तार / GRAM : विद्यानी / SCIENTIFIC Web-site : www.icmr.nic.in E-mail : icmrhqds@sanss-d.nic.in

Date: 06.02.2024



२ भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIAN COUNCIL OF MEDICAL RESEARCH

वी. रामिलंगस्वामी 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

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
	Trivitron healthcare Biocard sickle cell rapid test card of Trivitron Healthcare Pt. Ltd	2023-24	ICMR-NIIH Mumbai & ICMR- CRMCH, Chandrapur	290	100	100

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





आई सी एम आर - राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

ICMR-National Institute of Immunohaematology

Department of Health Research, Ministry of Health and Family Welfare, Government of India.

Date:02/02/2024

VALIDATION REPORT OF ErbaQik SICKLE CELL (A.S.C) RAPID TEST

ICMR-NIIH Mumbai and CRMCH Chandrapur evaluated **ErbaQik sickle cell (A,S,C) rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.)** by testing normal, sickle cell trait and sickle cell disease individuals (adults) with HPLC results on 250 samples.

Following are the details of the batches used for the evaluation from ErbaQik sickle cell (A,S,C) rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.)

Product Name	ErbaQik sickle cell (A,S,C) rapid test card (TRANSASIA DIAGNOSTICS Pvt.										
		Ltd.)									
Ref. Code	135340	135340 135340 135340									
Lot No	VRSCA2301	VRSCA2302	VRSCA2303								
Mfg. Date	Oct - 2023	Oct - 2023	Oct - 2023								
Exp. Date	Sep - 2025	Sep - 2025	Sep - 2025								
Total Test	100	100	100								
Testing Start											
Date	18/01/2024	Completion Date:	31/01/2024								

Details of Gold Standard test:

Prodct Code	Variant II β - thalassemia (HPLC) Kit
Product Made	Biorad
Lot No:	64536704
Mfg. Date	7/3/2023
Ex. Date	13/11/2025

Name of the Institute: ICMR-NIIH, Mumbai

Name of the Director: Dr. Manisha Madkaikar, ICMR-NIIH, Mumbai Phone No: 09892472552, Email ID: madkaikarmanisha@gmail.com

Name of the HOD: Dr. Prabhakar S Kedar, Scientist E, Dept. of Haematogenetics, ICMR-NIIH, Mumbai.

Phone No: 9969007500, Email ID: kedarps2002@yahoo.com

Name of the Operator: Mrs. Pratibha Sawant (Technical Officer) and Mrs. Manju Gorivale

(Technician)

Name of the Institute: ICMR-CRMCH, Mumbai

Name of OIC: Dr. Anand Bodade

Contact Details: 8080889764, Email ID: anand.bodade@icmr.gov.in

Name of Operator: Mr. Umesh Dhumne (Technical Officer, ICMR-CRMCH) Contact; 9822569572

ICMR-CRMCH-NIIH validated ErbaQik Sickle Cell rapid test card of Transasia Diagnostics Pvt. Ltd. by testing normal, sickle cell trait and sickle cell disease individuals and sample status was confirmed with HPLC Test

Sample	Gold Standard Test		Erba	Qik SICK	(LE POC	Card		Inference
ID .	HPLC	Diagnosis	Band	d develop	ed in Card	Diagnosis		
	Test		С	HA	HS	HC		
1.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
2.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
3.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
4.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
5.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
6.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
7.	AS	Sickle cell trait	+	·	-	- ,	Sickle cell trait	Both HPLC and POC
								card results matched
8.	AA	Normal	+	+	1-	-	Normal	Both HPLC and POC
								card results matched
9.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
10.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
11.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
12.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
13.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
14.	AS	Sickle cell trait	+	-	-	-,	Sickle cell trait	Both HPLC and POC
								card results matched
15.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
16.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
		ļ						card results matched
17.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
18.	SS	Sickle cell	+	-,	+	-	Sickle cell	Both HPLC and POC
10		diseases			4		diseases	card results matched
19.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
00	100	diseases					diseases	card results matched
20.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
04	100	0:-11					Ciakla aall trait	card results matched
21.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
22	00	Oi-M-					Cioklo os!!	card results matched
22.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
22	100	diseases	 	+.			diseases	card results matched Both HPLC and POC
23.	AA	Normal	+	+	-	-	Normal	card results matched
24	1 1 1	Normal		+			Normal	
24.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched

