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Laboratory evaluation of the iPonatic molecular point-of-care test for group B *Streptococcus* detection in pregnant Vietnamese women

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ABSTRACT

Background: Group B *Streptococcus* (GBS) is a leading cause of neonatal infection. Rapid identification of maternal colonization is essential for timely intrapartum prophylaxis. This study evaluated, under laboratory conditions, the diagnostic performance of a molecular point-of-care test (mPOCT) compared with a commercial real-time PCR assay in Vietnamese pregnant women.

Methods: Rectovaginal swabs from 404 pregnant women were tested using the iPonatic molecular point-of-care test (Sansure Biotech) and a commercial real-time PCR assay (Sacace™ Strep B Real-TM Quant). The study relied mainly on retrospective, frozen, archived specimens (363/404, 89.9%), with a smaller prospective subset of fresh samples (41/404, 10.1%). Discordant results were resolved using additional PCR assays targeting *cfb* and *sip* genes. Diagnostic accuracy metrics, likelihood ratios, and agreement statistics were calculated.

Results: Using a single-run protocol reflective of intended point-of-care use, the iPonatic mPOCT showed a sensitivity of 88.0% (95% CI: 80.7–93.3) and a specificity of 98.6% (95% CI, 96.5–99.6). While specificity was high, the observed sensitivity likely reflects the retrospective use of most archived specimens rather than limitations of the system, as sample storage and handling may have reduced the detectable bacterial load compared with fresh samples.

Conclusion: The iPonatic mPOCT demonstrated potential as a rapid molecular GBS detection test with a turnaround time of approximately 60 min. However, because the evaluation was conducted mainly on archived specimens under laboratory conditions, the findings should be interpreted as preliminary analytical evidence. Prospective studies using fresh intrapartum specimens and the intended point-of-care workflow are required before routine standalone implementation.

1. Introduction

Group B *Streptococcus* (GBS) remains a significant perinatal pathogen associated with adverse pregnancy outcomes, including early-onset neonatal infection, meningitis, and stillbirth. Despite advances in prenatal care, the incidence of GBS-related complications underscores the need for improved diagnostic strategies that facilitate timely and accurate detection to implement appropriate preventive measures.

Globally, GBS colonization affects approximately 10–30% of pregnant women, with an estimated 319,000 cases of invasive GBS disease and substantial neonatal mortality reported in global burden studies (Seale et al., 2017). International guidance has increasingly emphasized the timely identification of maternal GBS colonization to guide intrapartum antibiotic prophylaxis (IAP) (Verani et al., 2010). The 2024 WHO recommendation supports universal antenatal screening around 35–37 weeks' gestation, where feasible, with a risk-based alternative in settings where universal screening cannot be implemented (WHO, 2024). These recommendations highlight the need for rapid, accessible diagnostic platforms, particularly in resource-limited settings where culture-based screening and centralized PCR may be operationally difficult.

In Vietnam, the prevalence of maternal GBS colonization has been reported to range from 8% to 25.5%, depending on region, population, specimen type, and diagnostic method (Ha et al., 2024; Nguyen et al.,

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2025). At present, GBS screening is not uniformly implemented as a national routine program across all Vietnamese maternity settings; practice is largely institution-dependent and influenced by local resources. This creates a practical gap between international prevention strategies and routine implementation in Vietnam. In addition, GBS colonization is dynamic and may be intermittent, meaning that a negative antenatal result may not always reflect colonization status at delivery, and a woman may become colonized or decolonized between screening and labor. This biological variability supports the clinical rationale for rapid intrapartum testing, especially when antenatal screening is unavailable, delayed, or discordant with clinical risk factors (Ivanova Reipold et al., 2023).

The introduction of real-time polymerase chain reaction (PCR) has enhanced the landscape of infectious disease diagnostics, offering more rapid results than traditional culturing (Rahamat-Langendoen et al., 2019). Real-time PCR for GBS detection promises to significantly reduce turnaround time, potentially improving clinical outcomes through earlier intervention. However, traditional laboratory-based real-time PCR workflows, particularly those requiring nucleic acid extraction, thermocyclers, and trained personnel, still pose operational barriers to the widespread routine use in prenatal care in many low-resource maternity settings. Although cartridge-based systems such as the Cepheid GeneXpert have expanded access to near-point-of-care molecular testing, their high cost and limited availability in district-level hospitals in Vietnam continue to restrict routine intrapartum deployment. These constraints highlight the need for alternative molecular point-of-care platforms that are more affordable and operationally suited to decentralized maternity care environments (Pernica et al., 2021).

