# know now

*if she is progressing toward*
***cervical cancer***

## Introducing a biomarker-based triage test to identify transforming HPV infection

***CINtec® PLUS Cytology***

CINtec® PLUS
CYTOLOGY

# Know *now* so you can help clinicians 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 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*

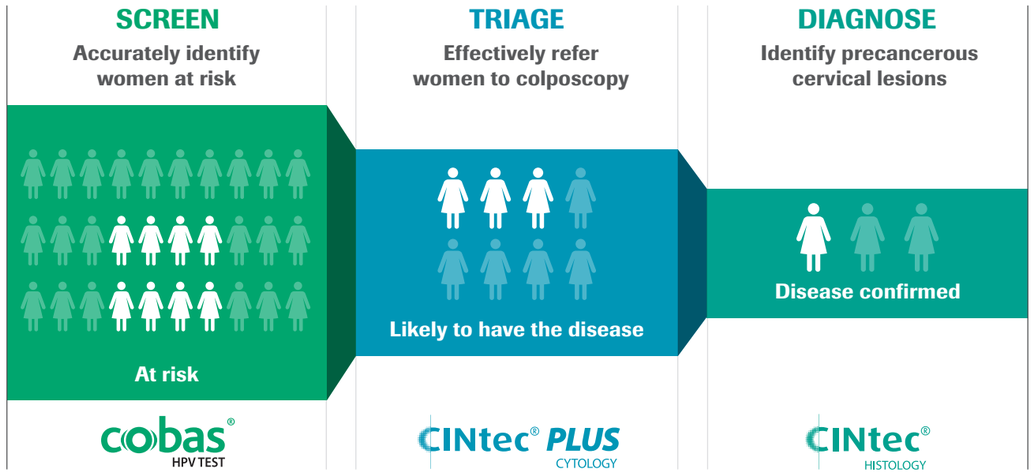
| SCREEN | TRIAGE | DIAGNOSE |
|---|---|---|
| cobas® HPV TEST | CINtec® *PLUS* CYTOLOGY | CINtec® HISTOLOGY |

# 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 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*

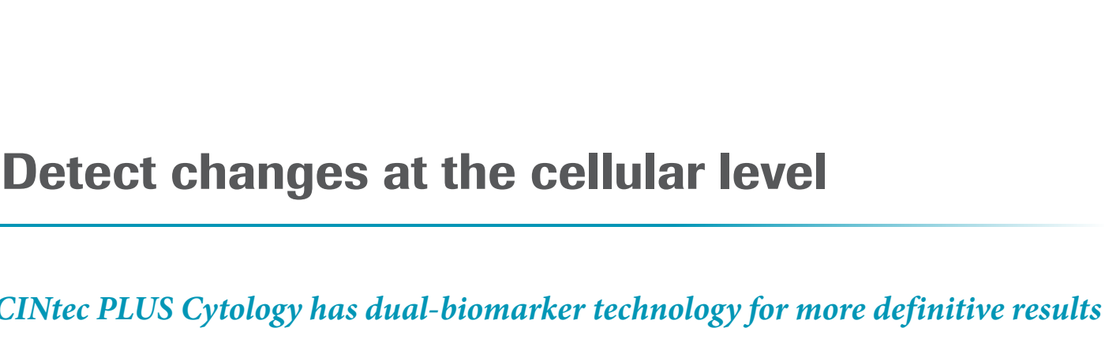
It's not enough to know that a patient is positive for HPV, but whether HPV is causing changes at the cellular level.

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 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 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*

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.

### 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

†Approved for use on cobas® 4800/6800/8800 instruments.

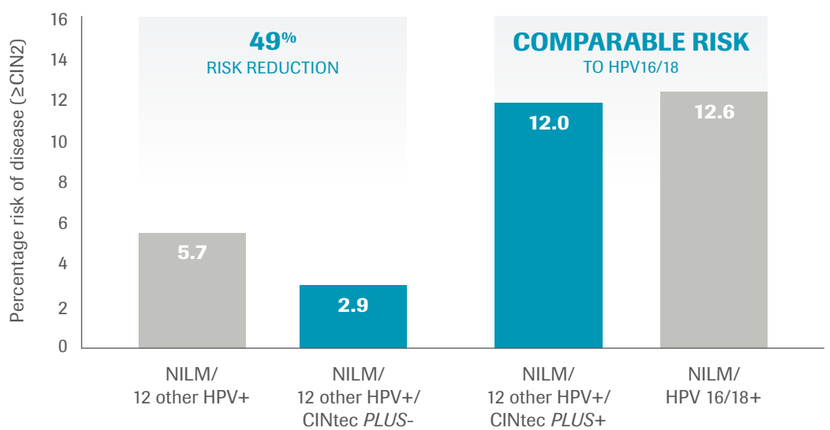
# Shown to find disease earlier

## *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**

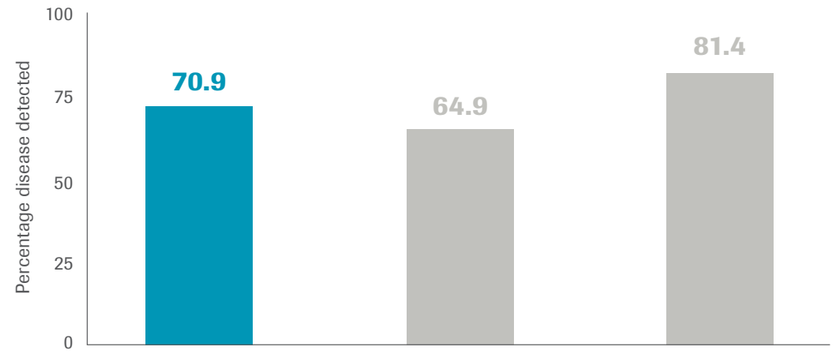
**NILM/HPV+ women today**

**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*

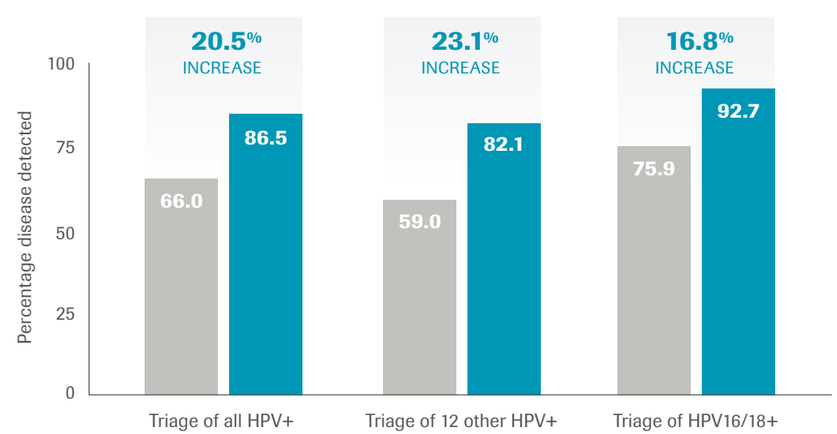
**Percentage of disease detected with CINtec *PLUS* Cytology in Pap normal/HPV+ women (CIN2, age 30-65)**[1]




**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 triage**

**Pap triage**

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



CINtec® PLUS CYTOLOGY

# 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.

| 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.

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



Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46256