Desar

25.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
26.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
27.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
28.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
29.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched Both HPLC and POC
00		Cialda anll			-		Sickle cell	card results matched Both HPLC and POC
30.	SS	Sickle cell diseases	+	-	+	-	diseases	card results matched
31.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
32.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
33.	SS	Sickle cell	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
04		diseases	+		+			Both HPLC and POC
34.	SS	Sickle cell diseases		-		-	diseases	card results matched
35.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
00	100	diseases		-			diseases	card results matched Both HPLC and POC
36.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
37.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
38.	SS	Sickle cell	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
39.	AA	diseases Normal	+	+	 	-	Normal	Both HPLC and POC
00.	700	Noma	·				Tromai	card results matched
40.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
41.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
42.	SS	Sickle cell	+	1-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
43.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
44.	SS	Sickle cell	+	+	+	+	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
45.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
46.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
47.	AA	Normal	+	+	-] -	Normal	Both HPLC and POC card results matched
48.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
49.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
50.	SS	Sickle cell	+	-	+	1-	Sickle cell	Both HPLC and POC
51.	AS	diseases Sickle cell trait	+	-	-	+	diseases Sickle cell trait	card results matched Both HPLC and POC
								card results matched
52.	SS	Sickle cell	+		+	-	Sickle cell	Both HPLC and POC



		diseases		T			diseases	card results matched
53.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
		Sionio son tran					Gioino don trait	card results matched
54.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
•							Cionio con tran	card results matched
55.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
00.	10	Olokic doll trait					Olokie celi tiait	card results matched
56.	AS	Sickle cell trait	+	_	-	-	Sickle cell trait	Both HPLC and POC
30.	۸۵	Sickle cell trait	l '	-	-	-	Sickle cell trait	card results matched
57.	SS	Sickle cell	+	+	+	-	Sickle cell	
57.	33	diseases	T	-	"	-	Sickle cell diseases	Both HPLC and POC
			-					card results matched
58.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases	.	+			diseases	card results matched
59.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
60.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
61.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
62.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
63.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
64.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
65.	AS	Sickle cell trait	+	1-	1-	-	Sickle cell trait	Both HPLC and POC
							Ciordo don dan	card results matched
66.	AA	Normal	+	+		_	Normal	Both HPLC and POC
00.	/**	Normal		'			Homai	card results matched
67.	AS	Sickle cell trait	+	-	+_		Sickle cell trait	Both HPLC and POC
01.	1,70	Olonic con trait	١.	-	-	-	Olokie Celi tiait	card results matched
68.	AS	Sickle cell trait	+	-	1-	-	Sickle cell trait	Both HPLC and POC
00.	7.0	Olokie Geli tiait	١.	-	-	-	Sickle Cell trait	card results matched
69.	AS	Sickle cell trait	+	+	+-	-	Sickle cell trait	Both HPLC and POC
09.	AS	Sickle cell trait	Т.	-	-	-	Sickle cell trait	5 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7
70		Named	+	+.			Marrial	card results matched
70.	AA	Normal	†	+	-	-	Normal	Both HPLC and POC
74		- I		+			-	card results matched
71.	AA	Normal	+	+	-	1-	Normal	Both HPLC and POC
							<u> </u>	card results matched
72.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
73.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
74.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases	1				diseases	card results matched
75.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
76.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
77.	SS	Sickle cell	+	1-	+	-	Sickle cell	Both HPLC and POC
	33	diseases					diseases	card results matched
78.	SS	Sickle cell	+	-	+	_	Sickle cell	Both HPLC and POC
70.	30	diseases			'		diseases	card results matched
79.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
13.	7.0	Sickle cell fiait	"	1-	-	-	SIUNIE CEII LI AIL	card results matched
								caru results materieu

