



know *now*

*if she has **cervical precancer***

The CERTAIN study – clinical study excellence with impactful results

The CERTAIN (**CER**vical **Tissue Adjunctive aN**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

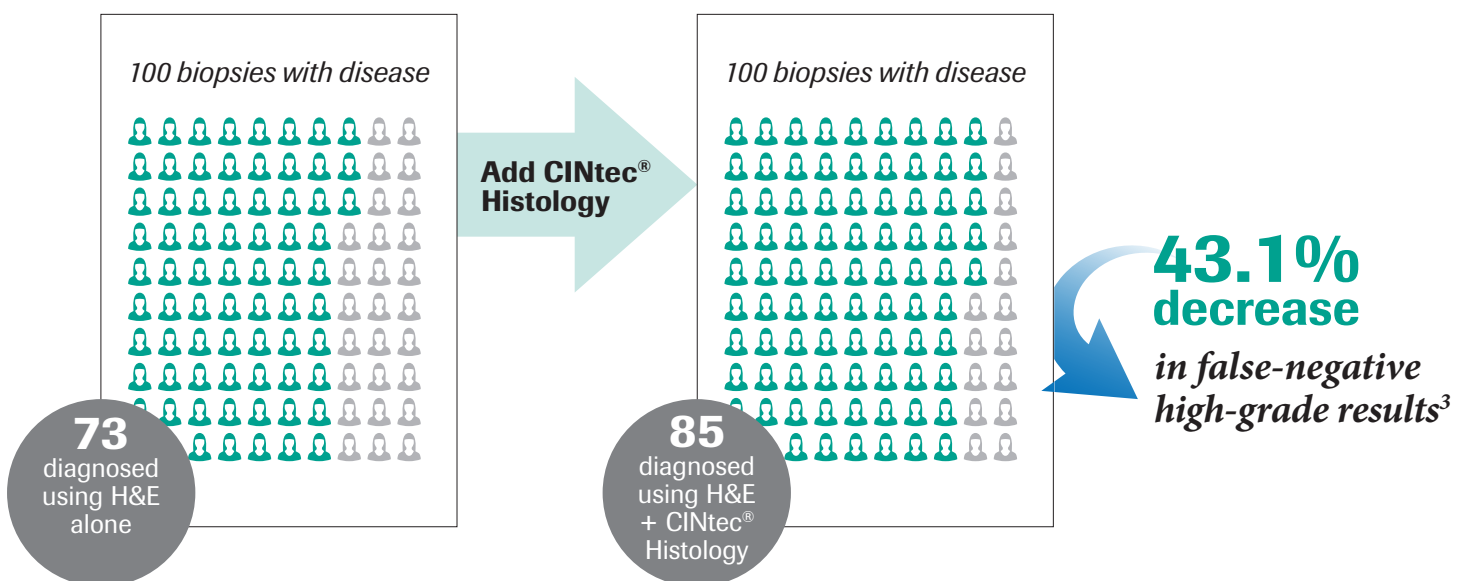
Global standard of care

CAP (College of the American Pathologists), the **ASCCP** 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

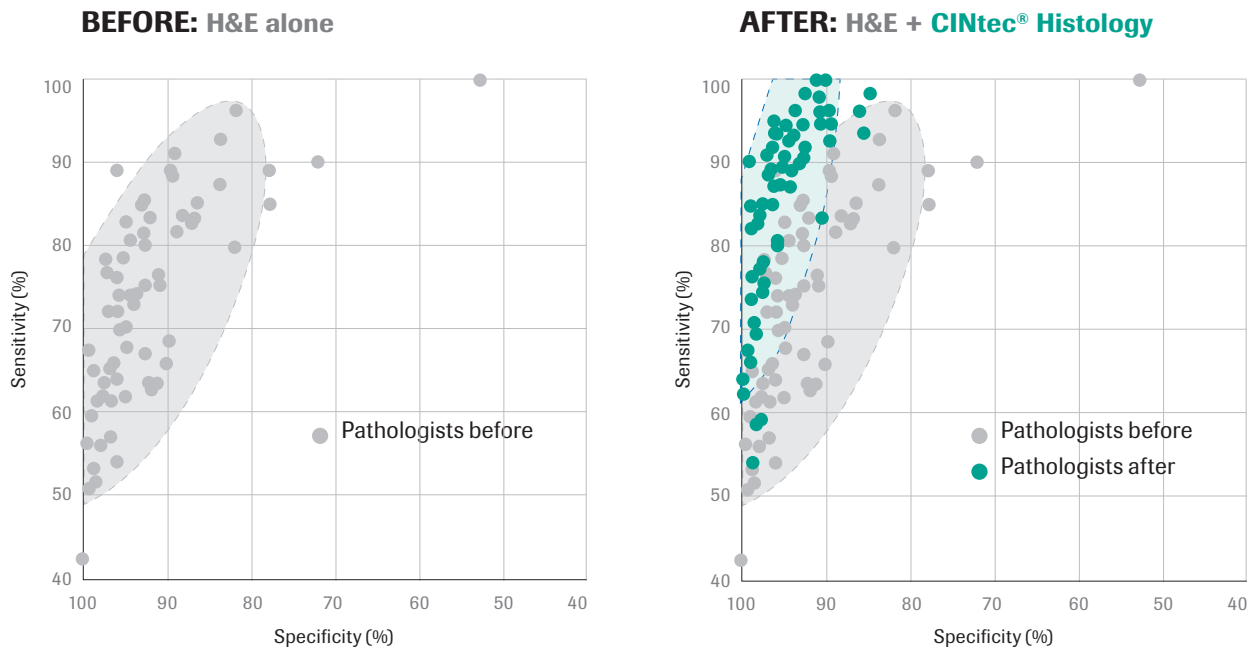
The Roche CINtec® Histology test is CE marked and the **only** U.S. 510(k) **p16 IHC** product for clinical use in the evaluation of cervical biopsy specimens.

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 or according to the LAST recommendations, individual pathologists demonstrated significant improvement in diagnostic sensitivity and specificity^{3,4}



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 on all cervical biopsies.

Sensitivity: correct identification of \geq CIN2 • Specificity: correct identification of \leq CIN1 • CIN: cervical intraepithelial neoplasia

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



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.

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 p16 advanced biomarker technology to provide clear visual confirmation of the presence of precancerous cervical lesions

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 Pathol.* 2018;42(8):1001-1009. **4.** Wright et al. *Am J Surg Pathol.* 2021 epub ahead of print Apr 7; <http://doi.org/10.1097/PAS.0000000000001709>

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