

EVALUATION OF THE APTIMA CERVICAL SPECIMEN COLLECTION AND TRANSPORT KIT

Authors: Nugent T¹, Weinbaum B¹, Dockter J¹, Breault C¹, Giachetti C¹, Getman D¹, Ratnam S²

Organization: Gen-Probe, Incorporated, San Diego, CA. ²Public Health Laboratory, St. John's, Canada

Background: We have developed a Cervical Specimen Collection and Transport (CSCT) Kit for use with the APTIMA HPV (AHPV) Assay as an alternative to using the PreservCyt LBC specimens. The AHPV Assay is a CE marked assay that detects E6/E7 mRNA of 14 high risk HPV types.

Objective: Determine the clinical performance of the APTIMA CSCT kit.

Methods: The CSCT kit consists of a cervical cleaning swab, a collection brush and a specimen collection tube. A total of 267 cervical specimens were collected from women (19 years of age or older) referred for colposcopy. For each subject enrolled in the study, a CSCT sample was collected followed by collection of a PreservCyt liquid based cytology (LBC) sample. The LBC sample was processed for cytology and an aliquot of the residual LBC solution was diluted into an APTIMA Specimen Transport tube. A single replicate of both the CSCT and diluted LBC sample were tested with the AHPV Assay according to Package Insert instructions. Concordance between the CSCT and LBC results was determined for all samples overall and by cytology category.

Results: The overall, positive and negative agreement between the CSCT and LBC samples was 94%, 98.2%, and 86.4%, respectively. For patients with a cytology diagnosis of \geq ASC, the percent positive agreement for the paired CSCT and LBC samples was 100%; the percent negative agreement was 81%. For patients with cytology diagnosis of LSIL and HSIL, there was 100% positive and negative agreement between the paired CSCT and LBC samples.

Conclusion: APTIMA Assay results showed good agreement between cervical specimens collected with the CSCT kit and PreservCyt LBC indicating the CSCT kit may be used for E6/E7 mRNA r testing of direct cervical samples. The use of the CSCT kit provides a cost effective alternative for molecular detection of HPV.