

MOLECULAR PATHOLOGY BRIEFS

MOLECULAR TEST NAME: HPV 16/18 Test (Cervista™ HPV 16/18)

LABORATORY LOCATION: Molecular Pathology Laboratory, 4th Flr Basic Science Bldg, Rm-4-125 B, D & 4-128

LABORATORY DIRECTOR: Felicitas L. Lacbawan, MD, FCAP, FACMG

TARGET PATIENT POPULATION:

Women with atypical squamous cells of undetermined significance (ASC-US) on cervical cytology
Women 30 years and older in conjunction with cervical cytology

TEST INDICATION:

The HPV 16/18 Test (Cervista™ HPV 16/18) is an *in vitro* diagnostic test for the qualitative detection of DNA from Human Papillomavirus (HPV) Type 16 and Type 18 in cervical specimens. As an adjunct to HPV HR test, it specifically detects HPV Type 16 and Type 18 in patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology. It is also used together with cervical cytology and HPV HR test in women 30 years and older to adjunctively screen the presence or absence of HPV Type 16 and Type 18 for guidance in patient management.

SPECIMEN TYPE:

Minimum volume of 5 mL cervical specimen in ThinPrep® Pap Test PreservCyt® Solution, collected by using devices such as broom-type device (e.g. Rovers Cervex® Brush, Wallach Papette®) or Endocervical brush/spatula. Transport and store at room temperature (25°C).

TEST METHODOLOGY:

HPV 16/18 (Cervista™ HPV 16/18) test is a **qualitative** test that uses the Invader® chemistry, a signal amplification method for detection of specific nucleic acid sequences of HPV type 16 and HPV type 18, using two types of isothermal reactions: a primary reaction that occurs on the targeted DNA sequence and a secondary reaction that produces a fluorescent signal.

TEST ORDERING PROCEDURE ON CYTOLOGY LABORATORY FORM:

All HPV test orders must be accompanied by a Cytology Laboratory Form. Refer to “Primer on Ordering HPV High Risk and Genotyping 16/18 Tests” available on the website. This is a reflex test so it is not necessary for the clinician to order this test through CERNER (LIS).

TEST TURN-AROUND TIME:

Results are made available in 2-3 weeks after specimen submission to Molecular Pathology Laboratory or reflex ordering.

FOR ADDITIONAL TEST INFORMATION:

Contact the Molecular Pathology Laboratory: 718-270-1837, or ext 8623, or ext 2648

Visit the website: <http://www.downstate.edu/pnp/lab/molecular%20diagnostics.html>