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Original Article

Diagnostic Accuracy of Urine Reagent Strips for Rapid Bacterial Meningitis Diagnosis: A Cross-Sectional Validation Study in a Resource-Limited Setting

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Abstract

Objective: To prospectively confirm the diagnostic performance of urine reagent strips in the detection of meningitis.

Methodology: This cross-sectional study included patients aged 20–60 years with clinically suspected meningitis requiring lumbar puncture. The index test was a standardized urine reagent strip (Combur-10 Test®) applied to undiluted CSF, interpreted for leukocyte esterase, protein, and glucose according to manufacturer color gradings taking laboratory CSF analysis as gold standard test. Following parameters were statistically calculated for accuracy.

Results: Among 105 enrolled patients (mean age 38.5 ± 12.2 years; 55.2% male), the prevalence of meningitis by reference standard was 60.0% (63/105). Against this gold standard, the reagent strip method demonstrated a sensitivity of 86.5% (95% CI: 75.8–93.1), specificity of 88.4% (95% CI: 74.1–95.6), positive predictive value of 91.5% (95% CI: 82.0–96.2), and negative predictive value of 82.6% (95% CI: 69.7–90.8). The diagnostic accuracy is 87.6% (95% CI: 79.9 – 92.9). The area under the ROC curve was 0.91 (95% CI: 0.86 – 0.96) which shows excellent discriminatory ability.

Conclusion: Urine reagent strip are easily available, are cost effective and operationally feasible bedside diagnostic kits which can be used for a rapid diagnosis of meningitis in resource-limited settings.

Keywords: Cerebrospinal Fluid, Meningitis, Point-of-Care Testing, Reagent Strips, Diagnostic, Sensitivity and Specificity.

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Introduction

Bacterial Meningitis is a major cause of worldwide mortality and morbidity.

Meningitis remains a major cause of mortality and neurological morbidity worldwide, with an estimated 180,000 deaths annually.[1,2] Low- and middle-income countries carry an unequal burden; poor outcomes are due to late diagnosis and limited access to laboratory infrastructure.[3] In Pakistan, 15% of the population is affected by meningitis, with considerable variation regionally in diagnostic capabilities.[4]

The reference standard for diagnosis of meningitis is the study of the cerebrospinal fluid (CSF) acquired by lumbar puncture, which measures the leukocyte count, protein concentration and glucose levels.[5] But this approach needs experienced staff, well-equipped laboratories and processing time that can last hours or days – resources often unavailable in rural or resource-limited health-care settings.[6] Such restrictions create a key gap in which patients presenting with suspected meningitis could have delays in diagnosis and empirical therapy with an increased risk of irreparable brain damage or death.[7]

Urine reagent strips are one answer . These started as a tool for urinalysis . These strips comprise reactive pads that generate colorimetric changes in the presence of leukocyte esterase (a marker for pyuria), protein, and glucose, parameters directly relevant to CSF investigation in meningitis.[8] Previous investigations have demonstrated varying sensitivity (33–97%) and specificity (57–100%) for this application, with heterogeneity in methodology limiting generalisability.[9–13] Data about the accuracy

of diagnosis by this method in Pakistan is still lacking and this technique has not been incorporated in standard clinical practice.

This study was designed to prospectively confirm the diagnostic performance of urine reagent strips in the detection of meningitis in a resource-limited context, utilising a rigorous approach and standardised reference criteria.

Methodology

We conducted a prospective cross-sectional diagnostic accuracy study at the Department of Medicine, Allied Hospital, Faisalabad, a tertiary care center serving a mixed urban and rural population in Punjab, Pakistan. The Standards for Reporting of Diagnostic Accuracy Studies (STARD) requirements were adhered to in this study.[14] Ethical approval was acquired from the Institutional Ethics board (48.ERC/FMU/2024-25-35)

