may continue to see 'Dtex' in reflex rules until compendia updates have been fully completed. This may take up to 4-6 weeks to resolve. During this timeframe, orders for Test Code: 0Dtex will be automatically converted to Test Code: 0CERF, and results will reflect this new methodology. If you have any questions, contact your local PathGroup account representative.

TEST PERFORMED: Monday - Friday **TURNAROUND TIME:** 3-5 days

For further questions, please contact Client Services at 615-562-9300 or 1-888-474-5227.