cobas® HPV

Delivering confidence with every result

The **cobas**® HPV for use on the **cobas**® 6800/8800 Systems (**cobas**® HPV) is an automated qualitative *in-vitro* test for the detection of human papillomavirus (HPV) DNA 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 HPV16 and HPV18 while concurrently detecting the other high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) at clinically relevant infection levels. Specimens are limited to cervical cells collected in PreservCyt® Solution, **cobas**® PCR Cell Collection Media and SurePath® Preservative Fluid.

Indications for use of cobas® HPV are:

A. **cobas**® HPV is indicated for use in screening patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.

B. **cobas**® HPV is indicated for use in screening patients with ASC-US cervical cytology results to assess the presence or absence of HR HPV genotypes 16 and 18.

C. **cobas**® HPV is indicated for use adjunctively with cervical cytology to assess the presence or absence of HR HPV types.

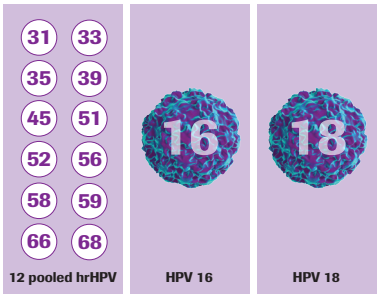
D. **cobas**® HPV is indicated for use adjunctively with cervical cytology to assess the presence or absence of HPV genotypes 16 and 18.

E. **cobas**® HPV is indicated for use as a first-line primary screening test to identify women at increased risk for the development of cervical cancer or presence of high-grade disease.

F. **cobas**® HPV is indicated for use as a first-line primary screening test to assess the presence or absence of HPV genotypes 16 and 18.

The results from **cobas**® HPV, 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 **cobas**® HPV are not intended to prevent women from proceeding to colposcopy.

The **cobas**® HPV for use on the **cobas**® 6800/8800 Systems delivers reliable, clinically validated assay performance for automated, cervical cancer screening. Clinical evidence behind the **cobas**® HPV test is based on a large, prospective clinical study evaluating the performance of the **cobas**® HPV for identifying high-grade cervical disease (CIN2, CIN3, cervical cancer or adenocarcinoma in situ [ACIS]) among consenting women 25-65 years old undergoing routine cervical cancer screening.



Roche

cobas® | The **cobas**® HPV **KNOW THE RISK**

CE-IVD performance specifications. Not available in all markets.

Built-in quality & safety features include:

- **Internal control:** The ß-globin internal cellular control helps prevent false negatives. Each sample is tested for the human ß-globin gene. HPV negative specimens with a negative ß-globin result are flagged as invalid, helping to prevent reporting of false negative results.
- **Use of AmpErase® enzyme:** Each reaction contains AmpErase® enzyme, reducing the risk of false positive results from carry-over contamination by differentiating amplification products from target molecules.
- **No cross-reactivity: cobas®** HPV demonstrates no cross-reactivity with non-high risk (hr) HPV genotypes, ensuring that positive results are clinically meaningful.

cobas® HPV product summary

Description	Summary
Sample type	PreservCyt® Solution, SurePath® Preservative Fluid, **cobas®** PCR Cell Collection media
Minimum amount of sample required (µl)	1,000
Sample processing volume (µl)	400
Internal cellular control	β-globin
Simultaneous 16/18 genotyping[1]	Yes; HPV 16, HPV 18 and 12 hrHPV
Genotypes	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68
Test duration	<3.5 hours for first HPV result

cobas® HPV ordering information

Material number	Product name	Tests per unit*
07460155190	**cobas®** HPV	480
07460171190	**cobas®** HPV Positive Control Kit	16 runs
07002238190	**cobas®** Buffer Negative Control Kit	16 runs
06526985190	**cobas®** Sample Prep Buffer (CSPB)[2]	480

* May vary based on workflow demands

Collection kits ordering information

Material number	Product name	Package size
04496094190	Sample Transport Collection Kit (collection brushes)	500 brushes
05619637190	**cobas®** PCR Cell Collection Media	250 vials
07994745190	Roche Cell Collection Medium (vials)[3]	250 vials
07994753190	Roche Cell Collection Medium (bottle)[3]	1 liter

[1] Results reported when HPV-GT analysis module is selected
[2] Only required when processing SurePath™ collected samples
[3] Currently only validated in combination with **cobas®** 4800 HPV assay

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