
Roche
Introducing a biomarker-based triage test to identify transforming HPV infection
CINtec® *PLUS* Cytology
Know now if she is progressing toward cervical cancer

Know *now*
so you can help clinicians more definitively take the right steps for cervical cancer screening and management

Now, 3 clinically validated tests bring greater diagnostic certainty

Challenges remain in current cervical cancer screening approaches that can now be addressed with more advanced technologies.

The molecular and biomarker-based tests in the Roche Cervical Cancer Portfolio bring greater diagnostic certainty to cervical cancer screening so the results you provide can guide clinicians and women along each step, removing ambiguity that can arise in current testing approaches.

Only the Roche Cervical Cancer Portfolio covers the entire spectrum of screening, triage, and diagnostic solutions

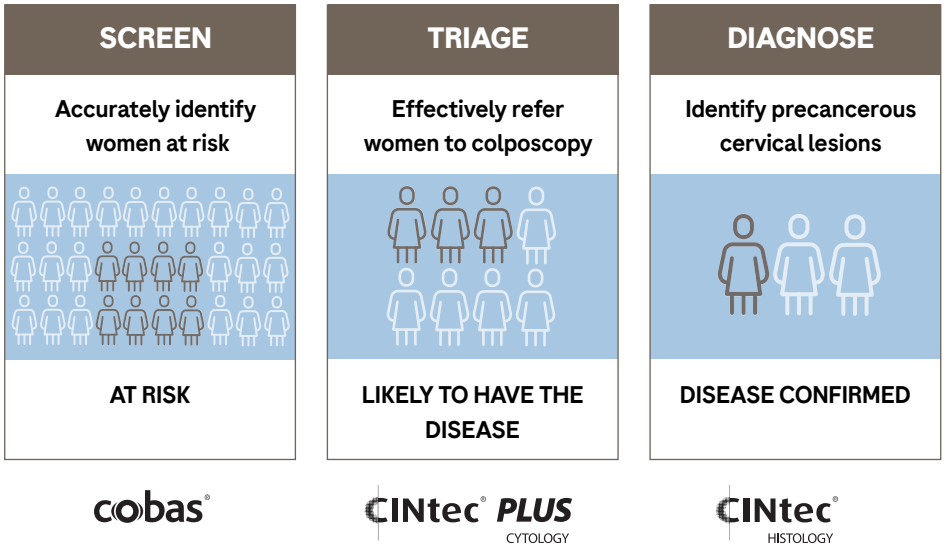
cobas® | CINtec® PLUS CYTOLOGY | CINtec® HISTOLOGY

The next evolution in cervical cancer screening

CINtec *PLUS* Cytology more clearly stratifies disease risk in HPV-positive patients

Not every HPV-positive woman will develop cervical cancer, so triage can determine who is most at risk and will benefit from more immediate follow-up, and who is at low risk and can be given more time to clear the infection on her own.

CINtec *PLUS* is a triage cytology test that helps stratify disease risk immediately, giving clinicians confidence when selecting the appropriate management for women at every level of risk.



CINtec *PLUS* Cytology provide a triage solution that informs better risk stratification for HPV-positive screening results.

Detect changes at the cellular level

CINtec *PLUS* Cytology has dual-biomarker technology for more definitive results

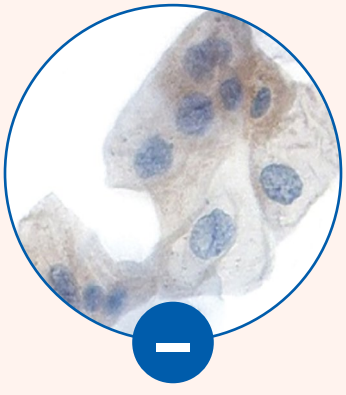
It's not enough to know that a patient is positive for HPV, but whether HPV is causing changes at the cellular level.

CINtec ***PLUS*** Cytology is the only FDA-approved triage test that uses dual-biomarker technology to simultaneously detect p16 and Ki-67 in women with HPV-positive results.

