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File No. 56/01/2024-SickleCell/Misc/NCD **Date: 08.04.2026**

Electrophoresis based Assay validated for screening of Sickle Cell Disease (SCD) by ICMR is as following:

S. No.	Assay type	Year	Validating Site	Sample* size	Sensitivity (%)	Specificity(%)
1.	Gazalle® HEMEXDx HB variant Test (miniaturized electrophoresis)	2026	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	300	100	100

This has approval of DG-ICMR.

Note

*Comparative done with the HPLC gold standard results (Biorad Variant I).

Training of the laboratory staff is required before use of the assays for avoiding technical errors.

Field-testing to be done for laboratory-validated assays

(Heena Tabassum)
Scientist & PO