In this context, molecular point-of-care tests (mPOCTs) have emerged as a promising alternative. mPOCTs represent a revolutionary step in managing perinatal GBS infections by enabling immediate testing and results at the site of patient care (Shen et al., 2021). These tests could streamline GBS screening, enabling real-time decision-making that may be crucial for preventing neonatal GBS infections. mPOCTs for GBS utilize advanced molecular techniques to detect bacterial DNA directly from swab samples, providing results within an hour. Such rapid diagnostics could not only expedite the administration of antibiotics during labor but also reduce unnecessary antibiotic usage in negative cases (Kaku et al., 2021).

This study aims to evaluate the diagnostic effectiveness of mPOCT compared to standard real-time PCR for detecting GBS in a population of pregnant Vietnamese women. By comparing these two methods in terms of sensitivity, specificity, and overall clinical utility, this research seeks to determine whether mPOCT can be considered a reliable alternative to real-time PCR for routine prenatal screening. This could have significant implications for improving perinatal outcomes, reducing healthcare costs, and enhancing patient-centered care practices (Relich and Abbott, 2022).

2. Materials and methods

2.1. Study design and population

We conducted a cross-sectional diagnostic accuracy study at the University Medical Center Ho Chi Minh City, Branch 2, Ho Chi Minh City, Vietnam, between November 2023 and July 2024. Pregnant women at ≥35 weeks' gestation who underwent routine GBS screening were included. The study included 404 rectovaginal swab specimens, comprising 363 retrospective, frozen, archived specimens and 41 prospectively collected, fresh specimens. All specimens were tested using the Portable Molecular Workstation (Model S-Q36A, iPonatic system; Sansure Biotech Inc., Changsha, China). Because most specimens were archived, this study should be interpreted as a laboratory evaluation rather than a full operational point-of-care implementation study.

2.2. Sample size

The minimum required sample size was calculated based on an expected GBS prevalence of 25.5%, as reported by Ha et al. (Ha et al., 2024), with 95% confidence and a margin of error of 0.05. The final target ($n = 322$) was increased by 20% to strengthen statistical power, resulting in 404 included specimens.

2.3. Sample collection and processing

Clinical specimens were collected based on a previously published protocol (Ha et al., 2024). For the retrospective component, rectovaginal swab specimens had previously undergone routine screening with the commercial real-time PCR assay and were then stored at −70 °C until further analysis. Before iPonatic testing, archived samples were thawed at room temperature and processed using a standardized concentration protocol. Briefly, 1 mL of the sample was centrifuged at 12,000 rpm for 3–5 min. The supernatant was reduced to approximately 100 μL, resuspended in 900 μL of phosphate-buffered saline, centrifuged again under the same conditions, and the supernatant was removed, leaving approximately 100 μL. The final concentrate was vortexed and briefly centrifuged before testing. The 41 prospectively collected specimens were processed according to the routine laboratory workflow without long-term frozen storage.

The additional centrifugation and concentration steps were applied to archived specimens because the available material had to be divided across the iPonatic assay and the in-house confirmatory assays. These steps were not part of the intended iPonatic point-of-care workflow. Concentration may increase the probability of detecting low-copy specimens by enriching bacterial cells or DNA; conversely, freezing, thawing, aliquoting, and transfer steps may reduce detectable target material, particularly in low-burden samples. We did not perform a paired experimental comparison of fresh unprocessed versus frozen/concentrated aliquots from the same patients; therefore, the potential effect of pre-analytical processing is acknowledged as a source of bias and is addressed in the Discussion and Limitations. To minimize inter-operator variability, both the mPOCT and real-time PCR assays were performed by the same trained laboratory personnel. All reagents and consumables were provided by Sansure Biotech Inc. (Changsha, China).