The co-expression of these two biomarkers is a strong indicator that an HPV infection is undergoing oncogenic transformation.

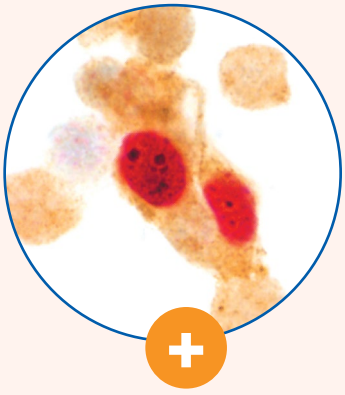
Co-expression of p16/Ki-67 biomarkers indicates transforming HPV infection

CINtec *PLUS* Cytology



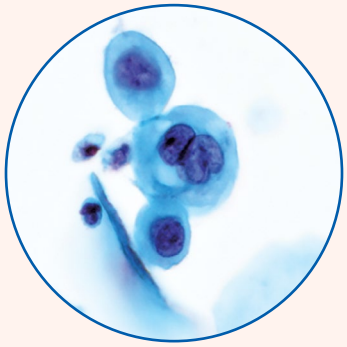
Expression of p16 *(brown)* signals halting of cell division.

Expression of Ki-67 *(red)* signals progression of cell division



Co-expression of p16 and Ki-67 *(brown and red)* indicates cell cycle deregulation

Pap Cytology



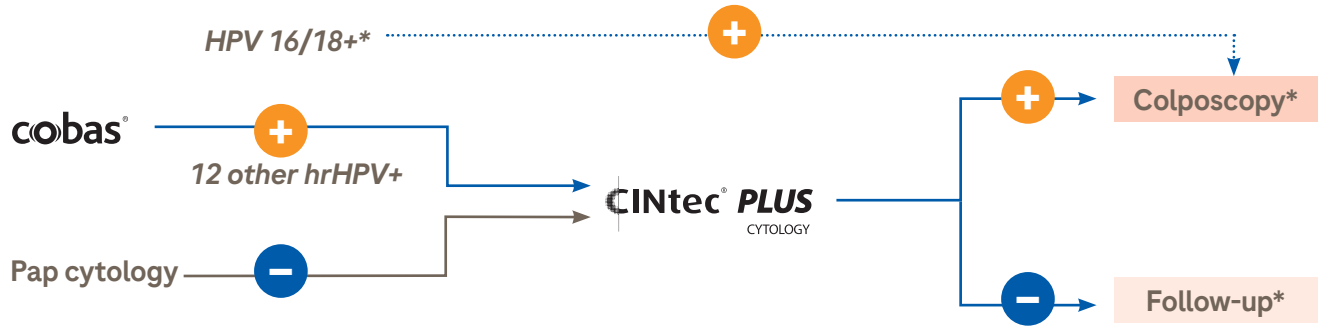
Reliant on intepretation of morphology

A triage test to guide patient management

In Pap/HPV co-testing, CINtec *PLUS* Cytology can be used as a triage test, improving the resolution of discrepant HPV-positive/Pap normal (NILM) screening results. This more clearly identifies women at high or low risk for cervical disease so you can give clinicians greater confidence when selecting the appropriate management for women at every level of risk.