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80.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
				-			-	
81.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
82.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
02.	' ' '	- Tronnan	1				110111101	card results matched
83.	AA	Normal	+	+	_		Normal	Both HPLC and POC
03.	\ AA	Noma	1	"	-	-	Noma	card results matched
0.4	A A	Name	+	-		-	Normal	Both HPLC and POC
84.	AA	Normal	*	+	-	-	Normai	card results matched
			-	 			A11	
85.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
		<u> </u>					<u> </u>	card results matched
86.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
87.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
						V		card results matched
88.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
89.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
		220 22 22						card results matched
90.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
00.	7.0	Ololilo Coll Lait		-	1		0.0	card results matched
91.	AA	Normal	+	+	+-	-	Normal	Both HPLC and POC
31.	~~	Normal	1.	1.			Homai	card results matched
02	AA	Normal	+	+		_	Normal	Both HPLC and POC
92.	AA	Normal	*	*	-	-	Noma	card results matched
			+	+			Newsel	
93.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
		<u> </u>						card results matched
94.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
95.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
96.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
97.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
				1	1			card results matched
98.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
55.								card results matched
99.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
55.	/**	Troillia.						card results matched
100.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
100.	AA	Nomia	'	'			Homai	card results matched
101	ΛΛ	Normal	+	+	+_	_	Normal	Both HPLC and POC
101.	AA	Nomial	٦	1	-	-	Noma	card results matched
400		Normal .	+.	+	_		Normal	Both HPLC and POC
102.	AA	Normal	+	+	-	-	Noma	
		1					Otalila B t - B	card results matched
103.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
							<u> </u>	card results matched
104.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
105.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
106.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
107.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
101.	, , ,	110111101						

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				T				card results matched
108.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
		1.1011116.					Tromia	card results matched
109.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
,,,,,	1						- Tromman	card results matched
110.	AS	Sickle cell trait	+	1-	-	-	Sickle cell trait	Both HPLC and POC
							Giorno don trant	card results matched
111.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
							- Torrinar	card results matched
112.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
							- Torrings	card results matched
113.	AA	Normal	+	+	T-	-	Normal	Both HPLC and POC
		52 54 500 762						card results matched
114.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
			1	1				card results matched
115.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
116.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
117.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
118.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
119.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
120.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
121.	AS	Sickle cell trait	+	-,	-	-	Sickle cell trait	Both HPLC and POC
			1			1		card results matched
122.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
123.	AS	Sickle cell trait	+	-,1	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
124.	AS	Sickle cell trait	+		-	-	Sickle cell trait	Both HPLC and POC
	*							card results matched
125.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
126.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
127.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
128.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases		\			diseases	card results matched
129.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
130.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
131.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
132.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
133.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
134.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched



405	100	0:11	Τ.	1	1.		T 0: 11	T - 11 11 - 1 - 1 - 1 - 1
135.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
136.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
137.	SS	Sickle cell	+	7-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
138.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
139.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
140.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
141.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
	N 22							card results matched
142.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
143.	AS	Sickle cell trait	+	-	-	1-	Sickle cell trait	Both HPLC and POC
								card results matched
144.	AA	Normal	+	+	1-	-	Normal	Both HPLC and POC
111.	' ' '	1 tomai					- Normai	card results matched
145.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
140.	1	Noma	l '	'	-	-	Normal	card results matched
146.	SS	Sickle cell	+	1_	+	-	Sickle cell	Both HPLC and POC
140.	33	diseases	Ι Τ	-	*	-	diseases	card results matched
4.47	SS				+.			
147.	55	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
440		diseases			ļ		diseases	card results matched
148.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
149.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
150.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
151.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
152.	AA	Normal	+	+	-		Normal	Both HPLC and POC
								card results matched
153.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
154.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
155.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
156.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
100.		diseases					diseases	card results matched
157.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
107.	1	Olokio ooli ti dit						card results matched
158.	AS	Sickle cell trait	+	1-	-	-	Sickle cell trait	Both HPLC and POC
100.	7.0	Sickle Cell trait	•				Cionio con trait	card results matched
159.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
108.	AS	SICKIE CEII LIAIL	7	-	-	-	Jone Jon Hall	card results matched
160	ΛΛ	Normal	+	+	-	-	Normal	Both HPLC and POC
160.	AA	Normal	т	*	-	1	INOIIIIAI	card results matched
404	00	0:-1:1-		-		+	Ciakla acli	Both HPLC and POC
161.	SS	Sickle cell	+	-	+	-	Sickle cell	
100	100	diseases					diseases	card results matched
162.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC



