Roche

be conclusive

SCREEN — TRIAGE — DIAGNOSE

The science that creates certainty.

CINtec®
HISTOLOGY

The CERTAIN study – clinical study excellence with impactful results

The CERTAIN (**CER**vical **T**issue **A**djunct**I**ve a**N**alysis) study is one of the largest, most rigorous immunohistochemistry clinical studies

38,500 *interpretations*

1,100 *biopsies*

70 *individual surgical pathologists*

3 *globally recognized expert gynecopathologists*

≥99% acceptability for:

- staining
- morphology
- background

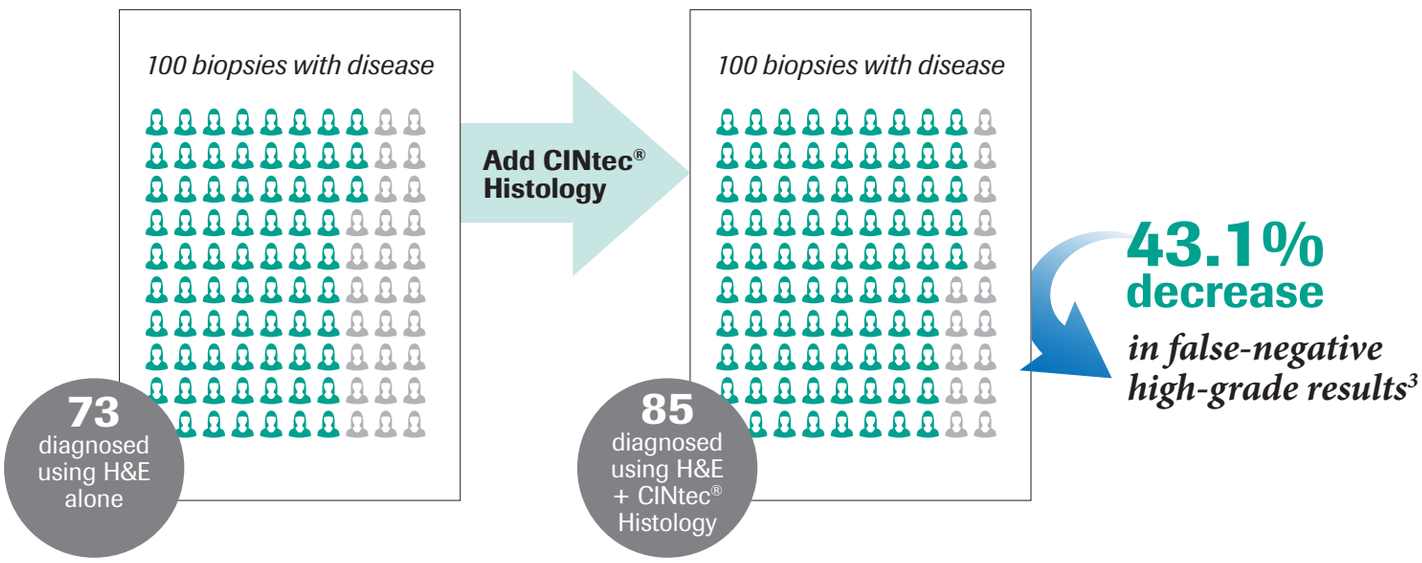
Global standard of care

CAP (College of the American Pathologists), the **ASCCP** (American Society for Colposcopy and Cervical Pathology) and **WHO** (World Health Organization) recommend the adjunctive use of p16 IHC in evaluation of cervical biopsies. Use of CINtec® Histology is supported by >100 peer-reviewed publications.[1,2]

CE marked and U.S. 510(k) IVD

The CINtec® Histology test is the **only p16 biomarker** test CE marked and U.S. 510(k) cleared for clinical use in the evaluation of cervical biopsy specimens.

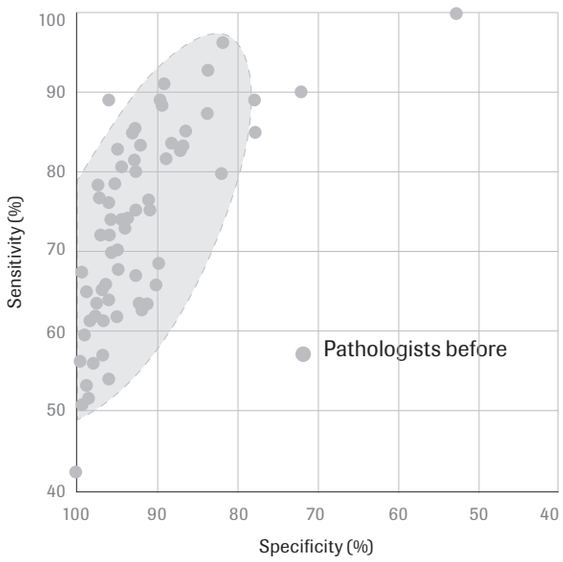
CINtec® Histology adds objectivity to cervical biopsy interpretation to help pathologists make informed diagnoses



