know now

*if she is at risk for **cervical cancer***

Screening with the cobas® HPV test

cobas® HPV TEST

Know *now* so you can take the right next steps for women undergoing cervical cancer screening

Early detection of human papillomavirus (HPV) can help protect cervical health

The ability to identify disease early in the screening process can reduce risk and provide the information you need to guide patient management.

The FDA-approved **cobas**® HPV test, the first step in the Roche Cervical Cancer Portfolio, objectively identifies women at risk and improves detection of high-grade disease in a single round of screening, utilizing molecular diagnostic testing for the presence of HPV.

This means you have a screening tool that can stratify a patient's risk.

Normal cytology does not always mean cancer free

Pap cytology has had a significant impact in the reduction of cervical cancer incidences and screenings. While the incidence has been greatly reduced, Pap cytology is subjective and poses the potential to miss disease.

A number of women are screened yet remain at high risk for cervical cancer. Up to one-third of cervical cancer occurs in screened women.[1,2]

32%

Kaiser Permanente and 2 other healthcare plans (N=833)

24%

Swedish healthcare system (N=1230)

***Percentage of invasive cervical cancer that occurred in women with normal cytology*[1,2]**

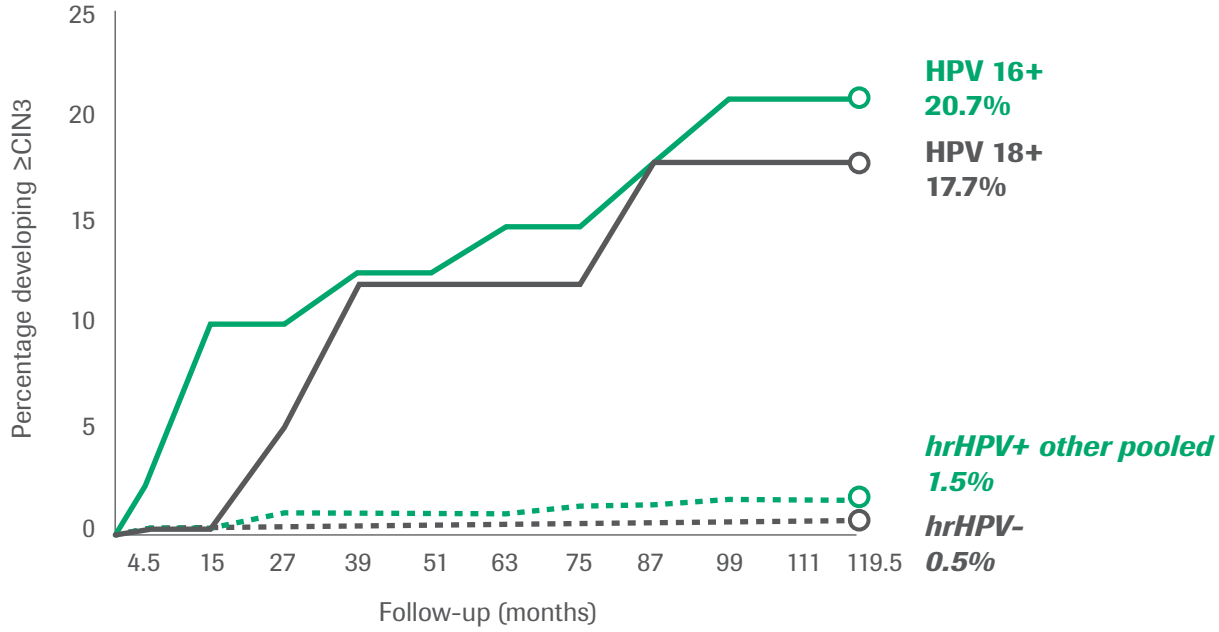
Genotyping enables actionable next steps

Co-testing is shown to be superior in detecting precancer and cancer of the cervix.[3]

When HPV genotyping information is included as part of the HPV-positive test result, women can be further risk stratified.

