

Research Article

Performance Evaluation of the HemoTypeSC™ Rapid Screening Test for the Detection of Hemoglobin A, S, and C Variants at the Fann National University Hospital

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Abstract

Hemoglobinopathies, particularly sickle cell disease, pose major public health challenges in resource-limited settings, where delayed diagnosis contributes to high morbidity and mortality. As the world's most common monogenic disorder, the vast majority of affected individuals reside in sub-Saharan Africa. This study evaluated the performance of the HemoTypeSC™ rapid test for detecting hemoglobin A, S, and C variants, in accordance with the NF EN ISO 15189 standard. A prospective analytical study was conducted at the Biochemistry-Hematology Laboratory of Fann National University Hospital Center. Patients referred for hemoglobin electrophoresis were tested using HemoTypeSC™, with the Emmel test and capillary electrophoresis (Capillarys 3 octa, Sebia) as comparative methods. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall agreement were calculated with 95% confidence intervals. Among the 126 samples, 19 had normal profiles and 107 had hemoglobinopathies. Compared with the Emmel test, HemoTypeSC™ showed 100% sensitivity and specificity. Compared with capillary electrophoresis, sensitivity was 98.16%, specificity 100%, PPV 100%, and NPV 90.48%. Two discrepancies in fine typing were observed among the 107 abnormal profiles, with no missed abnormal profiles. HemoTypeSC™ is a rapid, reliable, and easy-to-use test for first-line sickle cell disease screening in resource-limited settings. Positive results should be systematically confirmed by electrophoresis.

Keywords

Sickle Cell Disease, HemoTypeSC™, Hemoglobinopathies, Method Verification

1. Introduction

Hemoglobinopathies, particularly sickle cell disease, represent a considerable public health burden. In 2021, an estimated 7.74 million people worldwide were living with sickle

cell disease, 80% of whom were in sub-Saharan Africa [1, 2]. In this context, early screening is a major determinant of sur-

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vival among affected individuals. However, access to conventional diagnostic techniques, such as electrophoresis and high-performance liquid chromatography (HPLC), remains limited in many settings, which has contributed to the emergence of rapid Point-of-Care Testing (POCT) approaches that are less costly and do not require extensive technical infrastructure [3]. The HemoTypeSC™ kit, designed to detect hemoglobin A, S, and C from whole blood or capillary blood, belongs to this category of devices. However, the introduction of any new diagnostic test into routine practice requires prior and documented evaluation of its analytical reliability under the actual conditions of use in the adopting laboratory. This is precisely the purpose of method verification, a formal requirement of the NF EN ISO 15189 standard for the accreditation of medical laboratories. It consists of evaluating, quantifying, and assessing the performance of an analytical process according to predefined criteria and a standardized operating protocol [4]. This approach is an essential prerequisite before any test can be introduced into routine use, regardless of the performance claims made by the manufacturer. It is within this methodological framework that the present study was conducted, with the objective of verifying the analytical performance of the HemoTypeSC™ kit for the detection of hemoglobin A, S, and C variants.

2. Materials and Methods

This was a prospective analytical study conducted in the Biochemistry-Hematology Laboratory of Fann National University Hospital. Patients referred to the laboratory for hemoglobin electrophoresis were included if they had no history of blood transfusion within the 120 days preceding blood sampling, a period considered sufficient to exclude any interference related to the presence of transfusion-derived hemoglobin. For each patient, a blood sample was collected into an EDTA tube. Screening was first performed using the Hemo-

TypeSC™ rapid test and subsequently confirmed by hemoglobin electrophoresis using the Capillarys 3 octa analyzer (Sebia). The HemoTypeSC™ kit is based on a competitive lateral-flow immunochromatographic principle using monoclonal antibodies directed against hemoglobins A, S, and C. Directly from whole blood, it allows identification of the main hemoglobin phenotypes, including the normal profile (HbAA), homozygous forms (HbSS, HbCC), the compound heterozygous form (HbSC), and simple sickle cell traits (HbAS, HbAC). The Emmel test detects the sickling of red blood cells containing hemoglobin S under in vitro hypoxic conditions induced by sodium metabisulfite, a reducing agent. Capillary electrophoresis enables the separation, identification, and quantification of hemoglobin fractions according to their electrophoretic properties under the influence of an electric field. All collected data were entered and processed using Microsoft Excel 2016. Test performance verification included clinical sensitivity, clinical specificity, positive and negative predictive values (PPV/NPV), and overall agreement between HemoTypeSC™ and each of the two comparative methods: the Emmel test and capillary electrophoresis using the Capillarys 3 octa analyzer.

3. Results

3.1. Concordance Between HemoTypeSC™ and the Emmel Test

A total of 126 samples with known Emmel test results (negative and positive) were tested in parallel using the HemoTypeSC™ kit and the Capillarys 3 octa system, used as the comparative method. The contingency table comparing HemoTypeSC™ with the Emmel test (Table 1) showed no false-positive or false-negative results: all 107 Emmel-positive samples and all 19 Emmel-negative samples were correctly classified by HemoTypeSC™.

Table 1. Contingency table comparing HemoTypeSC™ with the Emmel test.

HemoTypeSC™	Emmel positive	Emmel négative	Total
Concordant	107 (TP)	0 (FP)	107
Discordant	0 (FN)	19 (TN)	19
Total	107	19	126

TP: true positive; FP: false positive; FN: false negative; TN: true negative

3.2. Concordance Between HemoTypeSC™ and Electrophoresis (Capillarys 3 Octa)

Compared with the reference electrophoretic profile, HemoTypeSC™ showed two (02) phenotypic discrepancies among the 107 abnormal profiles (Table 2), while all 19 normal (AA) profiles were concordant.