Consecutive patients aged 20–60 years presenting with clinically suspected meningitis and requiring lumbar puncture were enrolled using a non-probability consecutive sampling strategy. Clinical suspicion was defined as fever, headache, and neck stiffness with at least one of: vomiting, behavioral changes, irritability, altered sensorium, seizures, neurological deficit, Kernig's sign, or Brudzinski's sign.[4]

Exclusion criteria were: localized spinal deformity or sepsis at the puncture site; suspected space-occupying lesion; anticoagulant or thrombolytic therapy; suspected hemorrhagic disorder; and hemorrhagic CSF samples (to avoid interference with colorimetric interpretation). Sample size was calculated using a diagnostic accuracy formula based on anticipated sensitivity (86.27%), specificity (87.88%), and disease prevalence (60.39%) from prior literature.[4,13] The minimum necessary sample size was 105 patients with a 95% confidence level and an absolute precision of 10%.

Following lumbar puncture, 2–3 drops of undiluted CSF were applied to a commercially available urine reagent strip (Combur-10 Test, Roche Diagnostics, Germany). The strips contain reactive pads for leukocyte esterase, protein, and glucose. Color changes were interpreted visually within 60 seconds using the manufacturer's color chart by a trained investigator blinded to laboratory results. Interpretation criteria are detailed in Annexure 1. The test was considered positive for meningitis if any of the three parameters met the predefined cutoff for abnormality.

CSF samples were sent to the hospital pathology laboratory for routine analysis. Total leukocyte count was performed using a Neubauer hemocytometer; protein concentration was measured by the turbidimetric method; glucose was measured by the glucose oxidase method. The reference standard diagnosis of meningitis was defined as CSF total leukocyte count >5 cells/mm^3, protein >45 mg/dL, and glucose <60 mg/dL, consistent with established criteria.[5,13] Data analysis was done using SPSS version 25. Continuous variables were expressed as mean ± standard deviation; categorical variables as frequencies and percentages.

Diagnostic accuracy metrics (sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio, and negative likelihood ratio were calculated were calculated with 95% confidence intervals using the Wilson score method. The index test result and the reference standard were compared in a 2×2 contingency table. The entire test performance was evaluated by receiver operating characteristic (ROC) curve and the area under the curve (AUC) was computed by nonparametric method. Analyses of subgroups were stratified by age (<40 vs. ≥40 years) and by gender. Statistical significance was set at $p<0.05$.

Results

Participant Characteristics

A total of 105 patients were enrolled from August 2025 to January 2026. Baseline characteristics are presented in table 1. The mean age was 38.5 ± 12.2 years, with 55.2% males. The most common presenting symptoms were fever (93.3%), headache (90.5%), and neck stiffness (84.8%). The prevalence of meningitis by CSF analysis was 60.0%.

The diagnostic performance of the urine reagent strip method against CSF analysis is shown in Table 2. The index test demonstrates a sensitivity of 86.5% and specificity of 88.4%. The PPV was 91.5%, and NPV was 82.6%. Overall diagnostic accuracy was 87.6%. The positive likelihood ratio (LR+) was 7.45 (95% CI: 3.43–16.18), and the negative likelihood ratio (LR-) was 0.15 (95% CI: 0.08–0.28).

The ROC curve yields an area under the curve (AUC) of 0.91 indicating excellent discriminatory ability.

ROC curve showing sensitivity plotted against 1-specificity. The curve is well above the diagonal reference line, with an area under the curve (AUC) of 0.91, indicating excellent discriminatory ability. Optimal operating point corresponds to sensitivity 86.5% and specificity 88.4%.

