

POINT-OF-CARE DIAGNOSIS FOR HEMOGLOBINOPATHIES: NOVEL MICROCHIP ELECTROPHORESIS FOR DETECTION IN INDIAN POPULATIONS

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OBJECTIVE

- To assess the performance of a low-cost, point-of-care (POC), microchip electrophoresis technology (Gazelle Diagnostic Device) as a tool to detect abnormal hemoglobin (Hb) variants.
- Gazelle was compared against high-performance liquid chromatography (HPLC) in the evaluation of selected samples from two states in India with high prevalence of sickle cell disease (SCD) and other Hb variants.

IMPACT of Hb Variants in India

- The prevalence of carriers of sickle cell trait (SCT) is widespread among tribal populations in India: prevalence varies from 1-40%.
- Beta thalassaemia is also prevalent in some tribal populations, with frequencies being as high as 6-14%.
- Co-inheritance of SCD with beta thalassemia can also occur, resulting in a rare, compound heterozygous condition called sickle cell beta-thalassemia (S/β).
- SCD in India is generally not as severe as that in African populations: genetic modifiers reduce the impact of the disease. However, it is associated with increased morbidity and mortality.¹
- Most tribal populations in areas where SCD is common rely on remote primary health care facilities, which often lack resources for screening, treatment, and education.

PUBLIC HEALTH EFFORTS

- The National Sickle Cell Anemia Elimination Mission (NSCAEM), launched in July 2023, is a program in India that aims to eliminate sickle cell disease (SCD) as a public health issue by 2047.

- The overall goal is to enable access to affordable and quality health care to all SCD patients, and to lower the prevalence through awareness, change of practices and screening interventions.
- Effective and efficient quantitative Hb variant screening is a key element of addressing SCD in Indian states with high prevalence.

GAZELLE POC Technology

- The Gazelle Hb Variant Test uses a miniaturized version of the gold standard test: electrophoresis.
- When a disposable cartridge containing a lysed blood sample is inserted into the reader, a charge is applied to separate Hb types.
- In eight minutes, the algorithm determines Hb types and quantification.
- Quantification helps determine a patient's true condition, since most conditions have specified ranges of Hb type concentrations.
- Because Gazelle identifies and quantifies these different Hb types, it can offer interpretative statements for 19 different phenotypes and their resulting conditions.
- This includes SCD and SCT, as well as beta thalassemia disease (intermedia and major), beta thalassemia trait (beta thalassemia minor), and S/β.