2.4. Sample input volume and loading into the iPonatic system

For the iPonatic assay, 20 μL of processed sample was transferred into the sample-release tube according to the manufacturer's workflow. By contrast, the commercial real-time PCR workflow used a larger input volume for nucleic acid extraction or amplification, up to 200 μL depending on the kit procedure. This difference reflects the design of the two platforms: the iPonatic system is a compact, cartridge-based mPOCT optimized for rapid direct processing with a small input volume, whereas laboratory-based real-time PCR workflows generally accommodate larger input volumes after extraction. A smaller input volume may reduce the likelihood of capturing low-copy GBS DNA in a single run, especially when the bacterial burden is near the assay detection limit. This volume difference was therefore taken into account when interpreting discordant and false-negative results.

2.5. Commercial real-time PCR assay

GBS detection by the comparator commercial real-time PCR assay was performed using the Sacace™ Strep B Real-TM Quant kit (Sacace Biotechnologies, Italy), a CE-IVD assay for quantitative detection of *Streptococcus agalactiae* DNA. The assay was performed according to the manufacturer's instructions. Run validity was confirmed using positive, negative, and internal controls. The GBS-negative control was required to show no amplification, the internal control was required to be positive with Ct <40, and the GBS-positive control was required to show a typical

S-shaped amplification curve with Ct value ≤38.

2.6. Reference standard

A molecular consensus reference standard was used because bacterial culture was not available for the archived specimens. For discrepant results, the final consensus was determined using three independent molecular techniques: the commercial real-time PCR assay (Sacace™ Strep B Real-TM Quant), an in-house *cfb*-based real-time PCR assay, and an in-house *sip*-based real-time PCR assay, as previously described (Ha et al., 2024). A specimen was classified as consensus positive when at least two of these three assays were positive, and consensus negative when at least two of the three assays were negative. The repeated iPonatic results were not included in the reference standard, thereby avoiding incorporation bias.

The diagnostic accuracy of the mPOCT was evaluated against this three-assay molecular consensus reference. This approach was selected to reduce misclassification from any single molecular target and to provide a practical comparator in the absence of culture. However, because this reference is molecular rather than culture-based, sensitivity and specificity estimates should be interpreted as agreement with the molecular consensus, not as absolute clinical sensitivity and specificity against the conventional culture reference.

Although enriched culture remains the conventional reference for GBS colonization, it was not performed in this study because most samples were retrospective archived specimens intended for molecular testing. The absence of culture may influence diagnostic accuracy estimates: molecular methods can detect non-viable bacterial DNA and may classify some culture-negative specimens as positive, whereas culture may miss low-level or non-viable organisms after storage. This limitation is explicitly considered in the Discussion and should be addressed in future prospective evaluations incorporating culture-based reference standards.

2.7. Statistical analysis

Diagnostic accuracy indices (sensitivity, specificity, positive and negative predictive value, likelihood ratios, and accuracy) were calculated relative to the consensus molecular reference. Agreement was assessed using the kappa statistic and the Pearson correlation coefficient. Confidence intervals (95% CI) were calculated, and $p < 0.05$ was considered significant. Analyses were performed in SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

2.8. Quality control

Positive and negative controls were included in each run to ensure the reliability of the PCR assays. The performance of the iPonatic system was validated by comparing its results with the criteria. Regular calibration and maintenance of the Portable Molecular Workstation were performed in accordance with the manufacturer's instructions to ensure consistent performance throughout the study.

3. Results

Reporting follows the STARD 2015 guidelines for diagnostic accuracy studies. This research evaluated the diagnostic effectiveness of mPOCT compared with standard real-time PCR for detecting GBS in pregnant Vietnamese women. We explored the discrepancies between the two diagnostic techniques, evident after the initial screenings with the iPonatic system were performed.

3.1. GBS identification

For clinical interpretation, only the single-run (unadjusted) iPonatic results were considered representative of the intended point-of-care workflow. An additional repeat-testing ("adjusted") analysis was performed purely as an exploratory laboratory assessment to characterize analytical sensitivity in archived specimens.

The repeat-testing analysis represents an artificial laboratory scenario and does not reflect a clinically feasible intrapartum or point-of-care workflow. Because repeat testing is not practical in routine clinical settings and was not performed for the comparator commercial real-time PCR assay, the adjusted results should not be interpreted as indicative of real-world clinical performance. Accordingly, conclusions regarding clinical utility in this study are based exclusively on the single-run results.

