

A photograph of a woman with short, dark hair, wearing a light blue sweater, looking out towards the sea. Her hands are clasped near her neck. The background is a bright, slightly blurred outdoor setting, likely a beach or coastal area.

know *now*

*if she is progressing toward
cervical cancer*

***CINtec[®] PLUS Cytology is a biomarker-based test
offering enhanced risk stratification for earlier
cervical disease detection***

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



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 to 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

SCREEN

cobas[®]
HPV TEST

TRIAGE

CINtec[®] **PLUS**
CYTOLOGY

DIAGNOSE

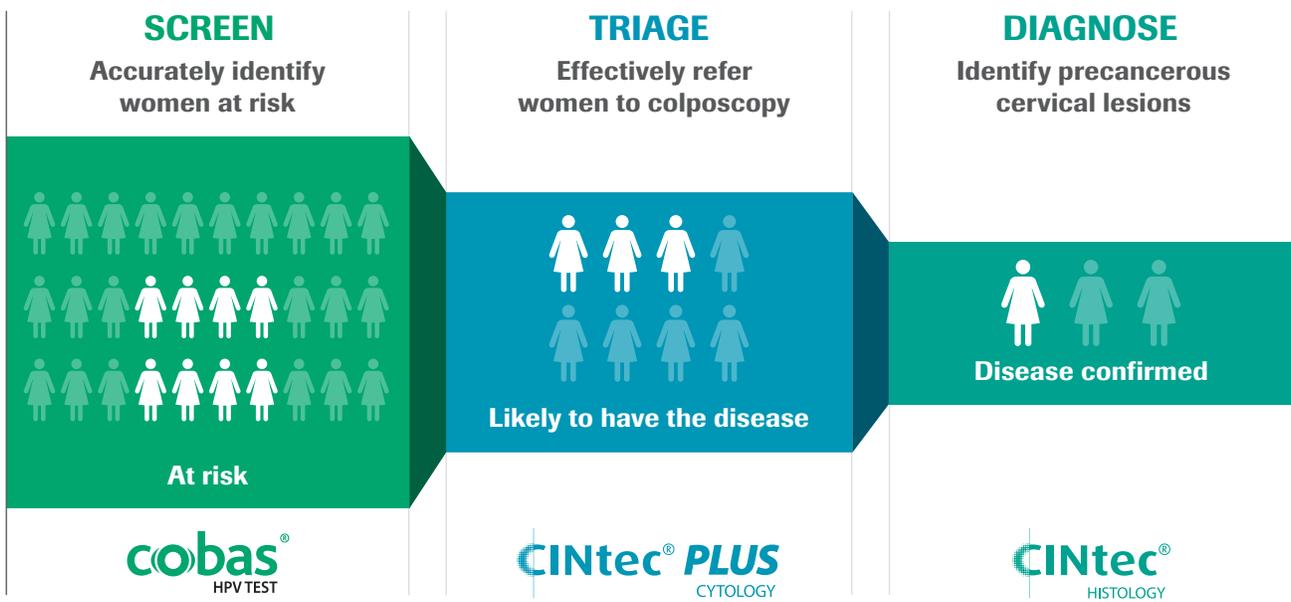
CINtec[®]
HISTOLOGY

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 provides 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

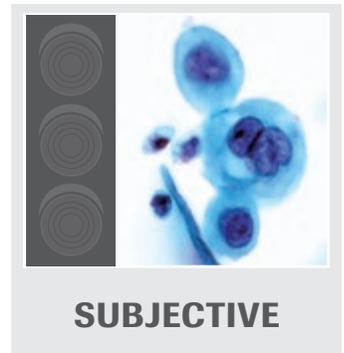
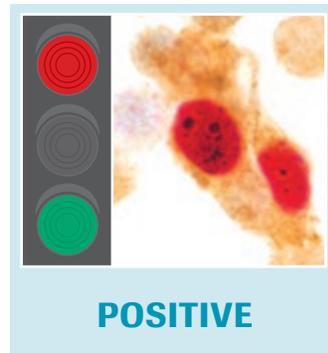
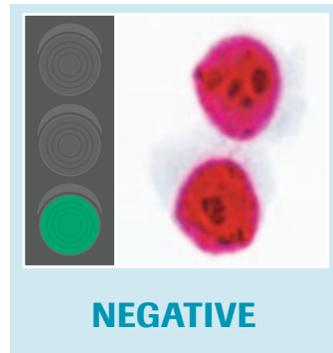
It's not enough to know that a patient is positive for HPV, but whether HPV is causing changes at the cellular level. CINtec *PLUS* Cytology is the only FDA-approved triage test that uses dual-biomarker technology to simultaneously detect p16 and Ki-67 in women with HPV-positive results.