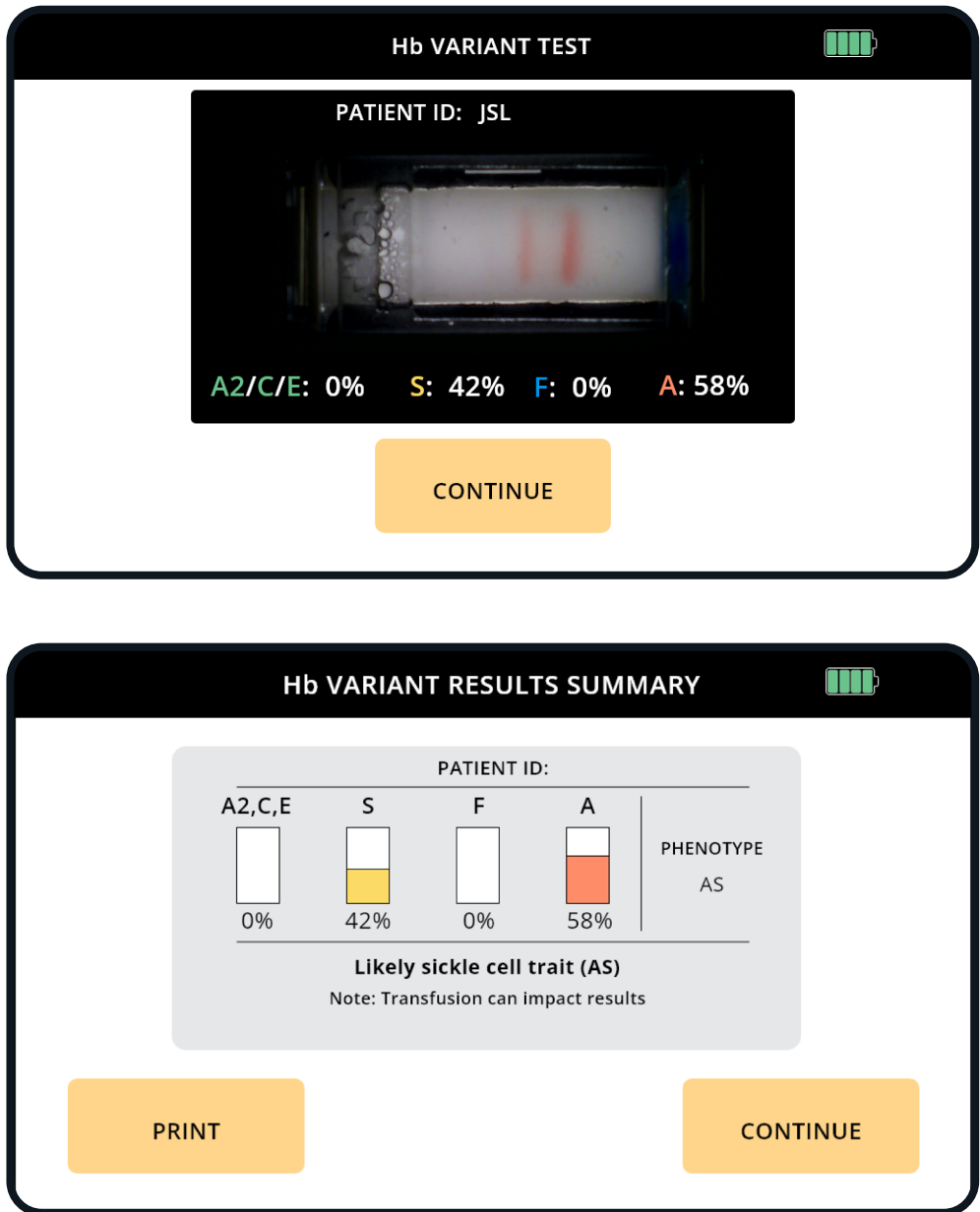


Figure 1. Miniaturized electrophoresis technology and AI-derived algorithms enable Hb variant detection, quantification, and interpretation with the Gazelle Diagnostic Device



METHODS

- 77 selected blood samples were taken from two states with high prevalence of SCD in India: 37 samples from Odisha, and 44 samples from West Bengal.
- Samples were tested for abnormal Hb variants, using both HPLC and Gazelle microchip electrophoresis technology.
- Testing results were compared to evaluate sensitivity, specificity, and accuracy of microchip electrophoresis versus HPLC.



Figure 2. The rugged, lightweight, battery-powered Gazelle Diagnostic Device can withstand high temperatures and humidity. No cold chain management is required.

RESULTS

- Out of 37 selected samples from Odisha, 32 hemoglobinopathies were detected.
- Out of 44 samples from West Bengal, 32 hemoglobinopathies were detected.
- Gazelle successfully detected multiple Hb variants, including sickle cell beta thalassemia and HbE beta thalassemia.
- Results showed 99% concordance for both the testing methods.

COMPARISON	SENSITIVITY	SPECIFICITY	ACCURACY
NORMAL VS DISEASE	100.00%	100.00%	100.00%
NORMAL VS TRAIT	100.00%	100.00%	100.00%
DISEASE VS TRAIT	96.00%	97.78%	97.14%
TRAIT VS DISEASE	96.55%	97.56%	97.14%

CONCLUSIONS

- **Gazelle's microchip electrophoresis-based technology enables identification and quantification of common Hb variants with the same accuracy as HPLC.**
- **Gazelle's ability to both detect and quantify variants aids in the accurate diagnosis of SCD and other hemoglobinopathies in low-resource regions where reliable electricity, lack of trained manpower and high cost are always prohibitive for phlebotomy-based community screening and SCD testing.**
- **The Gazelle Diagnostic Device is a useful tool in the pursuit of universal Hb variant screening in India.**



Figure 3: Dr Jena at Srirama Chandra Bhanja Medical College & Hospital working with the Gazelle™ Diagnostic Device

REFERENCES

¹ Colah RB, Mukherjee MB, Martin S, Ghosh K. Sickle cell disease in tribal populations in India. Indian J Med Res. 2015;141(5):509–515. doi:10.4103/0971-5916.159492. PMID: PMC4510747; PMID: 26139766.

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