Cervical disease by genotype 10-year cumulative incidence rate

Confirmed ≥CIN3 in women 30+ yrs with normal Pap cytology at baseline (n=12,976)[3]



hr = high risk

- HPV16+ or HPV18+ women were more likely to have ≥CIN3 over a 10-year period than women who were positive for other pooled hrHPV genotypes[3]
- For women who are HPV16+ at baseline, the incidence of ≥CIN3 rose sharply during the first year of the study[3]
- For HPV18+ women, the incidence of ≥CIN3 increased dramatically from around 2 years after baseline[3]

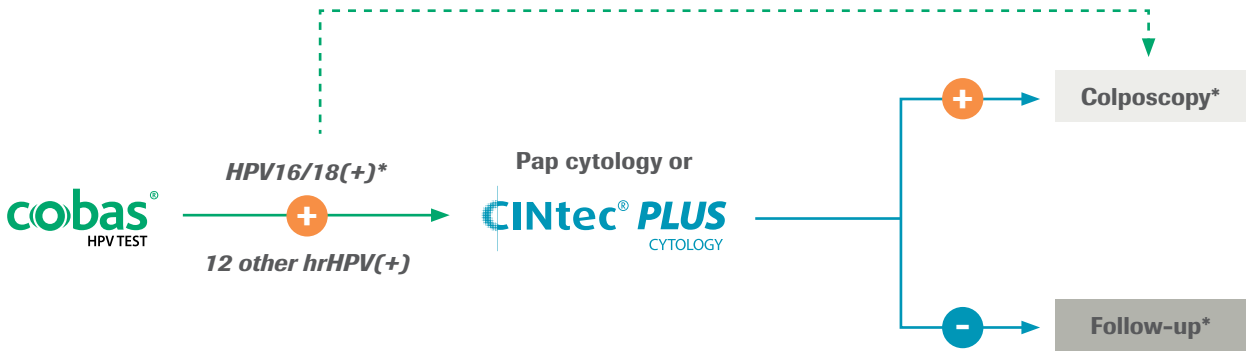
Genotyping results should provide information that leads to or would require immediate follow-up or a different or unique management strategy due to high inherent risk of high-grade disease.

Reassurance of precancer risk

HPV primary screening identifies women at risk for cervical cancer

It uses an algorithm that leverages the high sensitivity of HPV DNA, the built-in risk stratification of HPV genotypes 16 and 18, and triage with the high specificity of cytology for an optimal balance in cervical cancer screening.

- HPV primary screening is an important scientific and clinical advance in cervical cancer screening since it offers better reassurance of low cancer risk compared to cytology-only screening conducted at the same interval[4]
- HPV primary screening detected higher rates of CIN3-positives at first-round screening compared with cytology[5]
- HPV primary screening offers 2 triage options: Pap cytology and CINtec® *PLUS* Cytology[8,9]



*For HPV16/18+ use as additional information in conjunction with the physician's assessment of patient screening history, other risk factors, and professional guidelines to guide patient management.

Leading medical societies, such as the American College of Obstetricians and Gynecologists, the American Cancer Society, the American Society for Colposcopy and Cervical Pathology, the Society of Gynecologic Oncology, and the United States Preventive Services Taskforce, now support HPV primary screening as an option for cervical cancer screening for women ages 25 and older.[4-7]

This option for HPV screening can give you more information to manage your patients going forward.

Maximize your screening options

The cobas® HPV test gives you screening flexibility for your patients

The **cobas**® HPV test is the cervical cancer screening test approved for ASC-US reflex, co-testing, and primary screening, as well as for use with both types of specimen collection vials[8,9]* giving you the flexibility to choose the best screening method for your patients.

*SurePath™ is only available on **cobas**® 4800 System.

