

MOLECULAR PATHOLOGY BRIEFS

MOLECULAR TEST NAME: HPV HR Test (Cervista™ HPV HR)

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 cytology
Women 30 years and older in conjunction with cervical cytology

TEST INDICATION:

The HPV HR Screen (Cervista™ HPV HR) is an *in vitro* diagnostic test for the qualitative detection of DNA from 14 high-risk Human Papillomavirus (HPV) types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in cervical specimens. It is for screening of patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy. It is also used with cervical cytology in women 30 years and older to adjunctively screen the presence or absence of high-risk HPV types 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:

Cervista™ HPV HR test is a **qualitative** test that uses the Invader® chemistry, a signal amplification method for detection of specific nucleic acid sequences, 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 AND CERNER (LIS):

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.

Order “HPV HR Screen” for patients 30 years old and older in CERNER: Following the general procedure for ordering laboratory test, under the “Orderable”, select “HPV HR Screen” then hit Enter. All required fields must be filled in properly before submission. If entry is incomplete, no specimen can be collected from the patient.

TEST TURN-AROUND TIME:

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

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>