		diseases	Т	1			diseases	card results matched
163.	SS	Sickle cell	+		+		Sickle cell	Both HPLC and POC
103.	33	diseases	1	-	†	-	diseases	card results matched
164.	AA	Normal	+	+			Normal	Both HPLC and POC
104.	~~	Nomial	*	*	-	-	Noma	card results matched
165.	ΛΛ	Normal		- ,			Normal	Both HPLC and POC
100.	AA	Normal	+	+	-	-	INOITHAL	card results matched
166.	SS	Cialda aall		_	+		Sickle cell	Both HPLC and POC
100.	00	Sickle cell	+	-	*	-	diseases	card results matched
167.	AS	diseases	-				Sickle cell trait	Both HPLC and POC
107.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
168.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
100.	AS	Sickle cell trait	•	-	-	-	Sickle Cell trait	card results matched
169.	AS	Sickle cell trait	+	+	-	-	Sickle cell trait	Both HPLC and POC
109.	AS	Sickle cell trait	•	-	-	-	Sickle cell trait	card results matched
170.	AA	Normal	+	+	+-		Normal	Both HPLC and POC
170.	~~	Normal	*	"	-	-	Noma	card results matched
171.	SS	Sickle cell	+	+	+	-	Sickle cell	Both HPLC and POC
171.	33	diseases	T	-	"	-	diseases	card results matched
172.	SS		+	+	+	-	Sickle cell	Both HPLC and POC
172.	33	Sickle cell diseases	*	-	"	-	diseases	card results matched
173.	SS	Sickle cell	+	+	+	-	Sickle cell	Both HPLC and POC
173.	33	diseases	T	-	"	-	diseases	card results matched
174.	SS	Sickle cell	+	+	+		Sickle cell	Both HPLC and POC
1/4.	33	diseases	"	-	"	-	diseases	card results matched
175.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
175.	1	Nomai	"	"	1-	-	Normal	card results matched
176.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
170.	1	Normal	'	1.	-	-	Normal	card results matched
177.	AS	Sickle cell trait	+	+	-	-	Sickle cell trait	Both HPLC and POC
177.	1	Olokie celi tiait	l '	-	-		Olonic con trait	card results matched
178.	AS	Sickle cell trait	+	+-	-	_	Sickle cell trait	Both HPLC and POC
170.	1	Cloric con trait					Clottle con trait	card results matched
179.	AS	Sickle cell trait	+	1-	-	-	Sickle cell trait	Both HPLC and POC
170.	/.0	Cionio con dan					Cionio con a dia	card results matched
180.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
100.	1.51							card results matched
181.	SS	Sickle cell	+	1-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
182.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
183.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases		1			diseases	card results matched
184.	SS	Sickle cell	+	T -	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
185.	SS	Sickle cell	+	-	+	,-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
186.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
187.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
188.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
189.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched