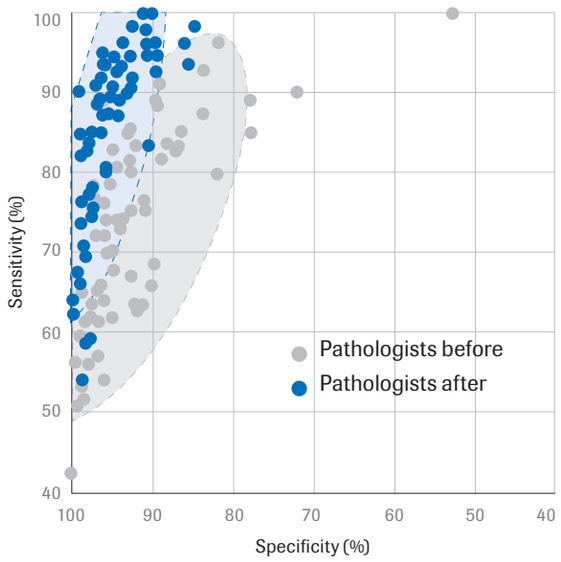
Diagnostic agreement and consistency among pathologists improved when using CINtec® Histology*

When CINtec® Histology was used on all cervical biopsies, individual pathologists demonstrated significant improvement in diagnostic sensitivity and specificity[3]

BEFORE: H&E alone



AFTER: H&E + CINtec® Histology



Experts benefited when using CINtec® Histology as well

You can be even better at what you do when you use CINtec® Histology

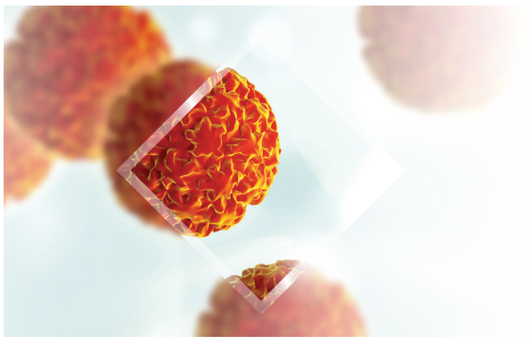
24.7% more

high-grade disease was identified compared to H&E alone.[3]

*Performance of individual surgical pathologists when using H&E alone vs. H&E + CINtec® Histology compared with the expert consensus diagnosis established using H&E + CINtec® Histology.

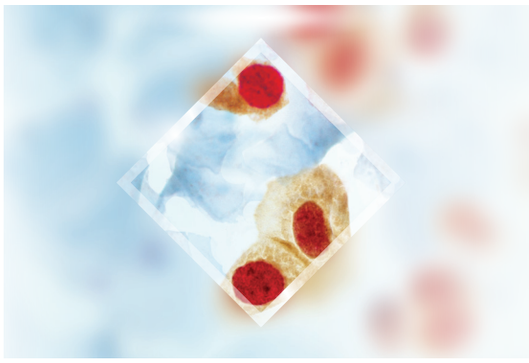
Sensitivity: correct identification of ≥CIN2 ▪ Specificity: correct identification of ≤CIN1 ▪ CIN: cervical intraepithelial neoplasia

CINtec® Histology, part of The Roche Cervical Cancer Portfolio. Find the focus you need to make decisions for each of your patients with confidence, certainty and conclusiveness. Using Roche's three clinically validated tests in powerful combination helps stratify women at risk and improves detection and confirmation of high-grade disease in the first round of testing.



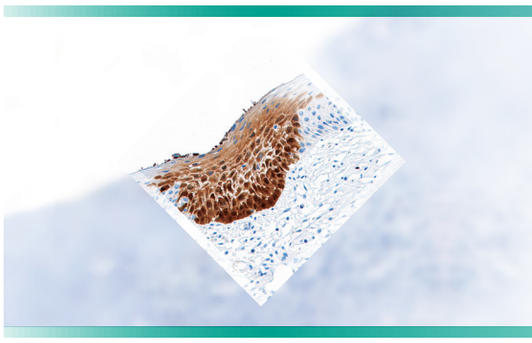
be confident

Screen with the **cobas®** HPV Test, the only FDA-approved and CE-IVD marked test for first-line primary screening in both major collection media. **cobas®** HPV delivers 3-in-1 results with detection of 14 hrHPV genotypes and simultaneous, individual results for HPV 16 and HPV 18 for actionable patient management.



be certain

Triage with **CINtec® *PLUS* Cytology**, the only test that uses dual-biomarker technology to simultaneously detect p16 and Ki-67 to provide a strong indicator of the presence of transforming HPV infection.



be conclusive

Diagnose with **CINtec® Histology** – Enhances identification of occult lesions that may be missed by H&E or morphologic interpretation alone.

References

1. Darragh et al. *Arch Pathol Lab Med.* 2012;136(10):1266-1297. **2.** Stoler et al. *Tumours of the Uterine Cervix*. In Kurman et al. (Eds.), *WHO Classification of Tumours of Female Reproductive Organs*. Lyon, France: IARC and WHO, 2014:169-206. **3.** Stoler et al. *Am J Surg Path.* 2018;42(8):1001-1009

Learn more about CINtec® Histology by contacting your local Roche representative.

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