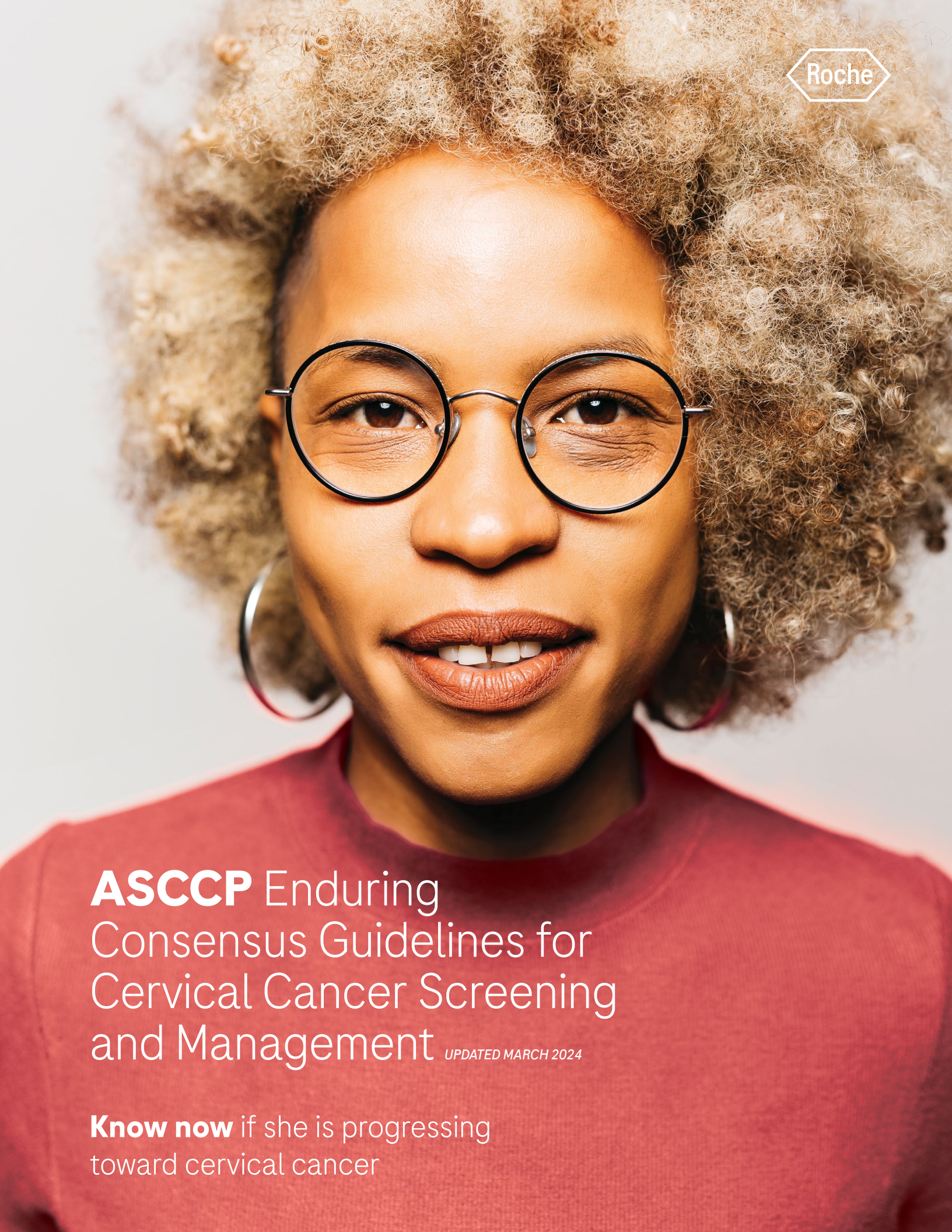
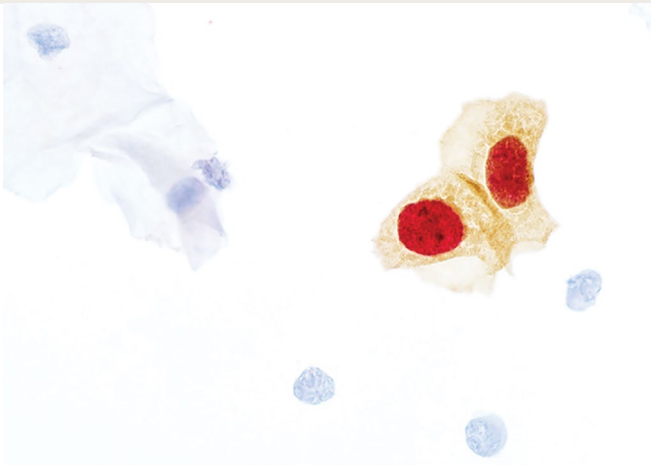


