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File No. 56/01/2024-SickleCell/Misc/NCD

Date: 14.08.2024

Point of Care Assays validated for screening of Sickle Cell Disease (SCD) by ICMR are as following:

S. No.	Assay type	Year	Validating Site	Sample size	Sensitivity (%)	Specificity (%)
1.	LordsMed ShapeDx AI Software-based POC system for the Sickle Cell Test of Lord's Mark Industries Pvt. Ltd	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	156	100	100
2.	Genebio Health Pvt. Ltd. Sickle Cell Rapid POC Device	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	150	97	100

This has approval of DG-ICMR.

Note

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

Appropriate training of the laboratory staff is required before use of the such assays for avoiding technical errors.

Heena

(Heena Tabassum)
 Scientist & PO