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190.	SS	Sickle cell	+	Τ_	+	Ι.	Sickle cell	Both HPLC and POC
190.	33	diseases	*	-	*	-	diseases	card results matched
191.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
101.	' ' '	rtormar		'		2	Nomia	card results matched
192.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
193.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched
194.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
195.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
196.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
197.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
198.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
199.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
200		diseases					diseases	card results matched
200.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		diseases					diseases	card results matched
201.	SS	Sickle cell	+	+	-	-	Sickle cell	Both HPLC and POC card results matched
	-	disease					disease	Both HPLC and POC
202.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
		Cielde		-			Cialda soll	Both HPLC and POC
203.	SS	Sickle cell	+	+	-	-	Sickle cell	card results matched
	1	disease Sickle cell	-			-	disease Sickle cell	Both HPLC and POC
204.	SS	Sickle cell disease	+	+	-	-	disease	card results matched
		uiscasc					uisease	Both HPLC and POC
205.	AA	Normal	+	-	+	-	Normal	card results matched
		Sickle cell					Sickle cell	Both HPLC and POC
206.	SS	disease	+	+	-	-	disease	card results matched
								Both HPLC and POC
207.	AA	Normal	+	-	+	-	Normal	card results matched
		Sickle cell	_	1.			Sickle cell	Both HPLC and POC
208.	SS	disease	+	+	-	-	disease	card results matched
	00	Sickle cell					Sickle cell	Both HPLC and POC
209.	SS	disease	+	+	-	-	disease	card results matched
040	00	Sickle cell					Sickle cell	Both HPLC and POC
210.	SS	disease	+	+	-	-	disease	card results matched
044	40	Cialda aall trait					Cialda aall trait	Both HPLC and POC
211.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
040	40	Cialda aall trait	+				Ciakla anll trait	Both HPLC and POC
212.	AS	Sickle cell trait	т	-	-	-	Sickle cell trait	card results matched
242	CC	Sickle cell	+	+			Sickle cell	Both HPLC and POC
213.	SS	disease	т	T	-	-	disease	card results matched
214	۸۵	Ciakla gall trait	+	_	_	_	Sickle cell trait	Both HPLC and POC
214.	AS	Sickle cell trait	т		_		Sickle cell traft	card results matched
215.	AS	Sickle cell trait	+	_	_	_	Sickle cell trait	Both HPLC and POC
210.	٨٥	OIONIC CEII LI AIL	'	_		-	Cickle cell traft	card results matched
216.	AS	Sickle cell trait	+	_	_	_	Sickle cell trait	Both HPLC and POC
								card results matched
217.	SS	Sickle cell	+	+	-	-	Sickle cell	Both HPLC and POC



		diagaaa	1	1	T		T	1 1 1
		disease					disease	card results matched
218.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
219.	SS	Sickle cell	+	+	-	_	Sickle cell	Both HPLC and POC
210.		disease		ļ ·	_		disease	card results matched
220.	SS	Sickle cell	+	+	_	_	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
221.	SS	Sickle cell	+	+	-	_	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
222.	SS	Sickle cell	+	+	_	-	Sickle cell	Both HPLC and POC
		disease Sickle cell					disease	card results matched
223.	SS	Sickle cell disease	+	+	-	-	Sickle cell	Both HPLC and POC
		Sickle cell					disease	card results matched
224.	SS	disease	+	+	-	-	Sickle cell	Both HPLC and POC
		Sickle cell					disease Sickle cell	card results matched Both HPLC and POC
225.	SS	disease	+	+	-	-	disease	card results matched
	1	Sickle cell			-		Sickle cell	Both HPLC and POC
226.	SS	disease	+	+	-	-	disease	card results matched
	100	Sickle cell					Sickle cell	Both HPLC and POC
227.	SS	disease					disease	card results matched
000	100	Cieldo eell tueit						Both HPLC and POC
228.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
229.	AS	Sickle cell trait					Oistals sell trait	Both HPLC and POv C
229.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
230.	ss	Sickle cell	+	+	_		Sickle cell	Both HPLC and POC
200.		disease	'	T	_	_	disease	card results matched
231.	AS	Sickle cell trait	+	_	_	_	Sickle cell trait	Both HPLC and POC
		- Closur Con Lan					Olokio ocii trait	card results matched
232.	AS	Sickle cell trait	+	_	_	-	Sickle cell trait	Both HPLC and POC
					-			card results matched
233.	AA	Normal	+	- 1	+	-	Normal	Both HPLC and POC
		Sickle cell					Sickle cell	card results matched Both HPLC and POC
234.	SS	disease	+	+	-	,-	Sickle cell disease	card results matched
		Sickle cell			+		Sickle cell	Both HPLC and POC
235.	SS	disease	+	+	-		disease	card results matched
	1						200	Both HPLC and POC
236.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	card results matched
007	1	1						Both HPLC and POC
237.	AA	Normal	+	-	+	-	Normal	card results matched
238.	SS	Sickle cell	+	1.			Sickle cell	Both HPLC and POC
230.	55	disease	т	+	-	-	disease	card results matched
239.	SS	Sickle cell	+	+	-		Sickle cell	Both HPLC and POC
200.	33	disease	т	<u> </u>			disease	card results matched
240.	AS	Sickle cell trait	+	_	-	_	Sickle cell trait	Both HPLC and POC
210.	Αυ							card results matched
241.	ss	Sickle cell	+	+	-	_	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
242.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC
								card results matched