Using the single-run protocol, the iPonatic system detected 103 true-positive and 15 false-negative samples, corresponding to a sensitivity of 88.0%. These false-negative results indicate that a proportion of GBS-colonized women would not be identified when testing is performed once, as intended in routine point-of-care use.

For comparison with the requested primary comparator, the commercial real-time PCR assay showed 108 consensus-positive and 8 consensus-negative positive results, and 10 consensus-positive and 278 consensus-negative negative results when evaluated against the three-assay molecular consensus reference (Table 1). Thus, before considering repeat iPonatic testing, the single-run iPonatic assay and the commercial real-time PCR assay both showed high specificity, but the iPonatic assay had a lower single-run sensitivity.

Repeat testing of archived specimens reduced the number of false-negative iPonatic results under laboratory conditions; however, this analysis was conducted specifically to explore the assay's detection limits in low-input samples and does not alter the clinical interpretation of single-run performance.

3.2. Analysis of discordant results and Ct values

Discordant samples were further examined using the commercial real-time PCR assay and the two in-house real-time PCR assays targeting *cfb* and *sip* genes. The distribution of discordant patterns is shown in Table 2. In general, discordance was concentrated in specimens with low target abundance, as reflected by late amplification in the positive PCR assays when Ct values were available. Such low-burden specimens are most likely to be affected by sampling variation, freezing-thawing, aliquoting, and differences in input volume between platforms.

The iPonatic system yielded several initial positive results that were

Table 1
Comparison of iPonatic results with routine commercial real-time PCR and with the molecular consensus reference standard.

Test	Test result	Commercial real-time PCR		Consensus	
		Positive	Negative	Positive	Negative
iPonatic (unadjusted)	Positive	94	13	103	4
	Negative	22	275	15	282
iPonatic (adjusted)	Positive	102	13	111	4
	Negative	14	275	7	282
Commercial real-time PCR	Positive	–	–	108	8
	Negative	–	–	10	278

Consensus reference standard: a specimen was considered positive when at least two of the three independent molecular assays (commercial real-time PCR, *cfb*-based real-time PCR, and *sip*-based real-time PCR) yielded concordant positive results. Adjusted iPonatic results were obtained through repeat testing of archived specimens for exploratory analytical purposes only and do not represent clinically applicable point-of-care performance.
In this study, "unadjusted" iPonatic results represent the outcome of a single test run and therefore best reflect the intended point-of-care workflow. "Adjusted" results were generated by repeat testing of archived specimens and classifying a specimen as positive if any repeat run yielded a positive result. Because repeat testing is not part of routine intrapartum point-of-care practice and was not performed for the comparator PCR assay, adjusted results should be interpreted only as an exploratory assessment of analytical sensitivity.

Table 2
Discordant result patterns and consensus classification.

Number of discordant samples (n)	iPonatic system			Commercial real-time PCR (Sacace™ Strep B Real-TM Quant)	*cfb*-based real-time PCR	*sip*-based real-time PCR	Consensus Results
	1st	2nd	3rd				
4	+	n/a	n/a	−	−	−	−
5	+	n/a	n/a	+	+	+	+
1	+	n/a	n/a	+	+	−	+
7	−	−	−	−	−	−	−
2	−	−	−	−	+	+	+
1	−	−	−	+	−	−	−
1	−	+	n/a	−	−	−	−
2	−	+	n/a	+	+	+	+
2	−	−	+	+	+	+	+
1	−	+	+	+	+	+	+

Positive and negative results are indicated by (+) and (−), respectively. (n/a) indicates that repeat iPonatic testing was not performed. Consensus classification was based only on the three independent reference assays: commercial real-time PCR, *cfb*-based real-time PCR, and *sip*-based real-time PCR; repeated iPonatic results were not included in the reference standard.

not supported by the molecular consensus reference. Conversely, some samples were negative by the first iPonatic run but positive by the commercial real-time PCR assay and/or the two in-house assays. These findings are consistent with differences in analytical sensitivity, target design, input volume, and stochastic sampling of low-copy DNA rather than a clear superiority of any single method.