The presence of both biomarkers, p16 and Ki-67, within the same cell is a strong indicator that an HPV infection is undergoing oncogenic transformation.

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

CINtec *PLUS* Cytology

Pap 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

Reliant on interpretation of morphology

A triage test to guide patient management

CINtec PLUS Cytology can help resolve discrepant co-testing results

When co-testing (Pap and HPV), 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 have greater confidence when selecting the appropriate management for women at every level of risk.

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

CINtec PLUS Cytology is approved as a triage:

- In HPV primary screening of women ages 25-65
- For discrepant co-testing results of women ages 30-65 when a woman is HPV positive but has a normal Pap



Ability to find disease earlier

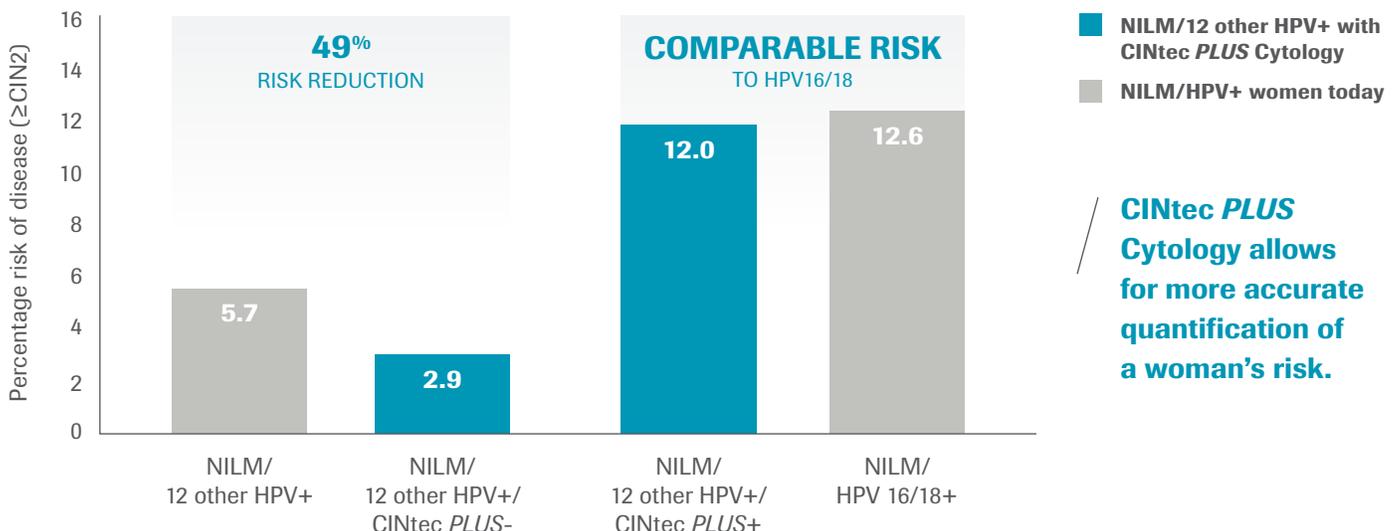
The IMPACT Trial was a landmark registrational cervical cancer portfolio trial¹



