# Design and development of a new EQA scheme to enhance diagnostic accuracy of Group B Streptococcus (GBS) screening in pregnant patients.

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Establish EQA's clinical importance for diagnostic needs → Conduct background research by sending questionnaires to labs → Design specimens to reflect real clinical samples → Assess stability, homogeneity, and viability of the samples → Run pilot studies with interested labs → Collate and analyse results to support EQA implementation → Proceed with a live scheme based on findings

**Figure 1: Schematic overview of Developing a New EQA Scheme**

## INTRODUCTION

**Group B Streptococcus (GBS),** also known as ***Streptococcus agalactiae***, is a major perinatal pathogen associated with neonatal sepsis, pneumonia, and meningitis, primarily transmitted through maternal vaginal colonisation (1).

According to the World Health Organization (WHO), GBS is responsible for approximately **147,000 stillbirths and infant deaths annually worldwide** (2).

Screening for GBS during pregnancy is essential, as up to 28% of pregnant women may carry GBS asymptomatically, increasing the risk of neonatal infection. This risk can be mitigated by administering intravenous antibiotics during labour, which reduces the likelihood of neonatal transmission (3).

External Quality Assessment (EQA) schemes play a pivotal role in ensuring accurate GBS detection in clinical laboratories, thus preventing neonatal infections and improving diagnostic accuracy.

This study utilises simulated vaginal specimens in Amies Charcoal Swabs, which closely resemble clinical samples, to assess the stability and viability of GBS in transport media, ensuring reliable and standardized results for EQA participation in clinical laboratories (4).

## AIM

This study aims to design and develop an EQA scheme to improve diagnostic accuracy for GBS detection in pregnant patients, enhancing laboratory performance and patient care outcomes.

## METHODS

**Pre-Pilot Study:**

- A pre-pilot questionnaire was sent to 711 clinical laboratories to assess interest in a GBS EQA scheme.
- GBS stability was tested in Lyophilised pellets, Liquid Amies Transwab, and Amies Charcoal Swabs over 8 weeks using Columbia Blood Agar (CBA), Colistin-Nalidixic Acid Agar (CNA), Colorex StrepB, Granada Agar and routine diagnostic tests.

**Pilot Study:**

**Sample of Choice:**

- Amies Charcoal Swabs were selected based on pre-pilot results.
- 100 µL of GBS was dispensed into swabs, and three positive specimens were sent to UK laboratories.

**Stability Testing:**

- Return Quality control (QC) was conducted 4 weeks after distribution, followed by biweekly stability checks for 3 months.
- Swabs were enriched in LIM broth for 24 hours, then streaked CBA, CNA, Colorex StrepB, and Granada Agar.
- Incubation conditions were 37°C in $CO_2$ for CBA, CNA, and Colorex StrepB, and aerobically at 37°C for Granada Agar, for 18-24 hours.
- Colony formation units (CFU) were recorded weekly, and identification was confirmed using microscopy, latex agglutination, and biochemical tests.

## RESULTS

- The **pre-pilot** questionnaire assessing interest in a GBS pilot program received 129 responses, with 78 laboratories expressing interest.
- The results confirmed that charcoal swabs are effective transport mediums for GBS samples within a new EQA scheme.

The **pilot study** demonstrated that the participants successfully detected the presence of GBS in simulated vaginal samples in Amies Charcoal Swabs.

**Table 1:** Intended results for pilot distribution 5792

| Specimen No. | Organisms | Result |
|---|---|---|
| 2527 | *Streptococcus agalactiae, Lactobacillus jensenii, Staphylococcus hominis* | Positive |
| 2528 | *Streptococcus agalactiae, Escherichia coli, Klebsiella pnuemoniae* | |
| 2529 | *Streptococcus agalactiae, Prevotella melaninogenica, Lactobacillus paracasei* | |
| 2530 | *Proteus mirabilis ,Enterobacter cloacae* | Negative |

Pre-incubation in LIM Broth enhanced growth consistency for all specimens, aligning with results from 75% of participants using the same method.

- Biweekly stability testing demonstrated sustained high growth (++++) for specimens 2527, 2528, and 2529 on CBA, CNA, Colorex Strep B, and Granada agar, with a slight decline observed after week 15, however, all specimens continued to pass stability QC.
- Streptococcus latex agglutination tests confirmed the presence of GBS, with distinct agglutination patterns in positive specimens, consistent with results reported by 57.1% of participants using this test.