The discordant specimens in Table 2 were classified as consensus-positive because at least two of the three reference assays (commercial real-time PCR, *cfb*-based real-time PCR, and *sip*-based real-time PCR) were positive. Repeated iPonatic results were not used to determine the consensus. Therefore, the consensus classification differs from an interpretation based solely on the first iPonatic run or on a four-test rule that includes repeated iPonatic results.

Where Ct data were available, divergent positive results generally occurred at high Ct values, suggesting low bacterial load near the assay detection threshold. Because the iPonatic workflow uses a smaller input volume than the commercial real-time PCR workflow, low-copy specimens may be more vulnerable to false-negative single-run results. This interpretation is biologically plausible but should be confirmed in future prospective studies using fresh specimens and paired quantitative measurements.

Overall, discordant results emphasize that the single-run iPonatic result is the clinically relevant estimate for point-of-care use, whereas repeat testing of archived specimens should be considered only an exploratory analytical assessment. These results also support the need for prospective field validation before the platform is used as a stand-alone intrapartum screening tool.

3.3. Determination of iPonatic values

Table 3 summarizes the diagnostic performance of the iPonatic system, with single-run (unadjusted) results representing clinically relevant point-of-care performance, and adjusted results included solely for exploratory laboratory assessment.

Using a single test run, the iPonatic demonstrated a sensitivity of 88.0% (95% CI: 80.7–93.3) and a specificity of 98.6% (95% CI: 96.5–99.6), with an overall accuracy of 95.9% (95% CI: 93.5–97.6). Agreement with the consensus reference was high, with kappa and Pearson correlation coefficients of 0.883 and 0.885, respectively, indicating strong concordance.

Repeat testing of archived specimens increased analytical sensitivity; however, this analysis was conducted in an artificial laboratory setting introduced only to explore assay detection limits under low-input conditions. Because repeat testing is not feasible in routine intrapartum or point-of-care workflows, these adjusted results do not reflect clinical performance and should not be used to infer real-world diagnostic accuracy.

Table 3
Diagnostic performance of the iPonatic molecular point-of-care test (mPOCT).

Values	*iPonatic*		*Real-Time PCR*
	Before adjustment	After adjustment	
Pearson's R	0.885 [0.835–0.931]	0.934 [0.892–0.970]	0.892 [0.841–0.941]
Kappa	0.883 [0.832–0.930]	0.934 [0.892–0.970]	0.892 [0.840–0.941]
Sensitivity	88.0 [80.7–93.3]	94.1 [88.2–97.6]	91.5 [85.0–95.9]
Specificity	98.6 [96.5–99.6]	98.6 [96.5–99.6]	97.2 [94.6–98.8]
Positive likelihood ratio	62.9 [23.7–167.0]	67.3 [25.4–178.2]	32.7 [16.5–64.9]
Negative likelihood ratio	0.12 [0.07–0.20]	0.06 [0.03–0.12]	0.09 [0.05–0.16]
Positive predictive value	96.0 [89.0–98.3]	95.8 [89.7–98.4]	91.8 [85.0–95.7]
Negative predictive value	96.0 [93.6–97.5]	98.0 [96.0–98.0]	97.1 [94.9–98.4]
Accuracy	95.9 [93.5–97.6]	97.5 [95.4–98.8]	95.8 [93.3–97.5]

Unadjusted values represent single-run results and reflect the clinically relevant point-of-care workflow. Adjusted values were obtained by repeated testing of the same archived specimen to explore analytical sensitivity under laboratory conditions and do not apply to routine clinical or point-of-care use. No repeat testing or reproducibility analysis was performed for the comparator commercial PCR assay; therefore, the adjusted results are not directly comparable across platforms.

Importantly, no repeat testing or reproducibility analysis was performed on the comparator commercial PCR assay. Therefore, adjusted iPonatic results cannot be directly compared with the comparator test under equivalent methodological conditions, and any apparent differences should be interpreted with caution.

Overall, the single-run iPonatic results show high specificity and strong agreement with the molecular consensus reference, but the sensitivity was lower than that of the comparator commercial real-time PCR assay (Fig. 1). While offering a substantially shorter turnaround time, the adjusted iPonatic analysis is presented only to illustrate possible detection-limit effects in archived specimens and should not be used to infer real-world diagnostic equivalence.

