



Memo to: Healthcare Personnel
From: Alverno Clinical Laboratories
Subject: **Test Methodology Conversion July 28, 2008 – Digene Hybrid Capture® 2 High-Risk HPV DNA Test™**

Alverno Clinical Laboratories is pleased to announce the transition from an in-house in-situ hybridization assay to the hybrid capture methodology used in the FDA-approved Digene system for HPV detection in liquid-based cervico-vaginal specimens. This qualitative assay detects high-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68.

This test is the first and only FDA-approved method for detecting high-risk HPV. It is the methodology recommended for use with the abnormal pap smear management algorithms of the American Society of Colposcopy and Cytologic Pathology (A.S.C.C.P).

SPECIMEN COLLECTION

Cytoc ThinPrep® Pap Test™ PreservCyt® Solution and the Digene HPVII Cervical Sampler.

Storage and Transport - Room temperature. Do not freeze.

Stability - 90 days at room temperature or refrigerated.

Unacceptable Conditions - Frozen or non-ThinPrep® specimens.

Production Schedule - Performed 3 times weekly.

CPT Code - 87621

Order Code – HPVVDG (on any result, as an individual test)
PAPDG (will be used for reflex testing strategies)

If you have any questions, please contact any of the following:

Jennifer Skeen, Ph.D. - Director of Molecular Biology
Thomas Roberts, M.D. - Medical Director Gynecologic Cytology
James Urban, M.D., Ph.D. - Medical Director, Alverno Clinical Laboratories

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For educational information please refer to the following references.

www.thehpvtest.com

<http://www.cdc.gov/STD/HPV/>