- 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*

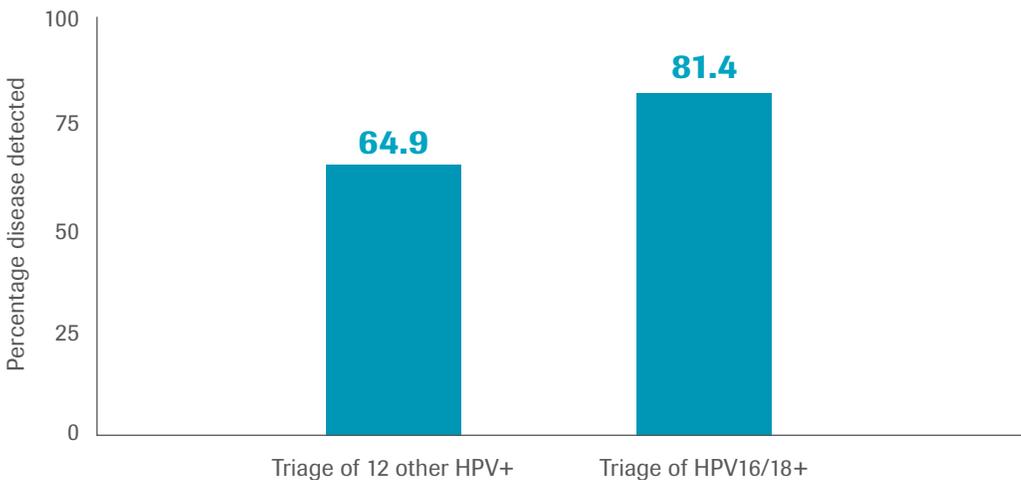
Risk of disease in Pap normal/HPV+ women (≥CIN2, age 30-65)¹



Increased testing sensitivity

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

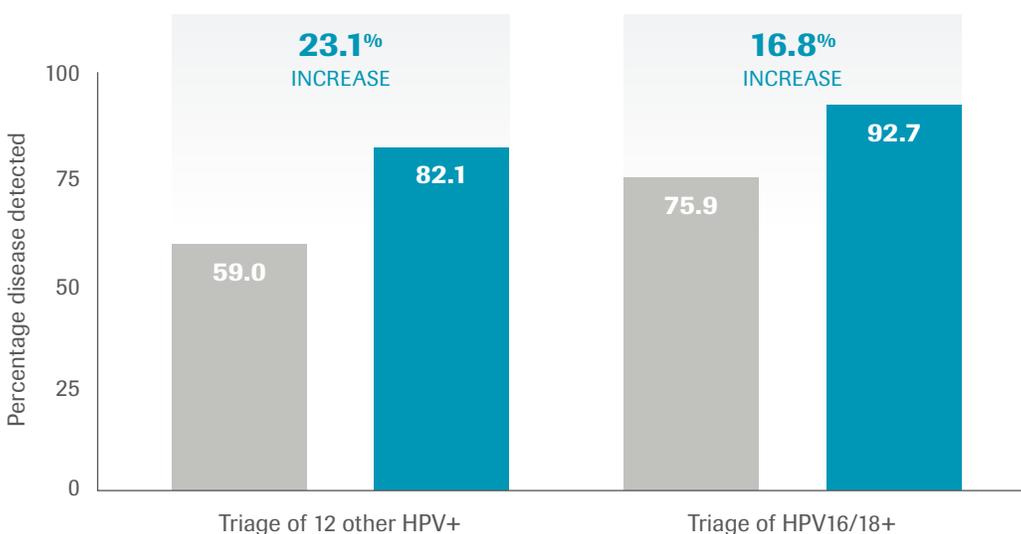
Percentage of disease detected with CINtec PLUS Cytology in Pap normal/HPV+ women (CIN2, age 30-65)¹



With CINtec PLUS Cytology, 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 you can provide reliable results with the confidence and clarity needed to determine the right next step for your patients.



SCREEN



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



TRIAGE women who will benefit from immediate intervention when transforming HPV infections are present.

DIAGNOSE



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.

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

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Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46256