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Physician Centered. Patient Focused.

TEST UPDATE
HPV HIGH RISK SCREEN
BY ROCHE COBAS®

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This change will take effect **October 20, 2014**

OVERVIEW AND CLINICAL UTILITY:

PathGroup is pleased to announce the availability of the FDA-approved **Roche cobas® HPV assay effective Monday, October 20**. This high-risk HPV test will replace the current Digene Hybrid Capture 2 assay. The new test will be performed on the fully automated cobas® 4800 System, for delivery of trustworthy results with PathGroup's industry-leading turnaround time.

The cobas® HPV Test individually identifies genotypes 16 and 18, the two highest-risk HPV genotypes responsible for more than 70 percent of cervical cancer cases, while simultaneously detecting 12 other high risk HPV genotypes (HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). This test shows very high specificity for the 14 known high risk HPV genotypes, eliminating any cross-reactivity with the low risk HPV genotypes and lowering the risk of a false positive result. The cobas® HPV Test also only requires 1 ml of ThinPrep specimen which will significantly reduce the risk of a "Quantity Not Sufficient" result. One test, in one run, from one patient sample delivers 3 results, eliminating the need for reflex HPV genotype testing.

PathGroup believes that the combination of Pap and HPV DNA testing for cervical cancer screening provides the best sensitivity for detecting women with this disease. Consequently, in a patient whose relevant gynecological history includes a negative Pap and negative HPV DNA test, you as the clinician have been provided reassurance that the development of cervical cancer is unlikely for several years to come.[2]

TEST METHODOLOGY:

Test performed using Roche cobas real-time PCR.

SENSITIVITY AND SPECIFICITY[1]:

	≥ CIN2	≥ CIN3
Sensitivity (%)	90.0	93.5
Specificity (%)	70.5	69.3

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ORDERING:

TEST CODE	TEST NAME	CPT
0HPVH	HPV High Risk	87621

SPECIMEN COLLECTION:

ACCEPTABLE:
→ Cervical cells in ThinPrep vial
→ 1 mL minimum volume required

RESULTING:

COMPONENT	RESULT REPORTING
HPV High Risk (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)	Detected or Not Detected
HPV Type 16	Detected or Not Detected
HPV Type 18	Detected or Not Detected

TEST PERFORMED: Daily **TURNAROUND TIME:** 24 hours

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

1. cobas® package insert
2. Sherman, M., Lorincz, A., Scott, D., Wacholder, S., Castle, P., Glass, A., ... Schiffman, M. (2003). Baseline Cytology, Human Papillomavirus Testing, and Risk for Cervical Neoplasia: A 10-Year Cohort Analysis. JNCI Journal of the National Cancer Institute, 46-52.