Interpretation: All samples tested with the POC of ErbaQik Sickle Cell rapid test card of Transasia Diagnostics Pvt. Ltd. card Kit show 100% sensitivity, 100% specificity and 100% accuracy for all the haemoglobinopathies tested.

Conclusion: The Indian Council of Medical Research (ICMR- CRMCH, Chandrapur) under ICMR- National Institute of Immunohematology, Mumbai tested 242 normal (AA) and sickle cell samples (AS and SS pattern) on ErbaQik Sickle Cell rapid test card of Transasia Diagnostics Pvt. Ltd as per instructions and compared it to HPLC results. ErbaQik Sickle Cell rapid test card of Transasia Diagnostics Pvt. L and HPLC as technology provided 100% accurate results as compared to the GOLD STANDARD (Biorad Variant II HPLC). The band intensities were found to be satisfactory as visible and clear to the naked eye.

Dr. Manisha Madkaikar

Director

निदेशक / Director आईसीएमआर-राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान ICMR - National Institute of Immunohaematology 13वीं मजिल, नई बहुवंजिली ईमारत, के इ एम अस्पताल परिसर, परेस्ट प्रेस्टि-४०० ०१२.

1300 Port New Markistoreyed Building, KEM Hospital Campus Perel, Building 450 012.

Dr. Prabhakar Kedar

HOD Haematogenetics

Dr. Prabhakar S. Kedar, Ph.D.
Scientist 'E', (Dy. Director)
ICMR National Institutre of Immunohacmatology
13th Floor, New Multistoreyed Bldg.,
KEM Hospital Campus, Parel,
Mumbai 400 012.





आई सी एम आर - राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान

स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

ICMR-National Institute of Immunohaematology

Department of Health Research, Ministry of Health and Family Welfare, Government of India.

Date:02/02/2024

VALIDATION REPORT OF MYLAB SICKLE CELL RAPID TEST KIT.

ICMR-NIIH Mumbai and CRMCH Chandrapur evaluated **MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd**. by testing normal, sickle cell trait and sickle cell disease individuals (adults) with HPLC results on 230samples.

Following are the details of the batches used for the evaluation from MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd

Product Name	MyLab Sickle cell Rapid Test Kit of	MyLab Discovery Solutions Pvt. Ltd <u>.</u>							
Product Code	135339								
	AG00046-D-1022001E,								
Lot No	AG00046-D-1022002E,	AG00046-D-1022003E							
Mfg. Date	10/2022	10/2022							
Exp. Date	09/2024	09/2024							
Total Test	200	100							
Testing Start									
Date	18/01/2024	Completion Date: 30/01/2024							

Details of Gold Standard test:

Prodct Code	Variant II β - thalassemia (HPLC) Kit
Product Made	Biorad
Lot No:	64536704
Mfg. Date	7/3/2023
Ex. Date	13/11/2025

Name of the Institute: ICMR-NIIH, Mumbai

Name of the Director: Dr. Manisha Madkaikar, ICMR-NIIH, Mumbai Phone No: 09892472552, Email ID: madkaikarmanisha@gmail.com

Name of the HOD: Dr. Prabhakar S Kedar, Scientist E, Dept. of Haematogenetics, ICMR-NIIH, Mumbai.

