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

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Non RDT Assays validated for screening of Sickle Cell Disease (SCD) by ICMR areas following:

S. No.	Assay type	Year	Validating Site	Sample size	Sensitivity (%)	Specificity (%)
1.	ALLWAYS SICKLESENSE Sickle Cell Solubility Test Kit	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	150	100	100
2.	ErbaMDx Sickle Cell qPCR kit with HbC (Transasia Diagnostic Pvt. Ltd. India)	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	254	100	100
3.	ErbaMDx Sickle Cell qPCR kit without HbC (Transasia Diagnostic Pvt. Ltd. India)	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	254	100	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