

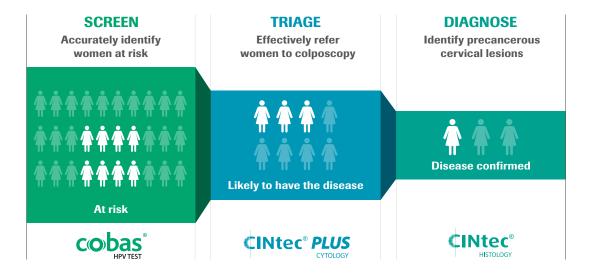


Stock photo. Posed by model.

### Now, 3 clinically validated tests bring greater diagnostic certainty

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







### CINtec® Histology (p16) was clinically validated by the CERTAIN Study

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

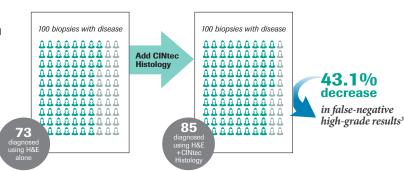
**CAP** (College of the American Pathologists), the **ASCCP** (American Society for Colposcopy and Cervical Pathology), and **WHO** (World Health Organization) recommend the adjunctive use of p16 IHC in evaluation of cervical biopsies. Use of CINtec Histology is supported by >100 peer-reviewed publications.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

#### **US 510(k) IVD**

The CINtec Histology test is the **only US 510(k) p16 biomarker** test for clinical use in the evaluation of cervical biopsy specimens.

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

The CINtec Histology test is the only US 510(k) p16 biomarker test for clinical use in the evaluation of cervical biopsy specimens.



## Use CINtec Histology (p16) for improved diagnostic agreement and consistency

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

References: 1. Darrah TM, Colgan TJ, Cox JT, et al. The Lower Anogenital Squamous Terminology Standardization Project for HPV-Associated Lesions: background and consensus recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology. *Arch Pathol Lab Med.* 2012; 136(10):1266-1297. 2. Stoler M, Bergeron C, Colgan TJ, et al. *Tumours of the Uterine Cervix*. In: Kurman RJ, Carcangui ML, Herrington CS, Young RH, eds. *WHO Classification of Tumours of Female Reproductive Organs*. Lyon, France: IARC and WHO; 2014:169-206. 3. Stoler MH, Wright Jr TC, Ferenczy A, et al. Routine use of adjunctive p16 immunohistochemistry improves diagnostic agreement of cervical biopsy interpretation: results from the CERTAIN Study. *Am J Surg Pathol*. 2018;42(8):1001-1009.

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