Title: A Novel Liquid Based ClearPrep Technique: Comparison to SurePath Methodology for Cervical Pap Smear

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Background: Current liquid based preparations (LBP) including ThinPrep and SurePath have proven their efficacy compared to traditional smears for the diagnosis of cervical pathology. However, both methods rely on manufacturer-provided instrumentation and solutions for the preparation of specimens. We describe a new LBP, the ClearPrep method, which is a manual preparation, conducted using on-hand fixative and staining solutions.

Design: A total of 101 remnants of SurePath liquid-based patient samples were studied. These were consecutive samples collected from a period of 2 months (from June to July, 2010). The samples were divided in half by volume, one half for ClearPrep preparation and the other half for SurePath preparation. For ClearPrep preparation, the sample was vortexed for 10 seconds, followed by centrifugation (3000 rpm x 2 min). The specimen was decanted leaving the pellet and 1.5 mls supernatant. Three mls of polymer agar solution were added and the specimen vortexed (10 sec). The specimen was pipetted onto the slide, creating an oval shaped aliquot (1-1.5 mm). Slides were air-dried, stained with Papanicolaou method and cover-slipped. Both SurePath and ClearPrep slides were screened separately by both a cytotechnologist and pathologist.

Result: The age of women ranged from 20-74 years (median=38 yrs). Among the 101 cases, SurePath diagnoses consisted of: 6 unsatisfactory, 20 negative for lesion or malignancy (NILM), 12 NILM with endometrial cells, 26 ASCUS, 4 AGC, 25 LSIL, 4 ASC-H, 4 HSIL. ClearPrep slide diagnoses correlated in 97/101 (96%) cases. Discrepancies consisted of 4/101 (4%) ASCUS diagnosed on SurePath, with ClearPrep demonstrating NILM with reactive changes. One of these 4 cases showed positive HPV test.

Conclusion: This preliminary study shows that ClearPrep is comparable to SurePath in providing reliable diagnostic material for cervical Pap smears with potentially lower cost. Additional larger prospective studies are needed to determine the true cost-benefit of this novel method.