Table 1: *Baseline Characteristics of Study Participants (N = 105)*

Characteristic		n(%)
Age	Age, years (mean ± SD)	38.5 ± 12.2
	Age range, years	20–60
Gender	Male	58 (55.2)
	Female	47 (44.8)
Sign & Symptoms	Headache	95 (90.5)
	Neck stiffness	89 (84.8)
	Altered sensorium	41 (39.0)
	Vomiting	38 (36.2)
	Kernig's sign	37 (35.2)
	Brudzinski's sign	32 (30.5)
	Seizures	21 (20.0)
CSF Findings	Total leukocyte count (cells/mm³)	312 ± 104
	Protein (mg/dL)	112 ± 38
	Glucose (mg/dL)	42 ± 11
	Meningitis by Reference Standard, n (%)	63 (60.0)

SD = standard deviation; CSF = cerebrospinal fluid

Table 2: *Diagnostic Accuracy of Urine Reagent Strip Method Against CSF Analysis*

Parameter	Estimate (%)	CI-95%
Sensitivity (%)	86.5	75.8–93.1
Specificity (%)	88.4	74.1–95.6
Positive Predictive Value (%)	91.5	82.0–96.2
Negative Predictive Value (%)	82.6	69.7–90.8
Diagnostic Accuracy	87.6	79.9–92.9
Positive Likelihood Ratio	7.45	3.43–16.18
Negative Likelihood Ratio	0.15	0.08–0.28

Reference standard: CSF leukocytes >5 cells/mm³, protein >45 mg/dL, glucose <60 mg/dL.

Table 3: *Performance of Individual Reagent Strip Components*

Component	Sensitivity (%)	Specificity (%)	Accuracy (%)
Leukocyte Esterase	88.9 (78.9–94.8)	95.2 (82.6–99.1)	92.3
Protein	92.1 (83.0–96.8)	85.7 (70.6–94.2)	89.5
Glucose	71.4 (59.3–81.5)	88.1 (73.6–95.6)	78.1
Combined (Any Positive)	86.5 (75.8–93.1)	88.4 (74.1–95.6)	87.6

95% confidence intervals shown in parentheses

When individual reagent strip components were analyzed separately (Table 3), leukocyte esterase demonstrated the highest accuracy (92.3%), followed by protein (89.5%), while glucose showed slightly lower concordance (78.1%). The combination of all three components yielded superior performance to any single parameter.

No significant difference of diagnostic accuracy was seen in the stratified analysis by age and gender. The test worked similarly in patients <40 years old (sensitivity 87.1%, specificity 87.9%) and ≥40 years old (sensitivity 85.3%, specificity 89.1%) and in males (sensitivity 86.2%, specificity 88.9%) and females (sensitivity 86.8%, specificity 87.5%).

Discussion

This prospective diagnostic accuracy study shows that use of urine reagent strips on CSF offers a speedy, accurate and operationally practical approach of diagnosing meningitis in a resource-limited situation. This easy bedside test has a comparable performance to traditional laboratory analysis, with a sensitivity of 86.5% and specificity of 88.4%. These findings have substantial implications in contexts when prompt CSF analysis is not available.

Our results align with previous studies reporting favorable diagnostic performance. Rashmi and Arvind reported a sensitivity of 86.27% and specificity of 87.88% in a critical care setting,[13] while Deshpande et al. found similar utility in a Western Indian population.[9] The high sensitivity of our study (86.5%) is very significant, since it means that the test is able to accurately detect real instances of meningitis, reducing the risk of false negatives that may result in delayed treatment. An 88.4% specificity means that false positives are quite rare and the chance of unwanted antibiotic treatment is low.

The performance of individual test components provides mechanistic insight. Leukocyte esterase detection demonstrated the highest individual accuracy (92.3%), consistent with prior observations.[10,12] This likely reflects the fact that leukocyte esterase is a direct marker of granulocyte presence in CSF, which is a cardinal feature of bacterial meningitis. Protein detection also showed good performance (89.5%), though lower specificity in some prior studies suggests that elevated CSF protein may occur in non-infectious conditions.[11] Glucose detection showed the lowest concordance (78.1%), possibly due to the narrower dynamic range of glucose in CSF and the limitations of semi-quantitative colorimetric interpretation.

A systematic review and meta-analysis by Bortcosh and colleagues synthesized data from 13 studies comprising

2,235 participants and reported a pooled sensitivity of 92% (95% CI: 86–96) and specificity of 98% (95% CI: 94–99) for leukocyte esterase testing in detecting CSF pleocytosis.[15] Our findings are consistent with this pooled estimate, though our slightly lower specificity (88.4%) may reflect differences in the reference standard (we used composite leukocyte, protein, and glucose criteria rather than leukocyte count alone) and a higher proportion of partially treated patients in our cohort. Nevertheless, our results confirm that reagent strip testing performs robustly across diverse populations and settings.