CINtec *PLUS* Cytology can help resolve discrepant co-testing results

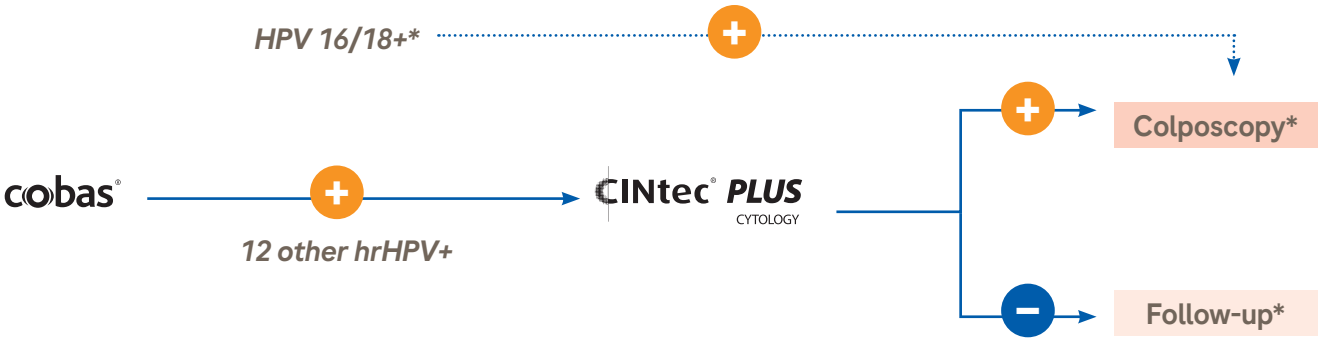
Pap/HPV Co-testing (age 30-65)



*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.

hr = high risk

Primary Screening (age 25-65)



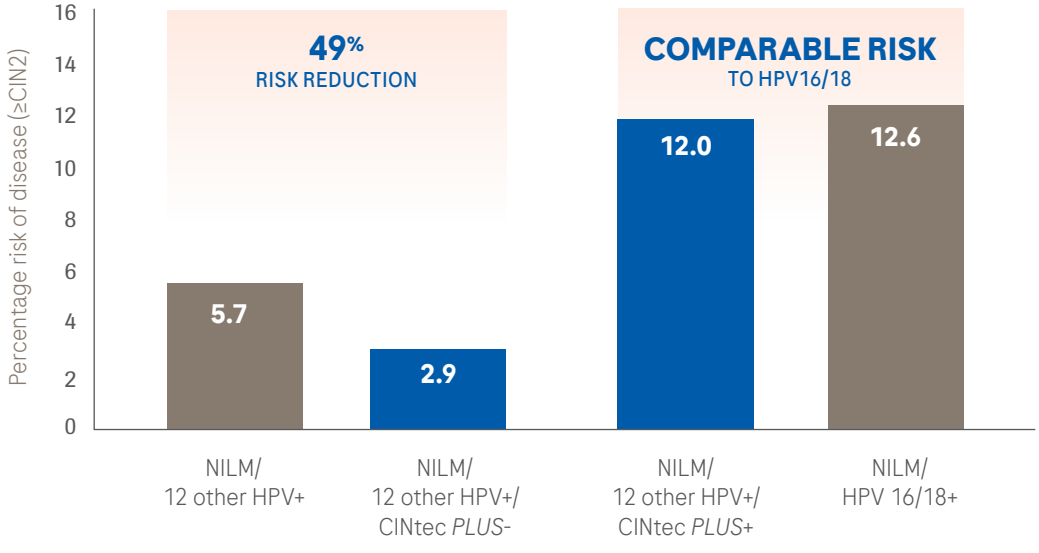
Shown to find disease earlier

The IMPACT trial was a landmark registrational cervical cancer portfolio trial[1]

- Included **cobas**® HPV test, CINtec *PLUS* Cytology, and CINtec® Histology
- Multicenter, prospective trial enrolling ~35,000 women at 32 collection sites across the US
- Representative of routine cervical cancer screening population in the US:
  - Ages 25-65
  - Non-vaccinated and vaccinated
  - Diverse races and ethnicities
- More than 5,000 HPV-positive subjects
- More than 530 ≥CIN2 disease cases

CINtec *PLUS* Cytology provides further risk stratification in 12 other HPV+ women

Risk of disease in Pap Normal/HPV+ women (≥CIN2, age 30-65)[1]