FDA-approved screening test means protection for more women

AGES 21+
ASC-US reflex

AGES 30-65
Co-testing

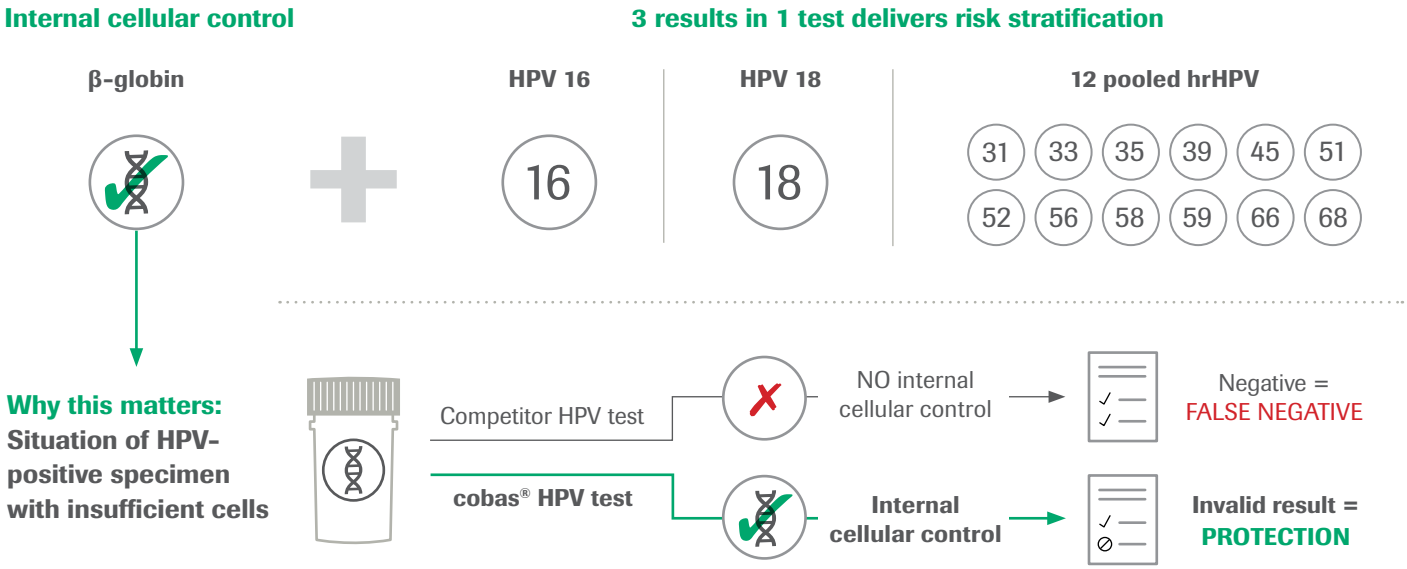
AGES 25+
HPV primary screening

cobas® HPV TEST

Test with confidence

Minimize the chance of false negatives

The **cobas**® HPV test is designed to help minimize the chance of false negatives and provide screening accuracy for all high-risk HPV genotypes. Internal cellular control monitors the presence of human cells and confirms reaction completion to prevent false-negative results.



The cobas® HPV test offers:

3 results in 1 test

Yields 3 results (HPV 16, HPV 18, 12 high-risk HPV pooled) in 1 test run, eliminating the need to reflex and giving you the information needed to make important clinical decisions.

No cross-reactivity

Demonstrates no cross-reactivity with low-risk HPV genotypes, helping to ensure that a positive result is a true positive.

HPV DNA detection

DNA is present and needed for the replication of the virus, when viral infections occur.[4] DNA-based testing is supported by 25 years of data following millions of women.

Robust clinical trials

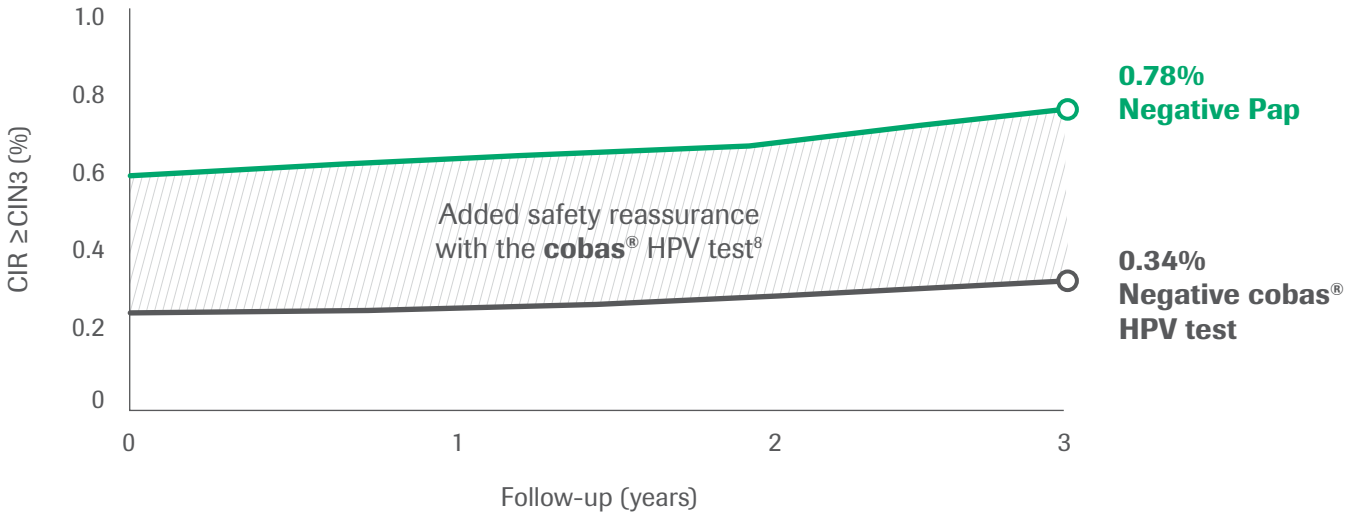
Clinically validated in 2 landmark trials