ASCCP Enduring Consensus Guidelines for Cervical Cancer Screening and Management *UPDATED MARCH 2024*

Know now if she is progressing toward cervical cancer

ASCCP
Management Guideline Update

Guidelines now include p16/ki-67 dual-stain biomarker (CINtec® *PLUS* Cytology) triage testing.



The American Society of Colposcopy and Cervical Pathology (ASCCP), has published their enduring consensus guidelines and now recognizes the use of p16/Ki-67 dual-stain biomarkers (CINtec® *PLUS* Cytology) as an important technology to help clinicians triage patients and determine if their human papillomavirus (HPV) infection is transforming into cervical pre-cancer or cancer.

The ASCCP management guidelines include CINtec *PLUS* Cytology dual-stain biomarker as an acceptable triage testing option in the following scenarios:

- For triage of HPV-positive results when limited genotyping is provided by the screening test
- For triage of HPV-positive cytology results in co-testing

**Please see ASCCP website (https://www.asccp.org/enduring-guidelines-process) for the full details on the updated guidelines.

CINtec® *PLUS* Cytology

Helping clinicians and patients **know now** the risk of cervical disease

CINtec® *PLUS* Cytology is the only FDA approved dual-stain triage test for patients who have a positive high-risk HPV (hrHPV) result.[1]

Simplifies sample collection and laboratory workflow

Performed with the same clinician collected sample used for HPV or Pap cytology tests means no repeat office visit for the woman.

Objective biomarker-based results provide clear "positive" or "negative" results with direct insight into the HPV's effect on cell biology

p16/Ki-67 dual-stain (brown & red co-expression within the same cell) clearly identifies an **oncogenically transforming** HPV infection.[2]

Clear direction for which women require immediate management and less anxiety for women that may require "watch and wait"

CINtec® *PLUS* Cytology positive results provides immediate management of women with transforming hrHPV infections and proven safety for women with CINtec® *PLUS* Cytology negative results independent of hrHPV genotype results.[3,4]

Clinicians can more effectively mitigate risk of cervical disease

Longitudinal safety for women with HPV positive/CINtec® *PLUS* Cytology negative results allows *"safe extension of follow-up intervals for 3 years"* independent of hrHPV genotype results.[5]

Summary of the ASCCP Enduring Consensus Cervical Cancer Screening and Management Guidelines

Primary HPV Screening with HPV Genotyping

HPV 16 and/or **HPV18 + result** → **Colposcopy**

12 other HPV + result → **p16/Ki67 DS testing** → *DS Result*
- (+) → **Colposcopy**
- (−) → **Retest in 1 year**

Co-testing (HPV testing with Pap Cytology)

HPV 16 and/or **HPV18 + result** → **Colposcopy**

12 other HPV + result with NILM,** Pap cytology results → **p16/Ki67 DS testing** → *DS Result*
- (+) → **Colposcopy**
- (−) → **Retest in 1 year**

**NILM (Negative for Intraepithelial Lesion or Malignancy),

References

[1] CINtec *PLUS* Cytology - US PMA Instructions for Use 2020.
[2] Killeen JL, et al. J Low Genit Tract Dis. 2014 Jan;18(1):1-7.
[3] Wright T, et al. Gynecol Oncol. 2017;144:51–56 3.
[4] Petry U, Gyn Oncol. 2011; 121:505-509.
[5] Clarke M, et al. JAMA Oncol. 2019 Feb 1;5(2):181-186. doi: 10.1001/jamaoncol.2018.4270.

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The Roche Cervical Cancer Portfolio

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