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

Date: 08.01.2026

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

No.	Assay	Year	Validating Site	Sample* size	Sensitivity (%)	Specificity (%)
1	LitLife-SiBThal217 Kit (PCR Test) Pg no. 398	2025	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	180	99.28	100

This has approval of DG-ICMR.

Note

*Comparative analysis was performed against the HPLC gold standard (Bio-Rad Variant I) for the evaluated kit. In addition, molecular confirmation using PCR assay was undertaken.

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

Every Batch should be checked for quality before use in the laboratory/field.

(Heena Tabassum)
Scientist & PO