The ATHENA Study is the largest HPV clinical trial ever to be conducted in the United States. Enrolling more than 47,000 women, this study evaluated the performance of the **cobas**® HPV test for ASC-US management, co-testing with cytology for screening, and primary screening.[8]

The IMPACT Trial, a landmark cervical cancer screening study, enrolled approximately 35,000 women. This study is representative of a routine cervical cancer screening population in the United States for co-testing and primary screening.[9]

Twice the safety reassurance

*A negative **cobas**® HPV test result provides twice the safety reassurance of a negative Pap cytology result over a 3-year screening interval.*[8]



CIR = cumulative incidence rate

The cobas® HPV test is clinically validated and supports safe and effective patient care by accurately identifying women at risk for cervical disease.[8,9]

cobas® HPV TEST

Know *now* what to do next

The **cobas**® HPV test is one of 3 tests in the Roche Cervical Cancer Portfolio covering the entire spectrum of screening, triage, and diagnostic solutions. Roche offers a comprehensive portfolio to help determine the individual level of risk a woman has so that you will know what to do next and when.

SCREEN	TRIAGE	DIAGNOSE
cobas® HPV TEST	CINtec® PLUS CYTOLOGY	CINtec® HISTOLOGY
SCREEN for the cause of cervical cancer and identify those who are safe to return to routine screening and those who are at risk.	***TRIAGE*** women who will benefit from immediate intervention when transforming HPV infections are present.	***DIAGNOSE*** with advanced biomarker technology to provide clear visual confirmation of the presence or absence of precancerous cervical lesions.

To learn more, visit go.roche.com/cervicalsolutions

Images shown are stock photos posed by models.

References: 1. Leyden WA, Manos MM, Geiger AM, et al. Cervical cancer in women with comprehensive health care access: attributable factors in the screening process. *J Natl Cancer Inst*. 2005;97(9):675-683. **2.** Andrae B, Kemetli L, Sparen P, et al. Screening-preventable cervical cancer risks: evidence from a nationwide audit in Sweden. *J Natl Cancer Inst*. 2008;100(9):622-629. **3.** Khan MJ, Castle PE, Lorincz AT, et al. The elevated 10-year risk of cervical precancer and cancer in women with human papillomavirus (HPV) type 16 or 18 and the possible utility of type-specific HPV testing in clinical practice. *J Natl Cancer Inst*. 2005;97:1072-1079. **4.** Huh WK, Ault KA, Chelmow D, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: Interim clinical guidance. *Gynecol Oncol*. 2015;136(2). **5**. Final Recommendation Statement: Cervical Cancer Screening. Accessed October 29, 2020. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening **6.** Updated Cervical Cancer Screening Guidelines Practice Advisory. April 2021. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines. Accessed January 13, 2023. **7.** Fontham E, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2020;0:1-26. **8. cobas**® HPV test. Package insert v17, US. Roche Diagnostics; 2018. **9. cobas**® HPV for **cobas**® 6800/8800. Package insert v1, US. Roche Diagnostics; 2020.

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