

Draft (Revised Communication/Corrigendum)

Subject: Clarification regarding the interpretation of ICMR communication dated 27.12.2023 on validated diagnostic approaches for Sickle Cell Disease screening

With reference to ICMR communication dated 27.12.2023 (File No. 56/02/2023-SCD-TH/BMS) regarding validated tests for screening of Sickle Cell Disease (SCD), the following clarification is issued to ensure uniform scientific understanding and implementation.

It is clarified that **Dried Blood Spot (DBS)** is a specimen collection and transportation methodology and not an independent diagnostic test or analytical platform. DBS involves collection of blood samples on specially designed filter paper/cards, which are subsequently subjected to analysis using validated laboratory diagnostic platforms such as High Performance Liquid Chromatography (HPLC), Capillary Electrophoresis (CE), or other validated methods as applicable.

A **Point-of-Care Test (PoCT)** refers to a diagnostic test system that performs the required analytical process at or near the site of patient care and provides results without requiring conventional laboratory-based processing.

Accordingly, DBS-based sample collection should not be interpreted as equivalent to PoCT or as a standalone diagnostic technology.

The classification of diagnostic approaches may therefore be considered as follows:

A. Validated Point-of-Care Diagnostic Tests (PoCT) for SCD Screening

S. No.	Test	Year of validation	Validating site	Remarks
1	HemoTypeSC	2018–2020	ICMR-NIIH, Mumbai	Validated PoCT for SCD screening
2	SickleSCAN	2021	AIIMS Delhi & Nagpur	Validated PoCT for SCD screening
3	Meriscreen	2023	ICMR-CRMCH, Chandrapur	Validated PoCT (validation cohort expansion ongoing)
4	SickleCHECK	2023	MRU @ M.K.C.G Medical College, Berhampur	Validated PoCT for SCD screening
5	Voxpress Rapid Kit	2023	ICMR-CRMCH, Chandrapur	Validated PoCT (validation cohort expansion ongoing)
6	Alpine Sickle Screen Rapid Test	2023	ICMR-CRMCH, Chandrapur	Validated PoCT
7	Rapichex Sickle Cell Rapid Kit	2023	ICMR-RMRC Bhubaneswar	Validated PoCT

B. Validated Laboratory-based Diagnostic Platforms / Approaches (including DBS as specimen type)

S. No.	Platform/Approach	Specimen type	Analytical method	Remarks
1	HPLC-based haemoglobin analysis	Whole blood / DBS (where validated)	HPLC	Laboratory-based diagnostic platform
2	Capillary Electrophoresis (CE)-based haemoglobin analysis	Whole blood / DBS (where validated)	CE	Laboratory-based diagnostic platform
3	Navigene HB™ DBS-based screening approach using HPLC Platform	DBS card sample	Requires analysis through validated laboratory platform (e.g., HPLC/CE)	DBS is a sample collection method and not a standalone diagnostic test

This clarification is intended to remove any ambiguity between specimen collection methods and diagnostic technologies and to facilitate consistent implementation, quality assurance, procurement planning, and interpretation across national SCD screening programmes.

The earlier communication dated 27.12.2023 may accordingly be read with the above clarification.