

I. Background

Unsatisfactory Pap smears are increasingly becoming a problem for patient, clinician and laboratories alike. The patient is forced to take more time out of her life to reschedule a new appointment. The clinician has his specimen collection technique questioned and is open to sales reps pushing other Pap processing methodology. The laboratory is open to questions of processing prowess and ability to interpret Pap specimens. The frequency of unsatisfactory cases yielded by the Hologic's ThinPrep® processing method is a political problem that needs management and solutions. It appears any non-cellular substance such as blood, inflammation or lubricant can clog the filter and prevent the transfer of any cell to the slide. Client education efforts have only been partially successful. Patients who show up to appointments during their period are not sent home with a new appointment due to the clinic's fear of losing the patient for further care. So the Pap is taken and the clinic hopes for a good result. Clinics have been given lists of approved lubricants and many swear they are using the correct type or none at all, yet the lubricant issue persists.

This lab views this as a problem and is enlisting Hologic and all affected facilities to find solutions to this persistent performance failure.

II. Materials & Methods

One hundred signed-out unsatisfactory cases were pulled for examination. All selected cases were processed using the ThinPrep Processing system. Only those cases signed out with the comment "No Cells" were selected. All 100 original slides were screened to verify the original diagnosis of Unsatisfactory for Insufficient Cellularity.

All corresponding vials were pulled and examined grossly. The volume of the residual fluid was ranked using a scale of 1 through 4:

1 = > 5 ml
2 = 5-9 ml
3 = 10-14 ml
4 = 15-20 ml

All vials were examined and given a visual description.

RBC – Described a vial with reddish color that may or may not have tissue clumps or mucus plugs.

SNO – Described a vial that was largely clear except that there were numerous floating whitish globules resembling the look of a snow globe. They could be judged light or heavy based on the density of the snowflakes.

CLD – Cloudy. Devoid of blood or globules, but not clear.

CLR – Clear. This describes specimens devoid of any foreign substance; most resembling the original ThinPrep fixative.

A new slide was prepared using an alternative processing system called ClearPrep®. This system pours a portion of the vial contents into a 15 ml centrifuge tube and is spun for 5 minutes at 1800 rpm. The supernatant is poured off and the cell button is vortexed with a solution that disperses the cells while ensuring adherence to the slide. The slides are then air dried for 1 hour and then stained on a Tissue-Tek DRS 2000 stainer using the standard Hologic Pap Stain used on all of our specimens. The slides were coverslipped and evaluated by a cytotechnologist. The tech established whether or not the specimen had enough cellularity (5000 cells) to be called satisfactory, the presence or absence of abnormal cells and any non-cellular condition that was present on the slide. Findings were logged on the specimen pull list.

III. Findings

100 Unsatisfactory Cases

Gross Category	
RBC	40
SNO	48
CLR	10
CLD	2

40 RBC Cases – Reprocessed Using ClearPrep

Satisfactory	31	77.5%
Unsatisfactory	9	22.5%

48 SNO Cases – Reprocessed Using ClearPrep

Satisfactory	31	64.6%
Unsatisfactory	17	35.4%

10 CLR Cases – Reprocessed Using ClearPrep

Satisfactory	1	10.0%
Unsatisfactory	9	90.0%

2 CLD Cases – Reprocessed Using ClearPrep

Satisfactory	2	100.0%
Unsatisfactory	0	0.0%

100 Total Cases – Reprocessed Using ClearPrep

Satisfactory	65	65.0%
Unsatisfactory	35	35.0%

Additional Abnormals Detected Among Reprocessed Cases

II	3
IIA	4
C1	0
C2	0
C3	0
ASC-H	1
G	0

IV. Discussion

The distribution of unsatisfactory cases points to two main causative factors. 88% of all unsatisfactory slides in this study can be attributed to either lubricant or excessive blood. Inflammation did not play a significant role in the creation of unsatisfactory cases.

The ClearPrep method had the best recovery results in the RBC category. 77.5% of all reprocessed cases yielded satisfactory specimens. The reprocessed cases showed numerous RBCs along with numerous epithelial cells clearly available for diagnosis.

More difficulty was experienced reprocessing the SNO specimens. The SNO category is correlated with the presence of excessive amounts of lubricant in the specimen sample. The lubricant poses more difficult dispersal problems on reprocessing. The lubricant and cells can ball up into impenetrable groups that cannot be read microscopically. This is the major reason why the success rate dips to 64% on this type of case.

The third most common category was CLR which usually correlated with a small residual fluid volume left in the vial. This profile correlates to a 10% retrieval rate on reprocess. It seems that cells never made it into the vial, possibly due to poor collection technique or some other factor such as excessive mucus. The poor retrieval rate would suggest not selecting cases with this profile for reprocessing moving forward.

V. Recommendations

Hologic's ThinPrep Processing Method dominates the Pap market with 70% of all specimens being processed by either the Imaging or manual method. However, one of the system's weak links is the higher rate of unsatisfactory cases generated using the vacuum filter technique compared to other competing platforms that use other methods. Non-cellular material such as lubricant or blood tends to clog the ThinPrep filter and block all epithelial cells from adhering to the slide. The cells are in the vial but not accessible using the filter-based technique. A solution would be to reflex those unsatisfactory cases fitting the most promising criteria using ClearPrep.