Performance Evaluation of the Automated Gram Stainer 1000 (AGS-1000) for Direct-from-Specimen Gram Staining

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Results

The study was conducted at Children's Medical Center of Dallas in Dallas, Texas on the Legacy hospital campus in Plano, Texas. The Legacy hospital campus is a licensed for 79 beds, including 12 intensive care unit (ICU) beds, and is exclusively dedicated to the care of children. The Legacy Hospital has an intensive Laboratory that provides a wide variety of testing including some microbiology testing. Laboratory staff on this campus are generalists responsible for all testing including specimen accessioning, running chemistry analyzers, reading hematology smears and microbiology Gram stains. The microbiology testing in this environment is low-volume making it difficult to maintain proficiency in Gram stain interpretation. For this reason, automating Gram stain preparation and minimizing stain-to-stain variation is an important part of improving Gram stain quality and consistency of result in this environment. The purpose of this study was to evaluate the performance of the AGS-1000 prior to implementing it for clinical use.

Methods

The study was conducted in two phases. In phase 1, 25 specimens received at the Children's Medical Center of Dallas laboratory (Blood (n=8), CSF (n=1)), Urine (n=16). These specimens were prepared for staining by a single technologist to eliminate user variation. Two slides were prepared and one was stained with a manual technique (by a single technologist) and one was stained by the AGS-1000. Both slides were blindly read by a single technologist. Results were compared for accuracy and included and evaluation of organism stain reaction, morphology and quantity (UR and CSF) and where appropriate P/MNs, Epithelial cells and RBCs were also assessed (UR and CSF). 7 QC slides were also processed throughout the study. Phase 2 was a post-implementation phase in which clinical specimens were Gram stained by the AGS-1000 and compared to culture results.

Results/Discussion

- The AGS-1000 provided high quality and reproducible Gram stain results in ~3 minutes.
- AGS-1000 correlated very well with manual Gram stain results when tested against blood culture bottles, urine specimens and CSF.
- AGS-1000 performed well across all specimens. Notably, the AGS-1000 was able to accurately decolorize specimens of varied thickness.
- Negative specimens (CSF N=13) were tested in between positive specimens. A few cases of crossover contamination were observed but were resolved after implementing cuvette washes before every CSF specimen.

Results Table

<table>
<thead>
<tr>
<th>AGS-1000 Gram stain result</th>
<th>Culture result</th>
<th>Conclade</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPCCL</td>
<td>Coagulase Neg. Staph (CONS)</td>
<td>YES</td>
</tr>
<tr>
<td>GPR</td>
<td>Staphylococal Typhi</td>
<td>N/A</td>
</tr>
<tr>
<td>GPCPRCH</td>
<td>Enterococcus faecalis</td>
<td>YES</td>
</tr>
<tr>
<td>GPCPR</td>
<td>Vanilinal Gra. Streptoocci</td>
<td>YES</td>
</tr>
<tr>
<td>GPCCL</td>
<td>Peulturehcal pili</td>
<td>N/A</td>
</tr>
<tr>
<td>GPCPR</td>
<td>CONS</td>
<td>YES</td>
</tr>
<tr>
<td>GPR</td>
<td>Rothia dentocari</td>
<td>N/A</td>
</tr>
<tr>
<td>GPCPRCH</td>
<td>Staphylococal aureus (MRA)</td>
<td>YES</td>
</tr>
<tr>
<td>GPCPR</td>
<td>Staphylococal aureus (MSSA)</td>
<td>YES</td>
</tr>
<tr>
<td>GPCCL</td>
<td>Streptococal pneumonia</td>
<td>N/A</td>
</tr>
<tr>
<td>GPCPRCH</td>
<td>Virilinal Gra. Streptoocci</td>
<td>YES</td>
</tr>
<tr>
<td>GPR</td>
<td>Bacillus spp.</td>
<td>YES</td>
</tr>
</tbody>
</table>

Abbreviation Legend for Tables 1 & 2

GPR = Gram positive cocci
GPC = Gram positive coccidi cocci
GPRCH = Gram positive cocci in chains
GPCPRCH = Gram positive cocci in clusters
GPCPR = Gram positive coccidi cocci
GPR = Gram positive cocci in chains
GPC = Gram positive coccidi cocci
GPR = Gram positive cocci in pairs
GPRCH = Gram positive coccidi cocci in pairs
GPRPR = Gram positive cocci in clusters
GPR = Gram positive cocci in chains
GPR = Gram positive cocci in pairs
GPR = Gram positive coccidi cocci
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