TRICORE

CINtec® PLUS IMMUNOCYTOCHEMICAL ASSAY

As part of its testing in women's health, TriCore offers CINtec® PLUS Cytology. CINtec® PLUS Cytology is a P16/Ki67 dual-stain Immunocytochemistry assay test. The presence of co-expression of P16/Ki67 helps identify women with transforming HPV infections and therefore the need for colposcopy.

TriCore utilizes a T2000 processor to prepare the slides and the BenchMark ULTRA to stain the slides with the P16/KI67 dual stain. A trained cytotechnologist will screen the slides and distribute to a pathologist. Finally, the pathologist specifically trained in interpreting these results will evaluate the CINtec® Plus slide and finalize the case. The test will be resulted as positive, negative, or unsatisfactory.

Guidance for CINtec® PLUS testing:

Collection Container	■ A ThinPrep® collection vial is required for CINtec® PLUS testing. ■ The SurePath™ collection vial has not been FDA approved for CINtec® PLUS testing.
Start With One of the following:	■ Pap and HPV co-testing on a woman age 30-65 years old. ■ Primary HPV testing on a woman age 25-65 years old.
Pretest Result(s) Requirements	■ If co-testing: Pap results must be negative and HPV results need to be positive (any genotype). ■ If HPV primary: HPV results must be positive (any genotype).
CINtec Plus® Ordering	■ Reflex testing via AOE when putting in PAPFP, HPVHR, or PRIHPV order. ■ Stand-alone order CINtec® Plus if pretesting was done outside of TriCore.
CINtec Plus® Results	■ CINtec® PLUS *Positive*: Patient should proceed to colposcopy. ■ CINtec® PLUS *Negative*: Patient management should follow professional society guidelines.

**Patient Management Guidelines following CINtec® PLUS testing, Roche Diagnostics.*

Turnaround Time: 5 days

Additional Guidance:

- To order Reflex CINtec® PLUS testing, fill in the mandatory AOE (ask on order entry) question or indicate Reflex CINtec® PLUS testing on the requisition. Reflex testing will only be done if the patient meets **all** the following requirements: patient age, ThinPrep™ specimen collection, and the appropriate PAP and/or HPV results.
- If CINtec® PLUS is ordered separately as a stand-alone test (CINTEC), do not answer "Yes" to the reflex AOE question as it will be considered a conflicting order which will require clarification and delay testing.
- A gynecological specimen may be sent in for CINtec® PLUS testing without TriCore also performing the initial Pap/HPV co-testing or the initial primary HPV screening.
- A pap test, primary HPV screening, and CINtec® PLUS Cytology are all performed on the same sample. Final results will be reported separately.
- The presence of vaginal douches, antifungal cream, and vaginal lubricant DO NOT affect CINtec® PLUS Cytology test performance. However, the presence of blood, leukocytes, mucus, lubricants, or vaginal deodorant in the sample MAY affect the slide cellularity before the slides are stained with CINtec® PLUS Cytology, thus altering the overall performance of the test. If there are visibly detected levels of blood meeting specific concentrations, the specimen can be lysed with glacial acetic acid (GAA) prior to processing to increase slide cellularity. The other elements cannot be remediated.

For any questions, please contact TriCore's Medical Directors of Cytopathology, Dr. Nancy Joste or Dr. Elena Gandara at 505.938.8800.

References

T.C. Wright Jr. et al., Triaging HPV-Positive Women with p16/Ki-67 Dual-stained Cytology: Results from a Sub-study Nested into the ATHENA Trial. Gynecologic Oncology 144 (2017) 51–56.Gynecol Oncol. 2017 Jan;144(1):51-56. doi: 10.1016/j.ygyno.2016.10.031

Wentzensen N., et al., Performance of p16/Ki-67 Immunostaining to Detect Cervical Cancer Precursors in a Colposcopy Referral Population. Clin Cancer Res. 2012 Aug 1;18(15):4154-62. doi: 10.1158/1078-0432.CCR-12-0270. Epub 2012 Jun 6.