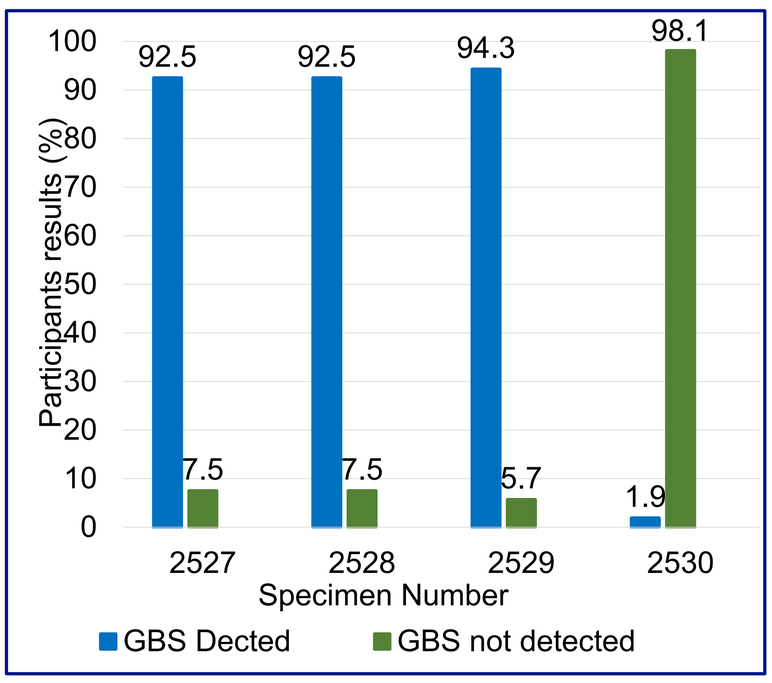


**Figure 2:** Detection rates of GBS in simulated specimens by participants

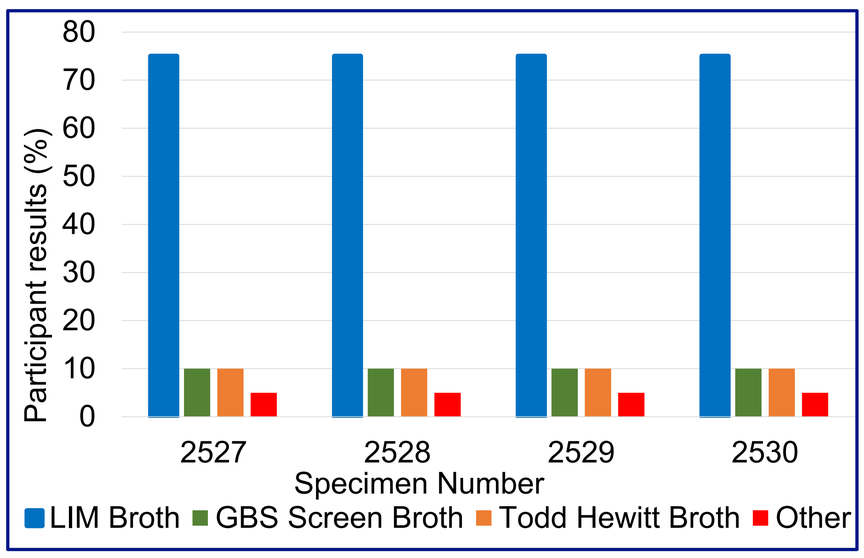


**Figure 3:** Detection of GBS in Simulated Specimens using Enrichment Broth by participants

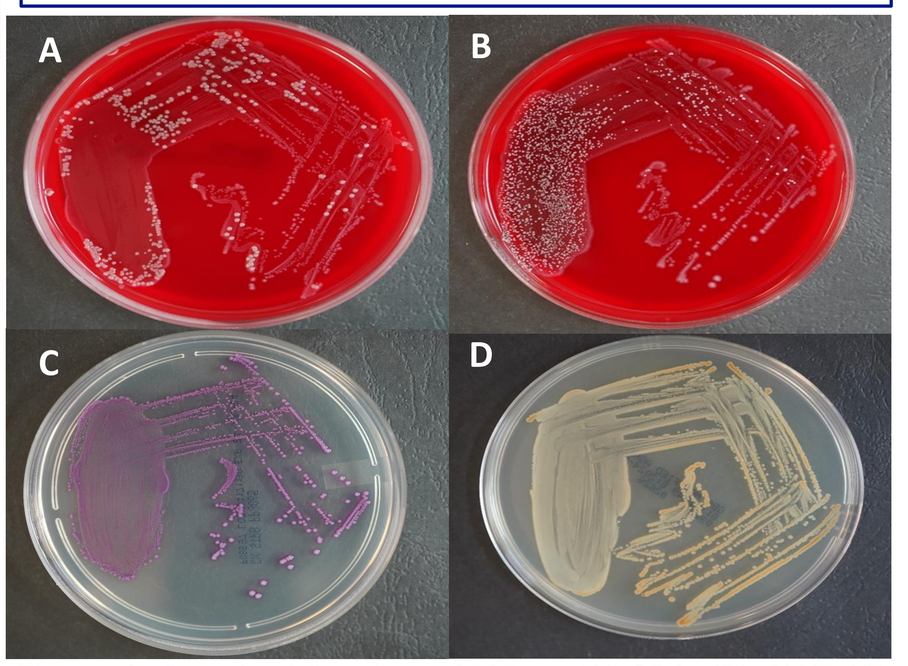


**Figure 4:** Growth of Specimen 2527 on (A) CBA, (B) CNA, (C) Colorex StrepB incubated at 37°C in $CO_2$, and (D) Granada Agar incubated aerobically at 37°C for 24 hours. Distinct beta-haemolytic *Streptococcus agalactiae* is evident on all agars.

## DISCUSSION

Compared to other transport media, charcoal swabs offer a nutrient-rich environment with amino acids, salts, and carbohydrates that enhance bacterial viability and provide greater stability over an 8-week period than alternative methods, ensuring reliable sample integrity during transport (3).

Detection rates for GBS were 92.5% for Specimens 2527 and 2528, slightly higher at 94.3% for Specimen 2529. Specimen 2530 (negative for GBS) was correctly identified by 98.1% of participants.

LIM broth enrichment improved GBS detection sensitivity by approximately two-fold compared to direct plating, as used by 75% of participants, allowing for visible colony growth for morphological analysis on various agars and further confirmation through latex agglutination tests (4).

## CONCLUSION

The study for the **new EQA scheme on GBS screening** in pregnant patients was successful, with Amies Charcoal Swabs demonstrating optimal stability as a GBS transport medium. All participants demonstrated exceptional performance in accurately detecting GBS in simulated vaginal samples, achieving detection rates above 92%. **The scheme was launched in April 2025** to support improved diagnostic accuracy and enhance maternal and neonatal health outcomes.

## ACKNOWLEDGMENT

Special thanks to the UK NEQAS for Microbiology – Bacteriology team for their invaluable contributions to the development of this EQA. We also thank the laboratories that participated in the pre-pilot and pilot distributions for their involvement.

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