Table 2. Contingency table comparing HemoTypeSC™ with capillary electrophoresis (Capillarys 3 octa).

HemoTypeSC™	Capillarys abnormal	Capillarys normal (AA)	Total
Concordant	105 (TP)	19 (TN)	124
Discordant	2 (FN)	0 (FP)	2
Total	107	19	126

TP: true positive; FP: false positive; FN: false negative; TN: true negative

The two discordant samples are presented in Table 3. In both cases, the discrepancy involved fine typing of the variant rather than failure to detect the abnormality, as the abnormality was detected by both methods.

Table 3. Description of the discordant samples between HemoTypeSC™ and capillary electrophoresis.

Sample No	Capillarys 3 octa	HemoTypeSC™	Nature of the discrepancy
1	SC	ASC	Divergent typing (additional A component reported by HemoTypeSC™)
2	AS	AS/borderline variant	Result close to the positivity threshold, requiring confirmation

3.3. Evaluation of HemoTypeSC™ Test Performance

The clinical performance indicators of HemoTypeSC™ were calculated separately against each of the two comparative methods (Emmel test and Capillarys 3 octa capillary electrophoresis), along with their 95% confidence intervals (Table 4).

Table 4. Summary of HemoTypeSC™ Performance Indicators Compared with the Two Comparative Methods.

Indicator	vs. Emmel Test	95% CI	vs Capillarys 3 octa	95% CI
Sensitivity	100% (107/107)	96.6 - 100%	98.16% (105/107)	93.4 - 99.8%
Specificity	100% (19/19)	82.4 - 100%	100% (19/19)	82.4 - 100%
PPV	100%	96.6 - 100%	100% (105/105)	96.5 - 100%
NPV	100%	82.4 - 100%	90.48% (19/21)	69.6 - 98.8%
Overall agreement	100% (126/126)	97.1 - 100%	98.41% (124/126)	94.4 - 99.6%

PPV: positive predictive value; NPV: negative predictive value; 95% CI: 95% confidence interval

4. Discussion

This study enabled the local verification of the performance of the HemoTypeSC™ kit for the detection of hemoglobins A, S, and C, in accordance with the requirements of the NF EN ISO 15189 standard for the accreditation of medical laboratories and ISO 15197. The results showed an overall sensitivity and specificity of 100% compared with the Emmel test. When compared with the reference electrophoretic profile (Capil-

larys 3 octa), sensitivity was 98.16%, while specificity remained 100% with both comparative methods. The positive predictive value (PPV) was 100% regardless of the comparator, whereas the negative predictive value (NPV) was 100% compared with the Emmel test and 90.48% compared with electrophoresis. These results are consistent with those reported in several studies conducted in Africa and Asia [5]. Kakou et al., in Côte d'Ivoire, reported sensitivity and specificity of 98.2% and 99.7%, respectively, which are very close to our findings [6]. Adegoke et al., in Nigeria in 2022, reported

sensitivity and specificity of 100% each [7], whereas Mukherjee et al., in 2020, reported values of 98.1% and 99.1%, respectively [8]. The convergence of these results, obtained in different epidemiological settings, strengthens the robustness of the performance observed for this test. From a practical perspective, our results confirm that HemoTypeSC™ is a reliable, accurate, and rapid test that can be used at the point of care, including in resource-limited settings. Its rapid turnaround time makes it a relevant tool for supporting newborn screening programs, where early diagnosis directly determines the implementation of appropriate care. However, the sensitivity of 98.16% observed compared with the electrophoretic profile, and particularly the NPV of 90.48% in the same comparison, indicate that a screening result cannot replace a confirmatory test. Any positive HemoTypeSC™ result should therefore be confirmed by hemoglobin electrophoresis, which is the only method allowing accurate determination of the phenotype and the relative proportions of the different hemoglobin fractions. The test nevertheless has a limitation that should be emphasized: although it readily detects hemoglobins A, S, and C, it cannot identify other compound heterozygous hemoglobinopathies, such as sickle cell disease associated with thalassemia, sickle cell disease with SO-Arab, or sickle cell disease with SD-Punjab [7]. This limitation should be taken into account when interpreting negative results, particularly in populations where these rare variants circulate. Overall, the HemoTypeSC™ rapid test can be recommended as a reliable screening tool in our setting, in addition to clinical suspicion, provided that positive results are systematically confirmed by hemoglobin electrophoresis.

5. Conclusion

The HemoTypeSC™ kit demonstrated satisfactory performance for the detection of hemoglobins A, S, and C. Simple to implement, rapid, and cost-effective, this test represents a relevant first-line screening tool for sickle cell disease, particularly in high-prevalence and resource-limited settings, where it could effectively support early screening initiatives. However, its use should remain appropriately controlled: all positive HemoTypeSC™ results should be confirmed by hemoglobin electrophoresis to accurately determine the phenotype and the proportions of the different hemoglobin fractions, particularly for rare variants not covered by the test.

Abbreviations

POCT	Point-of-Care Testing
PPV	Positive Predictive Value
NPV	Negative Predictive Value
TP	True Positive
TN	True Negative
FP	False Positive
FN	False Negative

Author Contributions

Sene Moustapha Ndep: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Resources, Software, Visualization, Writing – original draft, Writing – review & editing

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Thioune Ndeye Mareme: Resources, Software, Supervision, Validation

Ndiaye Siny: Formal Analysis, Investigation, Methodology

Djite Moustapha: Writing – original draft, Writing – review & editing

Ndour El Malick: Investigation, Methodology

Gueye-Tall Fatou: Methodology

Gueye Papa Madieye: Visualization

Conflicts of Interest

The authors declare no conflicts of interest.

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