HPV Detection and Genotyping

HPV Screening with HPV 16/18 Genotyping

See Technical Bulletin- HPV Method Change

CPAL is proud to announce the availability of the real-time PCR, FDA-approved cobas® HPV Test from Roche Diagnostics. Thetest is performed on the fully automated cobas® 4800 System. 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). **One test, in one run, from one patient sample delivers 3 results, eliminating the need for reflex testing.** Only 2 ml of patient sample is required, reducing the risk of QNS. The performance of the cobas® HPV test is clinically validated in the landmark Athena study which shows proven equivalency in performance against HC2 in the ASC-US population.

IMPORTANT GUIDELINES

Intended Use:

The cobas® HPV Test is a qualitative in vitro test for the detection of Human Papillomavirus in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). The cobas® HPV Test is indicated:

(a) To screen patients 21 years and older with ASC-US (Atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy.

(b) To be used in patients 21 years and older with ASC-US cervical cytology results, to assess the presence or absence of high-risk HPV genotypes 16 and 18. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy.

(c) In women 30 years and older, the cobas® HPV Test can be used with cervical cytology to adjunctively screen to assess the presence or absence of high risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

(d) In women 30 years and older, the cobas® HPV Test can be used to assess the presence or absence of HPV genotypes 16 and 18. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

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