

INTRODUCTION

Streptococcus agalactiae (STRB), is a leading cause of sepsis, meningitis, and death among newborns. The Centers for Disease Control and Prevention recommends the screening for group B streptococcal colonization in pregnant women.

WASPLab® solution (COPAN) automates the culture steps for STRB screening (plate inoculation, incubation and image reading) but the plate interpretation is still made by the user.

OBJECTIVES

The aim of the study was to establish the performances of the Color Detection Module (CDM) algorithm (COPAN) for the detection of *Streptococcus agalactiae* on CHROMID® STRB (bioMérieux) in order to segregate positive from negative specimens in a fully automated workflow.

METHODS

A total of 50 vaginal Eswabs™ clinical samples were inoculated by the WASP™ onto CHROMID®STRB both directly and after enrichment in LIM broth (COPAN). Among the 50 specimens, 40 were positive to *Streptococcus agalactiae* and 10 negative.

In order to cover all the methodologies used in clinical laboratories, different volumes of samples were seeded onto the plates by the WASP™ using a Five Quadrant Type 1 streaking pattern (5QT1):

- 10, 30µL directly from the ESwab™
- 10, 30, 90µL after enrichment in LIM Broth

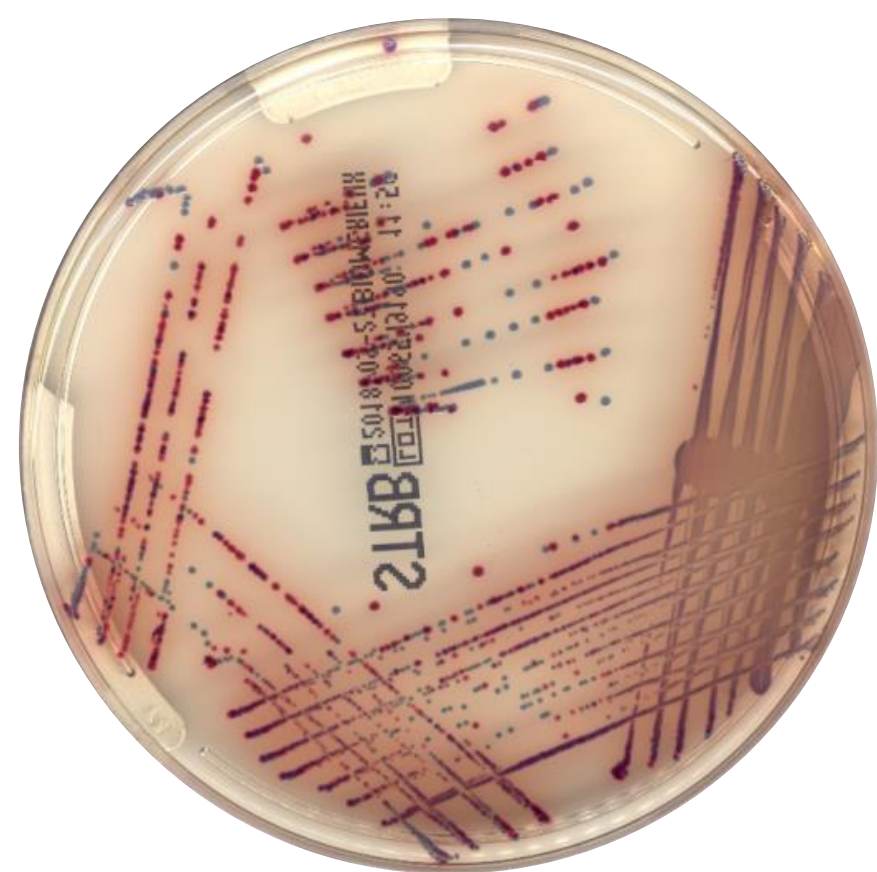


Figure 1: Vaginal Eswab inoculated onto the WASP™ with a 5QT1 pattern with 10µL

The plates were incubated into the WASPLab® at 35°C in aerobiosis with an imaging time at:

- 0, 24h, 48 h for the direct inoculation
- 0, 24h for the plates inoculated after enrichment

Images were read blindly by the operator who looked for the presence of characteristic coloration of STRB on the plate (pale pink to red, round and pearly). CDM algorithm was applied, and performances of the system were evaluated compared to results obtained by image visual reading.

RESULTS

A total of 374 images were analyzed:

- 261 after 24h of incubation
- 113 after 48h of incubation

Compared to the image visual reading, CDM algorithm showed a

- Sensitivity of 100 % at 24h and 24+48h,
- Specificity of 98,4% at 24h and 96.7% at 24+48h.

Results after 24h

| CDM Algorithm | | Visual reading | | |
|---------------|----------|----------------|----------|-------|
| | | Negative | Positive | Total |
| | Negative | 126 | 0 | 126 |
| | Positive | 2 | 133 | 135 |
| | Total | 128 | 133 | 261 |

Results after 24h+48h

| CDM Algorithm | | Visual reading | | |
|---------------|----------|----------------|----------|-------|
| | | Negative | Positive | Total |
| | Negative | 185 | 0 | 185 |
| | Positive | 6 | 183 | 189 |
| | Total | 191 | 183 | 374 |

Table 1: Sensitivity and Specificity of detection of CDM algorithm

At 24h, 2 false positive results were found.