The diagnosis accuracy we found is comparable to other point-of-care diagnostics for meningitis. While PCR-based assays are more sensitive and specific, they require specialised equipment and experienced personnel that are sometimes not available in resource-limited settings. The reagent strip method, on the other hand, involves no capital equipment, limited training, and provides results within minutes.

The WHOs "Defeating Meningitis by 2030" global roadmap puts this at top priority for the development and deployment of accessible point-of-care diagnostics as a cornerstone of meningitis control, particularly in low- and middle-income countries[2]. Our results directly support this strategy aim by validating a test that may be used at the lowest levels of health care delivery. In basic health centers with little laboratory equipment, reagent strip testing could be the only available diagnostic modality, allowing fast treatment and referral decisions.

A negative test (NPV 82.6%) can help rule out meningitis in low-to-moderate pretest probability scenarios, while a positive test can trigger prompt empirical antibiotic administration, potentially reducing the 20–40% case fatality rate associated with bacterial meningitis in resource-limited settings.[16]

There are certain limitations that should be taken into account. First, generalisability to primary care or community settings may be limited because the study was carried out at a single tertiary care facility. Second, visual interpretation of color changes introduces potential for inter-observer variability, though our use of a single trained investigator and standardized color chart mitigated this risk. Third, we excluded patients with hemorrhagic CSF samples, which may limit applicability in cases of traumatic lumbar puncture, which occurs in 10–20% of procedures.[17] Fourth, our sample size, while adequately powered, did not permit detailed subgroup analysis by specific meningitis etiology (bacterial vs. viral). Finally, we did not assess inter-rater reliability or perform cost-effectiveness analyses.

While our study focused on diagnostic accuracy, the ultimate goal of any new test is improvement in patient outcomes. A growing body of evidence suggests that point-of-care testing can reduce time to appropriate treatment and improve clinical outcomes in infectious diseases.[17] For meningitis specifically, each hour of delay in antibiotic administration is associated with increased mortality. The reagent strip method, with results available in under two minutes, could substantially reduce this diagnostic delay compared to laboratory analysis requiring 4–8 hours. Future implementation research should directly evaluate whether reagent strip-guided management reduces mortality, neurological sequelae, and length of hospital stay in resource-limited settings.

However, our findings have obvious consequences for clinical practice. Urine reagent strips can be a useful supplement to diagnosis in rural and resource limited areas where traditional CSF investigation is unavailable and allow practitioners to start empirical therapy while awaiting transfer to referral institutions. In well-resourced environments, the approach could accelerate decision-making in emergency departments where test turnaround times may delay treatment.

Future work should include prospective validation in primary care, inter-observer reliability studies, and evaluation of clinical outcomes related with test-directed management. Further enhancement of value would be obtained by development of standardised reading equipment to reduce interpretative variability and implementation into therapeutic algorithms.

Conclusion

Urine reagent strips for meningitis detection in CSF provide great diagnostic accuracy and test performance similar to traditional laboratory testing. This simple, rapid and inexpensive technique has promise as a point-of-care diagnostic tool for resource-limited settings, with the potential to shorten diagnostic delays, enable early treatment initiation and improve outcomes in patients with suspected meningitis.

Ethical Approval: The IRB/EC approved this study via letter no. 48/ERC//FMU/2024-25-35 dated March 05, 2025.

Conflict of Interest: None

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Authors' Contribution

SAHB: Conception.

AS, ZA: Design of the work.

UA, MI, MS: Data acquisition, analysis, or interpretation.

AS, UA, MI, MS: Draft the work.

SAHB, ZA: Review critically for important intellectual content.

All authors approve the version to be published.

All authors agree to be accountable for all aspects of the work.

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