

# Comparison of the Conventional Pap Smear and GluCyte™ Thin-Layer Preparation with Cervical Biopsy as the Gold Standard

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## ABSTRACT

**INTRODUCTION:** The study is performed in order to compare the relative sensitivity of a new lower cost manual liquid based thin-layer preparation to conventional Pap smears using the cervical biopsy as the standard for comparison.

**MATERIALS AND METHODS:** Patients were selected based upon Pap smears previously screened as positive by conventional cytology or suspect for cervical cancer in the city of Barueri. Results from GluCyte™ liquid based preparations, another conventional Pap smear, and biopsy were compared in this study. Patients had colposcopic examination and a new sample from the uterine cervix was obtained using the Rovers Cervex Brush.

A new conventional smear was made and the brush consisting of residual material was sent to the lab in the Synermed Preservative Vial. The Pap test samples were processed utilizing the GluCyte™ method and both samples (conventional and liquid based) were stained using the conventional Pap staining method. When the Biopsy was performed, it was sent at the same time to the lab and processed in the routine manner.

The liquid based and conventional smears were identified and randomly mixed, blinded, and read by three expert cytologists. The results of conventional and liquid based cytology smears were compared to evaluate the diagnostic agreement between the cytology preparations and the biopsies.

**RESULTS:** In 100 patients, 59 biopsies were performed. From these cases, 27 were low grade and 3 high grade. The study showed that the conventional cytology had an agreement in 61% of the biopsies. Synermed GluCyte™ liquid based thin-layer preparations yielded results that coincided with biopsy results in 81% of the cases.

**CONCLUSION:** The report suggests the GluCyte™ liquid based method is more sensitive than the conventional cytology in comparison with biopsies as the gold standard for diagnosis of cervical cancer. More randomized studies comparing the two methods and biopsies are being performed.

## INTRODUCTION

Over the past decade there has been an abundance of literature supporting the benefits of liquid based cytology methods over the conventional Pap technique. However, the current commercially available methods are too expensive for many impoverished areas of the world. One new alternative is the GluCyte™ Liquid Based Thin-Layer Preparation system. This technique offers both a manual method and automated system for specimen preparation. The increased sensitivity of the manual method over the conventional Pap is the focus of this study.

## MATERIALS AND METHODS

The study is comprised of one hundred patients with previous conventional cytology that is positive or suspect for cervical cancer. At the time of colposcopy, a conventional Pap smear was performed and the cervical brush tip was removed and placed into the Synermed preservative vial and sent to the laboratory for processing using the GluCyte™ method. Both preparations were stained using the Papanicolaou technique, and the slides were randomly mixed, blinded and diagnosed by three experienced cytotechnologists.

## RESULTS

One hundred patient samples were evaluated and compared in the study. Agreement between the two cytology methods on all cases was 76%. Fifty nine of these cases had corresponding biopsies that were used as the gold standard. Of these biopsies, there were 3 HSIL, 27 LSIL, and 29 negative diagnostic interpretations. Table 1 shows the correlation between the conventional method and the biopsy. Table 2 shows the correlation between the GluCyte™ method and the biopsy.

Table 1

	Biopsy				
	Negative	LSIL	HSIL	Total	
Conventional	Negative	19	12	1	32
	ASCUS	9	0	0	9
	LSIL	1	15	0	16
	HSIL	0	0	2	2
	Total	29	27	3	59

Sensitivity for Squamous Intraepithelial Lesion = 57%  
Specificity = 63%

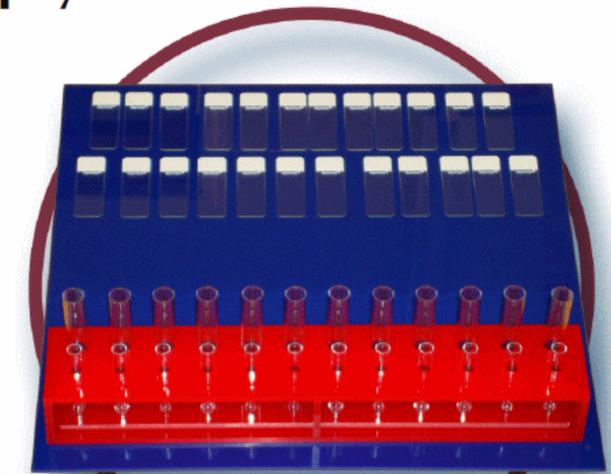
Table 2

	Biopsy				
	Negative	LSIL	HSIL	Total	
GluCyte	Negative	24	6	0	30
	ASCUS	5	0	0	5
	LSIL	0	21	0	21
	HSIL	0	0	3	3
	Total	29	27	3	59

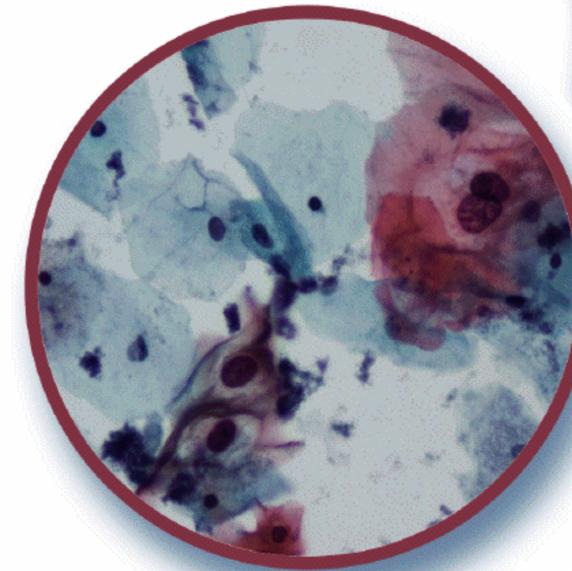
Sensitivity for Squamous Intraepithelial Lesion = 80%  
Specificity = 83%

## CONCLUSIONS

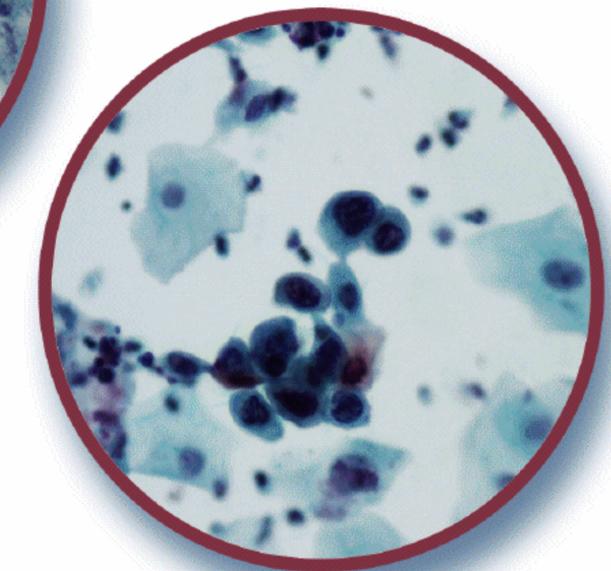
The study suggests that the GluCyte™ method is the more sensitive and specific method for cytology evaluation when compared to cases that have biopsy confirmed abnormalities as the gold standard. The low cost of equipment and training of laboratory personnel makes the GluCyte™ method an appealing screening technique for patients at high risk of developing cervical cancer.



GluCyte™ Processing Rack



LSIL GluCyte™ Preparation



HSIL GluCyte™ Preparation

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