cobas® HPV test

Delivering confidence with every result

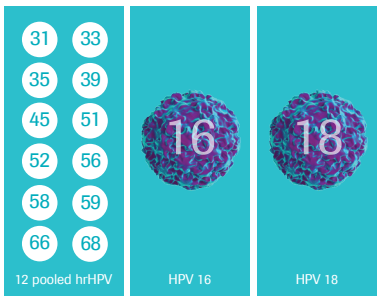
*The **cobas**® HPV test for use on the **cobas**® 6800/8800 Systems (**cobas**® HPV) is an automated qualitative in-vitro test for the detection of human papillomavirus (HPV) DNA in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid 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. Cervical cell specimens can be collected using either PreservCyt®, Roche Cell Collection Medium, or SurePath™ liquid-based cytology media.*

Indications for use of cobas® HPV test are:

A. **cobas**® HPV test 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 test 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 test is indicated for use adjunctively with cervical cytology to assess the presence or absence of HR HPV types.
D. **cobas**® HPV test is indicated for use adjunctively with cervical cytology to assess the presence or absence of HPV genotypes 16 and 18.
E. **cobas**® HPV test 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 test, together with the physician's assessment of medical history, other risk factors, and professional guidelines, may be used to guide patient management. The results of **cobas**® HPV test are not intended to prevent women from proceeding to colposcopy.

The **cobas**® HPV test for use on the **cobas**® 6800/8800 Systems delivers reliable, clinically validated assay performance for automated, cervical cancer screening and received FDA approval in 2020. Clinical evidence behind the **cobas**® HPV test is based on a large, prospective clinical study evaluating the performance of the **cobas**® HPV test 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.



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

Built-in quality & safety features include:

- **Internal Cellular Control:** The ß-globin internal cellular control helps prevent false negatives. Each sample is tested for the human ß-globin gene which is present in every human cell. 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 potential carry-over contamination by differentiating amplification products from target molecules.

cobas® HPV test product summary

Description	Summary
Sample type	PreservCyt® Solution, SurePath™ Preservative Fluid, Roche Cell Collection Medium
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 other 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 test ordering information

Material number	Product name	Package size
07460155190	**cobas**® HPV Test	480 rxn
07460171190	**cobas**® HPV Positive Control Kit	16 runs
07002238190	**cobas**® Buffer Negative Control Kit	16 runs
07958048190	**cobas**® PCR Media Secondary Tube	1,000 pieces
07958056190	**cobas**® PCR Media Tube Replacement Cap	1,000 pieces
06526985190	**cobas**® Sample Prep Buffer (CSPB)[2]	480 rxn

Collection kits ordering information

Material number	Product name	Package size
08399832190	Cervical Collection Brush (bulk)	500 brushes
08779040190	Cervical Collection Brush (sterile)	100 brushes
07994745190	Roche Cell Collection Medium 20 ml vial	250 vials

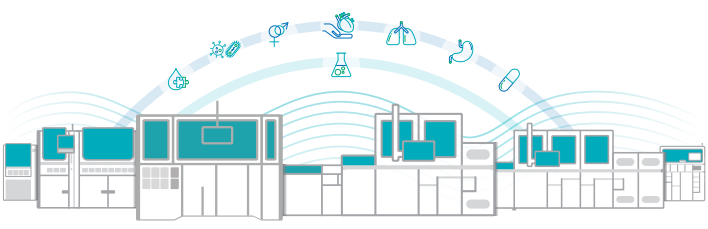
References

1 *Results reported when HPV-GT analysis module is selected*

2 *Only required when processing SurePath™ collected samples*

cobas® HPV and the Molecular Work Area.

Optimal assay performance.
Fully integrated workflow.



Published by:
Roche Molecular Systems
4300 Hacienda Drive
Pleasanton, CA 94588 USA

diagnostics.roche.com/cervicalcancer

PP-GBL-00707

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