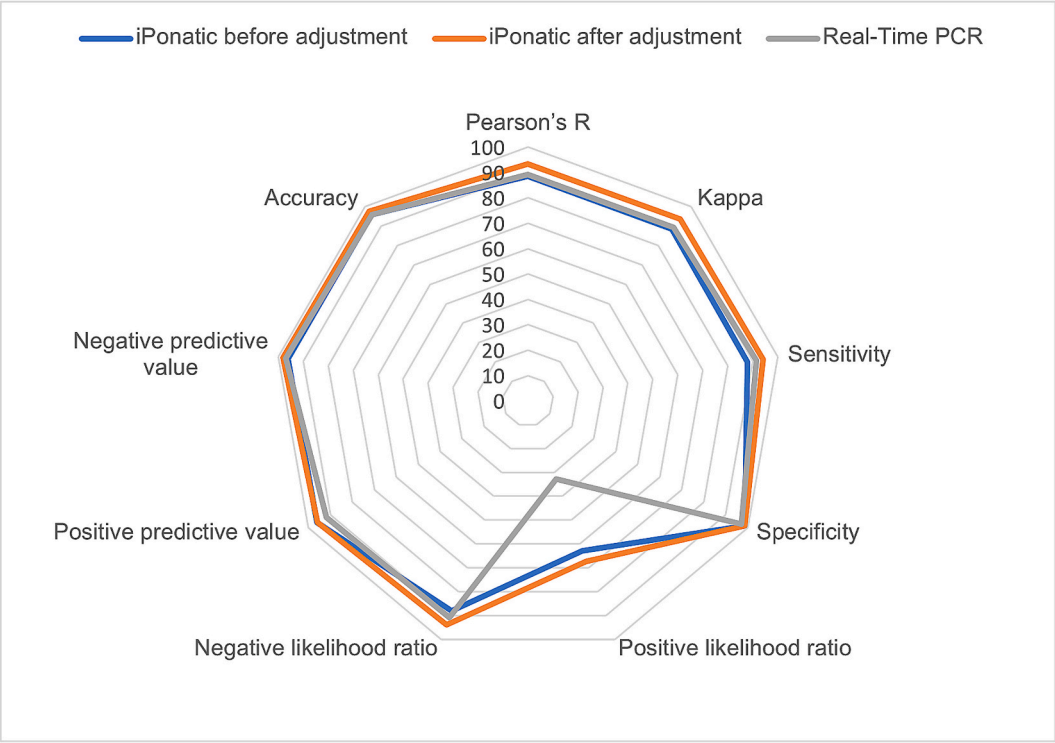

Fig. 1. Radar plot comparing diagnostic performance metrics of the iPonatic system (before and after adjustment) and real-time PCR for Group B *Streptococcus* screening. Metrics include Pearson's R, kappa, sensitivity, specificity, likelihood ratios, predictive values, and overall accuracy. For visualization, negative likelihood ratio values were transformed to (1 – actual value) × 100 to align with the 0–100 scale used for other diagnostic metrics.

4. Discussion

4.1. Principal findings

In this diagnostic accuracy study, the iPonatic molecular point-of-care system demonstrated high concordance with a molecular consensus reference for detecting Group B *Streptococcus* (GBS) in pregnant women. When evaluated using a single-run protocol reflective of its intended point-of-care use, the assay achieved a sensitivity of 88.0% and a specificity of 98.6%, with strong overall agreement ($\kappa = 0.883$). These findings indicate that the iPonatic system has the potential to provide rapid molecular screening with performance comparable to that of laboratory-based PCR methods.

However, an important limitation of this study is its use of retrospective specimens. The samples had undergone collection, storage, and transport processes that were not optimized for point-of-care molecular testing. Degradation of bacterial cells or target DNA during storage may have reduced detectable GBS concentrations, particularly in low-burden specimens, and could therefore have contributed to the reduced sensitivity observed in the single-run analysis.

Repeat testing under controlled laboratory conditions demonstrated higher analytical sensitivity; however, these analyses were conducted exclusively to characterize the system's limit of detection and do not represent a clinically feasible point-of-care workflow. In addition, because repeat or reproducibility testing was not performed for the comparator commercial PCR assay, the adjusted iPonatic results cannot be directly compared with the reference method under equivalent conditions.

