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वी. रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
 V. RAMALINGASWAMI BHAWAN. ANSARI NAGAR. POST BOX 4911. NEW DELHI - 110 029

File No. 56/02/2023-SCD-TH/BMS

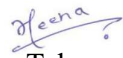
Date: 27.12.2023

Point of care tests (PoCT) validated for screening of Sickle Cell Disease (SCD) by ICMR areas following:

S. No.	POCT/ HPLC	Year	ValidatingSite	Samplesize	Sensitivity (%)	Specificity (%)
1.	HemoType SC	2018- 2020	ICMR-NIIH Mumbai	1559	98.1	99.1
2.	SickleSCAN	2021	AIIMS Delhi & Nagpur	404	>92.4	>99.1
3.	Meriscreen	2023	ICMR- CRMCH, Chandrapur	35 (To be increased)	100	100
4.	SickleCHE CK	2023	MRU @ M.K.C.G Medical College, Berhampur	359	98.14	99.03
5.	Voxpressrapid kit	2023	ICMR- CRMCH, Chandrapur	70 (To be increased)	100	100
6.	Alpine Sickle Screen Rapid test	2023	ICMR- CRMCH, Chandrapur	240	99.04	99.04
7.	Rapichex Sickle Cell Rapid Kit	2023	ICMR-RMRC- BBSR, Bhubaneswar	207	98.55	99.0
8.	Navigene HB TM (in DBS)	2023	ICMR- CRMCH, Chandrapur	240	99.2	99.2

This has approval of DG, ICMR.

Note # Appropriate training of the field workers is required before use of the PoCT for avoiding errors in interpretation.


 (Heena Tabassum)
 Scientist & PO



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File No. 56/02/2023-SCD-TH/BMS

Date: 06.02.2024

Point of care tests (PoCT) validated for screening of Sickle Cell Disease (SCD) by ICMR areas following:

S. No.	POCT/ HPLC	Year	Validating Site	Sample size	Sensitivity (%)	Specificity (%)
1.	ErbaQik Sickle cell rapid card (A,S,C) of Transasia Diagnostic Pvt. ltd.	2023-24	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	242	100	100
2.	ErbaQik Sickle cell rapid card of Transasia Diagnostic Pvt. ltd. (without HbC)	2023-24	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	250	100	100
3.	MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd	2023-24	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	230	100	100
4.	Trivitron healthcare Biocard sickle cell rapid test card of Trivitron Healthcare Pt. Ltd	2023-24	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	290	100	100

This has approval of DG-ICMR.

Note # Appropriate training of the field workers is required before use of the PoCT for avoiding errors in interpretation.

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File No. 56/02/2023-SCD-TH/BMS

Date: 21.02.2024

Point of care test (PoCT) validated for screening of Sickle Cell Disease (SCD) by ICMR is as following:

S. No	POCT/ HPLC	Year	Validating Site	Sample size	Sensitivity (%)	Specificity (%)
1.	Lords Med Sickle cell rapid test kit of Lord's Mark Industries Pvt. Ltd.	2023-24	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	300	100	100

This has approval of DG, ICMR.

Note # appropriate training of the field workers is required before use of the PoCT for avoiding errors in interpretation.

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File No. 56/02/2023-SCD-TH/BMS

Date:15.03.2024

Point of care tests (PoCT) validated for screening of Sickle Cell Disease (SCD) by ICMR areas following:

S. No.	POCT	Year	Validating Site	Sample size	Sensitivity (%)	Specificity (%)
1.	BioSci True-Detect Sickle Cell Rapid Test Device	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	120	100	100
2.	Vimek SUPERVELOCE Sickle Cell Rapid Test kit	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	300	96.67	100

This has approval of DG, ICMR.

Note # Appropriate training of the field workers is required before use of the PoCT for avoiding errors in interpretation.

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

Date: 18.04.2024

Point of care tests (PoCT) validated for screening of Sickle Cell Disease (SCD) by ICMR areas following:

S. No.	POCT	Year	Validating Site	Sample* size	Sensitivity (%)	Specificity (%)
1.	Mediclone Biotech Sickle Cell Test card	2024	ICMR-RMRC, Bhubaneswar	55 (To be increased)	98.18%	>99%
2.	BI0GENIX INC. PVT.LTD. Sickle Cell Rapid Test Kit	2024	ICMR-NIIH Mumbai & ICMR-CRMCH, Chandrapur	300	100	100

This has approval of DG, ICMR.

Note

*The band intensity of HbA and HbS was low and needs further improvement; Sample Size needs to be increased

Appropriate training of the field workers is required before use of the PoCT for avoiding errors in interpretation.

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