NILM/12 other HPV+ with CINtec *PLUS* Cytology

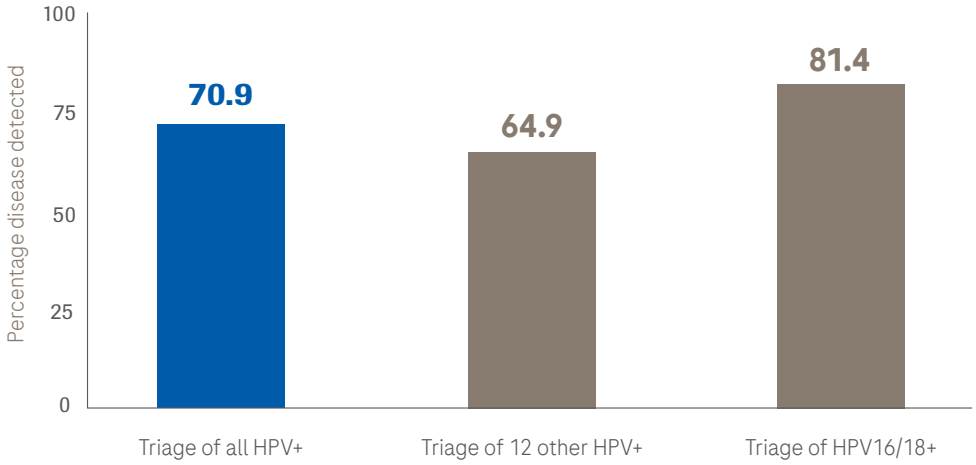
NILM/HPV+ women today

CINtec *PLUS* Cytology allows for more accurate quantification of a woman's risk.

Increased testing sensitivity

CINtec *PLUS* Cytology can find disease earlier with discrepant co-testing results

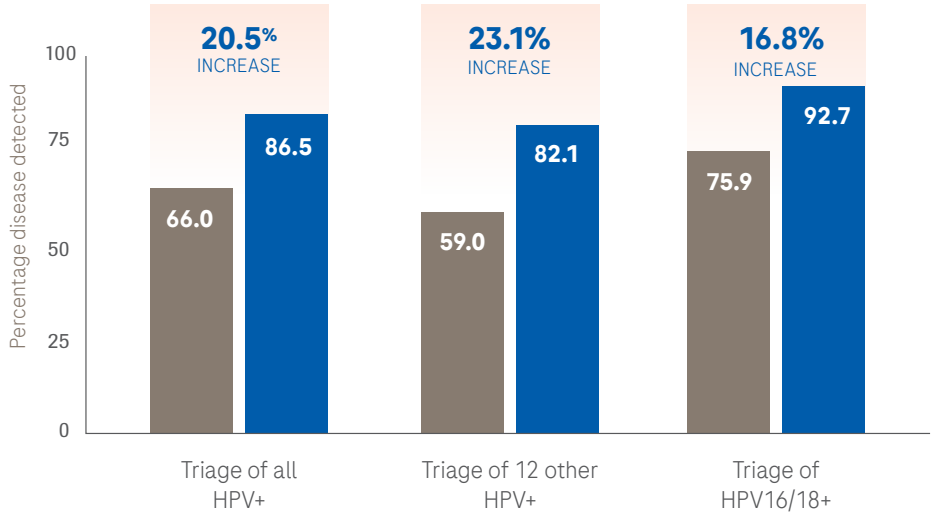
Percentage of disease detected with CINtec PLUS Cytology In Pap normal/HPV+ women (CIN2, age 30-65)[1]



With CINtec *PLUS* Cytology, 7 out of 10 women with disease could be identified earlier in their screening.[1]

CINtec *PLUS* Cytology offers greater sensitivity compared to Pap cytology

Percentage of disease detected (≥CIN2, age 25-65)[1]



CINtec *PLUS* Cytology improves disease detection independent of genotype, patient age, or vaccination status.

Know now what to do next

The 3 tests in the Roche Cervical Cancer Portfolio bring greater diagnostic certainty to cervical cancer screening. Now your lab can provide reliable results that give clinicians the confidence and clarity needed to determine the right next step for their patients.

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

Images shown are stock photos posed by models.

1. CINtec® *PLUS* Cytology. Package insert. Roche Diagnostics; 2020.

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The Roche Cervical Cancer Portfolio

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