



## भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIAN COUNCIL OF MEDICAL RESEARCH

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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)<br>Pg no. 398 | 2025 | ICMR-NIIH Mumbai &<br>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