BD SurePath Direct to Slide Processing Validation: An LBC Method for Laboratories with Limited Resources
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Objectives: To expand liquid-based cytology (LBC) screening into regions of the world with limited resources, we developed a manual LBC processing method that incorporates the cell enrichment advantages of the BD SurePath™ Liquid-based Pap Test (BD SurePath), using only a modified slide holder and common tabletop centrifuge. This simplified method lowers the cost to produce a high quality LBC slide. We report here the validation of rare event detection and slide quality features of the BD SurePath Direct to Slide (DTS) processing method.

Methods: Slides were produced by utilizing modified slide holders that hold a BD PreCoat™ slide and standard BD Settling Chamber. 1mL of BD Density Reagent was placed onto each settling chamber. 2mL of a BD SurePath specimen was then layered on top of the Density Reagent. The specimens were centrifuged for 2 min at 200×g, decanted, washed with alcohol, and manually stained using standard Papanicolaou methods. This method was used to prepare 48 slides from a rare event pool that was constructed by spiking cultured SiHa cells into a pool of normal cervical samples at a concentration of 1:6,025. In addition, 384 BD SurePath DTS slides were prepared from individual BD SurePath cervical specimens to evaluate slide quality features.

BD SurePath Direct to Slide Process
The BD SurePath DTS method was developed to require only a standard benchtop centrifuge and can produce about 6 slides in 10 minutes. BD SurePath DTS slide holders were designed to fit standard centrifuge bucket dimensions. A single slide holder fits a standard BD SurePath centrifuge bucket and the triple slide holder fits a 96 well microtiter place centrifuge bucket.

BD SurePath Direct to Slide Images

Results: All 48 slides produced from the rare event pool had at least 2, and an average of 5 SiHa cells on each slide. 384/384 individual slides were scored optimal or acceptable for Stain Quality, Cellular Preservation, and Cellular Distribution (95% CI (99%, 100%)). For Total Cellularity, 383/384 slides were scored as having >5,000 cells per slide (95% CI (98.5%, 100%)�.

Rare Event Data

<table>
<thead>
<tr>
<th>Score</th>
<th>Cellular Preservation</th>
<th>Cellular Distribution</th>
<th>Stain Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Optimal)</td>
<td>48</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>1 (Acceptable)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3 (Unacceptable)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acceptance Criteria</td>
<td>48/48</td>
<td>48/48</td>
<td>48/48</td>
</tr>
</tbody>
</table>

Number of Acceptable Slides Percentage 95%CI

- Cellular Preservation
  - Optimal: 384 (100.0%) 0 (0.0%)
  - Unacceptable: 0 (0.0%)
  - Total: 384

- Cellular Distribution
  - Optimal: 378 (98.4%) 6 (1.6%)
  - Unacceptable: 0 (0.0%)
  - Total: 384

- Stain Quality
  - Optimal: 367 (95.6%) 17 (4.4%)
  - Unacceptable: 0 (0.0%)
  - Total: 384

- Cellularity
  - >90K: 0 (0.0%)
  - >40K – 90K: 83 (21.6%)
  - 5K – 40K: 309 (78.1%)
  - (Unacceptable) <5K: 1 (0.3%)
  - Total: 384

Conclusion: These data demonstrate that high quality LBC slides can be produced from this manual BD SurePath DTS method using only modified holders and a common tabletop centrifuge. This method retains the advantages of the BD SurePath Liquid-based Pap Test: decreased inflammatory and red blood cells with an enriched population of diagnostically relevant cells. Laboratories with limited resources may benefit from incorporating this manual LBC method.