Although the iPonatic system demonstrated high specificity, the observed single-run sensitivity of 88% indicates that a clinically relevant proportion of GBS-colonized women may remain undetected. This limitation should be interpreted in the context of the retrospective study design and specimen quality rather than as a definitive measure of system performance under prospective, real-world intrapartum conditions. Prospective studies using freshly collected specimens processed according to the intended point-of-care workflow are therefore warranted to more accurately define the clinical performance of the iPonatic system for intrapartum GBS screening.

4.2. Clinical implications

Beyond analytical performance, the clinical value of mPOCT must also be weighed against feasibility, workflow, and cost. In this laboratory-based evaluation, the iPonatic molecular point-of-care test (mPOCT; Sansure Biotech, China) showed high specificity and strong agreement with the molecular consensus reference. However, because the study was conducted primarily using archived specimens by trained laboratory personnel, the results reflect analytical rather than operational performance in labor wards.

Cartridge-based molecular systems such as the Cepheid GeneXpert platform have demonstrated clinical utility for rapid molecular diagnostics, including intrapartum GBS screening in previous studies. However, the present study did not directly compare iPonatic with GeneXpert. Therefore, all references to GeneXpert are limited to general contextual discussion of cartridge-based POCT implementation, cost, and workflow, and no inference is made regarding comparative diagnostic performance between iPonatic and GeneXpert.

The iPonatic platform evaluated in this study integrates sample processing, nucleic acid amplification, and fluorescence detection into a compact system, delivering results in approximately 50–60 min. This rapid turnaround potentially useful for intrapartum decision-making, particularly in settings where antenatal GBS results are unavailable. Nevertheless, its clinical implementation should be supported by prospective validation using fresh rectovaginal specimens processed in accordance with the intended point-of-care workflow.

The repeat-testing analysis increased apparent analytical sensitivity, but it should not be interpreted as routine clinical performance. Because repeat testing was performed only on archived iPonatic specimens, not

on the comparator commercial PCR assay, the adjusted results cannot be used to claim equivalence or superiority. We therefore base clinical interpretation on the single-run sensitivity of 88.0% and specificity of 98.6%.

4.3. Diagnostic value and stewardship

This study showed that the iPonatic mPOCT had lower single-run sensitivity but comparable specificity relative to the commercial real-time PCR assay when both were interpreted against the molecular consensus reference. The high positive likelihood ratio suggests that a positive iPonatic result strongly supports GBS colonization. However, the negative likelihood ratio and observed false-negative results indicate that a single-run negative result should be interpreted with caution, particularly in high-risk clinical situations or when specimen quality is uncertain. Rapid intrapartum diagnostic tools may support the timely administration of IAP and reduce unnecessary antibiotic exposure in GBS-negative women, but this potential stewardship benefit requires confirmation in prospective clinical implementation studies.

4.4. Feasibility and implementation

Although the mPOCT demonstrated analytical performance comparable to commercial real-time PCR assays, several factors must be considered before large-scale implementation. Key challenges include initial equipment investment, user training, and integration into existing hospital workflows (Chokkalla et al., 2023). Variability in operator technique and device calibration may also influence diagnostic reliability (Ivanova Reipold et al., 2023; Abdul Raffay Khan et al., 2024). Pilot deployment in intrapartum care units is therefore recommended to evaluate real-world performance, workflow compatibility, and its impact on neonatal infection rates and antibiotic stewardship (Daniels, 2023). Future studies should extend beyond diagnostic accuracy to include multicenter evaluations of clinical and economic outcomes, such as neonatal GBS incidence, maternal antibiotic use, and cost-benefit analyses, to inform sustainable adoption. Continued technological improvements could yield faster turnaround times and greater accuracy, while expanding the detection panel to include resistance genes would enhance clinical value (Lee and Liu, 2023).

In Vietnam, the feasibility of mPOCT further depends on affordability and long-term sustainability. Although upfront costs for portable molecular workstations and consumables exceed those of conventional culture, these may be offset by reductions in neonatal intensive-care admissions and unnecessary antibiotic use, generating overall healthcare savings (El Helali et al., 2019; Saweri et al., 2021). The iPonatic system's ease of use and minimal training requirements make it suitable for deployment in district-level maternity wards, particularly in rural or resource-limited regions. Integration into national perinatal guidelines and bulk procurement of test cartridges could further reduce unit costs. Taken together, despite initial financial and operational barriers, the potential improvements in maternal-neonatal outcomes and downstream cost savings suggest that mPOCT represents a feasible and cost-effective strategy for Vietnam's healthcare system (You et al., 2017).