After a second visual review, one false positive result at 24h by CDM was not confirmed due to some pale pink colonies missed by the reader during the first visual reading.

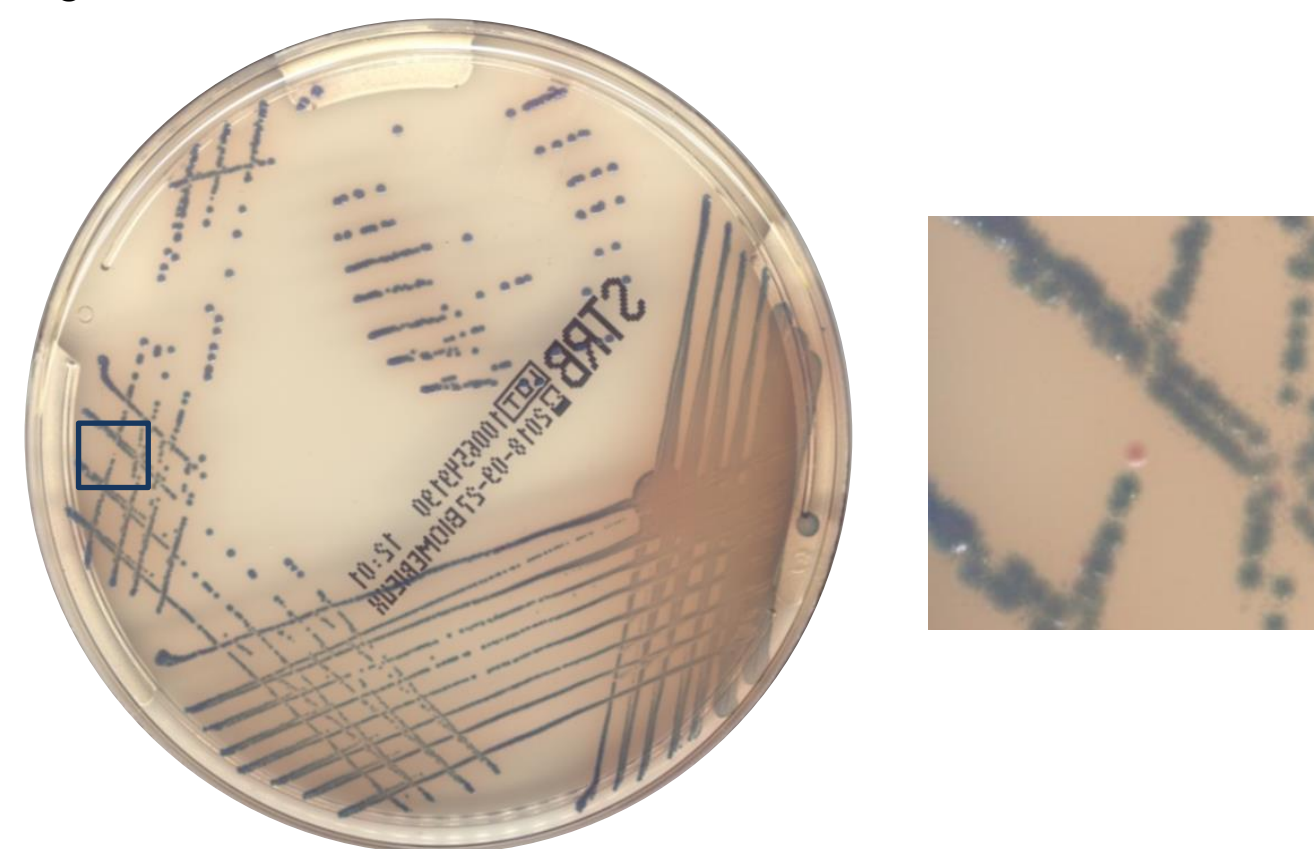


Figure 2: Colony not detected by the first visual reading of the operator

The second review of all the discrepancies (2 at 24h and 6 at 24+48h) led to an improvement of the specificity to 99,2% and 97,4% respectively at 24h and 24+48h

Remaining false positive were due to:

- the spontaneous coloration of the medium due to the presence of enzyme in the specimen itself (1 at 24h and 24+48h)



Figure 3: Image at T0 and T24h with spontaneous coloration of the medium

- The presence of pink halo around the colonies (4 at 48h)



Figure 4: Image at 48h with pink halo around the colony

CONCLUSION

Through the WASPLab™ solution, the CDM algorithm fully automates the detection of *Streptococcus agalactiae* on CHROMID® STRB medium. The high sensitivity of the algorithm enables a better detection of *S. agalactiae* compared to the visual reading even in case of very low concentration of bacteria.

The full automation of the culture and reading steps of B Streptococci screening at a high level of confidence and reproducibility constitutes a real improvement of the laboratory workflow and productivity.