4.5. Limitations

This study has several significant limitations that should be considered when interpreting the findings. First, the study relied primarily on retrospective frozen archived specimens (363/404, 89.9%) and only a small subset of prospectively collected fresh specimens (41/404, 10.1%). This design is the main potential source of bias. Freezing, thawing, aliquoting, transport, and delayed testing may reduce or variably affect detectable GBS DNA, especially in low-burden specimens. Therefore, the findings primarily reflect laboratory analytical performance and may not fully capture operational performance under real-world point-of-care conditions using intrapartum samples.

Second, additional pre-analytical processing steps, including centrifugation and sample concentration, were introduced for archived specimens because the remaining sample volume had to be divided across multiple molecular assays. These steps do not represent the standard iPonatic POCT workflow. They could theoretically increase analytical sensitivity by enriching for bacterial cells or DNA, but they could also introduce variability due to pellet loss, incomplete resuspension, or aliquot-to-aliquot heterogeneity. Because we did not perform paired experiments comparing fresh, unprocessed aliquots with frozen/concentrated aliquots, the net direction and magnitude of this bias cannot be quantified.

Third, the clinically relevant performance of the iPonatic system corresponds to the single-run results. The unadjusted iPonatic results included 15 false negatives (15/404, 3.7%), a proportion that decreased after repeat testing. Although repeat testing increased analytical sensitivity, this approach was employed solely to explore detection limits in low-copy-number archived specimens and is not compatible with routine clinical or point-of-care workflows. The initial false-negative rate remains clinically important because undetected GBS-positive cases could affect intrapartum prophylaxis decisions.

Fourth, bacterial culture, the conventional reference standard for GBS colonization, was not performed (Ha et al., 2024; Carrillo-Avila et al., 2018). Instead, this study used a three-assay molecular consensus reference. This design may influence estimates of sensitivity and specificity because molecular assays can detect DNA from non-viable bacteria and may be more sensitive than culture in some low-burden specimens. Therefore, the reported diagnostic indices should be interpreted as performance against a molecular consensus reference rather than against enriched culture.

Fifth, repeat-testing or reproducibility analyses were not conducted for the comparator commercial real-time PCR assay. Consequently, adjusted iPonatic results cannot be directly compared with the comparator test under equivalent methodological conditions, limiting cross-platform interpretability.

Finally, this was a single-center study conducted in a tertiary hospital in southern Vietnam. The prevalence of GBS colonization and operational performance of molecular POCT may differ across healthcare settings. Therefore, multicenter studies involving diverse maternity populations are needed to confirm the generalizability of our findings.

5. Conclusion

In conclusion, the iPonatic molecular point-of-care test demonstrated high specificity and moderate sensitivity when evaluated in a single-run workflow that reflects its intended clinical use. While the platform offers a substantially shorter turnaround time and operational advantages over conventional laboratory-based PCR, the sensitivity observed in this study may have been influenced by the retrospective nature of the specimens and associated pre-analytical factors. Consequently, although the findings support the potential role of the iPonatic system as a rapid molecular screening approach for intrapartum Group B *Streptococcus* detection, further technical optimization and prospective clinical evaluation using freshly collected specimens are warranted before routine standalone implementation in clinical practice can be recommended.

CRediT authorship contribution statement

Manh-Tuan Ha: Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Supervision, Writing – review & editing. **Tuan-Anh Nguyen:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Writing – original draft, Writing – review & editing. **Van-Trinh Bui:** Data curation, Investigation, Methodology, Resources, Visualization. **Nguyen-An-Khang Doan:** Data curation, Formal analysis, Investigation, Software, Visualization. **Huu-Trung Nguyen:**

Investigation, Project administration, Resources, Software, Supervision.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The study was approved by the ethics committee of the University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam (reference number: 4314/HĐĐĐ-ĐHYD, dated December 27, 2024). All procedures performed in this study involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee, as well as the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards. Written informed consent was obtained from all individual participants included in the study.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

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