Phone No: 9969007500, Email ID: kedarps2002@yahoo.com

Name of the Operator: Mrs. Pratibha Sawant (Technical Officer) and Mrs. Manju Gorivale (Technician)

Name of the Institute: ICMR-CRMCH, Mumbai

Name of OIC: Dr. Anand Bodade

Contact Details: 8080889764, Email ID: anand.bodade@icmr.gov.in

Name of Operator: Mr. Umesh Dhumne (Technical Officer, ICMR-CRMCH) Contact: 9822569572

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ICMR-CRMCH-NIIH validated MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd. by testing normal, sickle cell trait and sickle cell disease individuals and sample status was confirmed with HPLC Test

Sample ID	Gold St	Gold Standard Test My Lab SICKLE POC Card						Inference	
	HPLC	Diagnosis	Band	d develo	ped in C	ard	Diagnosis	3	
	Test		С	Α	S	С			
† .	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
*									card results matched
2.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
3.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
4.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
5.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
•		- I		+	-		Manage		card results matched
6.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
7	- 00	0:-11-	<u> </u>	-	+	_	O'-l-l-		card results matched
7.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
8.	SS	disease	+	+	+		disease Sickle		Both HPLC and POC
0.	33	Sickle cell disease	+	-	+	-	disease	cell	card results matched
9.	AA	Normal	+	+	+		Normal		Both HPLC and POC
3 .	1	Normal	*	"	-	-	Noma		card results matched
10.	AS	Sickle cell trait	+	+	+	+-	Sickle	cell	Both HPLC and POC
10.	7.0	Olokie celi trait	١.	1.	1.	-	trait	CCII	card results matched
11.	AA	Normal	+	+	+-	+-	Normal		Both HPLC and POC
	700	Normal	ļ ·	'			Homia		card results matched
12.	AA	Normal	+	+	-	T-	Normal		Both HPLC and POC
	1	1							card results matched
13.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
14.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
15.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
16.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				_	disease		card results matched
17.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
40	- 00	O'alda aall	<u> </u>		+		0:11		card results matched
18.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
40	100	disease	.	+	+.		disease	11	card results matched
19.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
20.	AS	Sickle cell trait	+	+.	+.		trait	المم	card results matched Both HPLC and POC
20.	AS	SICKIE CEII II AIL	"	+	+	-	Sickle trait	cell	card results matched
21.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
21.	1	Itomai	'	'	1	-	INOITINAI		card results matched
22.	AA	Normal	+	+	+-	+	Normal		Both HPLC and POC
_ 	1.						- Tomical		card results matched
23.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
24.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC



		disease					disease		card results matched
25.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
26.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
27.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
28.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
29.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
30.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
31.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
32.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
33.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
34.	SS	Sickle cell disease	+	-	+	-	Sickle disease	cell	Both HPLC and POC card results matched
35.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
36.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
37.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
38.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
39.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
40.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
41.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
42.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
43.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
44.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
45.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
46.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
47.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
48.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
49.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
50.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched

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51.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
					-	-			
52.	AS	Sickle cell trait	+	+	+	-	Sickle trait	cell	Both HPLC and POC card results matched
53.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
00.							trait		card results matched
54.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				1	disease		card results matched
55.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
56.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
00.		disease					disease		card results matched
57.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
01.	1	11311113							card results matched
58.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
00.	/**	Normal		-			Homai		card results matched
59.	AA	Normal	+	+	-	+-	Normal		Both HPLC and POC
39.	~~	Noma	*	*	-	-	Nomai		card results matched
00	100	Named		+.		-	Marmal		
60.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
04		Named	<u> </u>	+	-	_	Marraal		
61.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
62.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
63.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
64.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
65.	SS	Sickle cell	+	1-	+	1 -	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
66.	SS	Sickle cell	+	1-	+	-	Sickle	cell	Both HPLC and POC
		diseases					diseases	OOII	card results matched
67.	SS	Sickle cell	+	† <u>-</u>	+	+	Sickle	cell	Both HPLC and POC
01.	00	diseases			'	-	diseases	CCII	card results matched
68.	AA	Normal	+	+	1-	-	Normal		Both HPLC and POC
00.	~~	Noma	"	"	-	-	INOITHAL		
60		Normal	 	+.		-	Manus al		card results matched
69.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
70		<u> </u>	_	-					card results matched
70.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
71.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
72.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
73.	AS	Sickle cell trait	+	+	+	T-	Sickle	cell	Both HPLC and POC
							trait		card results matched
74.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
75.	AS	Sickle cell trait	+	+	+	+-	Sickle	cell	Both HPLC and POC
	1.5					1	trait	0011	card results matched
76.	SS	Sickle cell	+	1-	+	-	Sickle	cell	Both HPLC and POC
		disease	Ι΄.		Ι.	1	disease	OGII	card results matched
77.	SS	Sickle cell	+	-	+	-	Sickle	coll	Both HPLC and POC
	33	disease	Ι΄.	-	"	-	I	cell	
		นเจนลงช					disease		card results matched



		T				_			
78.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
79.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
80.	AA	Normal	+	+ /	- '	-	Normal		Both HPLC and POC
									card results matched
81.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
01.	1,4,	Tronna.		1					card results matched
82.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
02.	1 ~~	Noma	·	'			110111101		card results matched
00	100	Sickle cell trait	+	+	+	†-	Sickle	cell	Both HPLC and POC
83.	AS	Sickle cell trait	T	*	"	-	trait	Cell	card results matched
							liait		card results matched
84.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
85.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
86.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				1	disease		card results matched
87.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
07.	00	disease	ļ .		'		disease	00	card results matched
00	AA	Normal	+	+		-	Normal		Both HPLC and POC
88.	AA	Noma	1	1	1	-	Nominal		card results matched
	1	N		.		-	Mannal		Both HPLC and POC
89.	AA	Normal	+	+	-	-	Normal		
							ļ		card results matched
90.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
91.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
92.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
93.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
94.	SS	Sickle cell	+	_	+	-	Sickle	cell	Both HPLC and POC
04.		disease					disease	,	card results matched
95.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
35.	30	disease	١.		· ·		disease	OCII	card results matched
00	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
96.	AS	Sickle cell trait	"	*	"	-		CEII	card results matched
07	100	Cialda anll too!t		+.	 		trait	المم	
97.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
	1			-			trait		card results matched
98.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
99.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
100.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
101.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
.5		3.55 50					trait		card results matched
102.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
102.	33	disease					disease	5511	card results matched
102	SS		+	+	+		Sickle	cell	Both HPLC and POC
103.	33		"	-	"	-		CEII	card results matched
404	1 4 4	disease	ļ.,	+.			disease		
104.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC



			Т		1				card results matched
105.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
100.		Nomai	'	1'	-	-	INOITHAL		card results matched
106.	AA	Normal	+	+	_		Marmal		
100.	~~	Normal	*	*	-	-	Normal		Both HPLC and POC
107		Namal	١.	+.			Managara		card results matched
107.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
400		Name	.	+					card results matched
108.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
100		0'-11-	+				01.11		card results matched
109.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease	-				disease		card results matched
110.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
			-						
111.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
112.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
113.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
114.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
				1			trait		card results matched
115.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
116.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
117.	AS	Sickle cell trait	+	+	+	T -	Sickle	cell	Both HPLC and POC
							trait		card results matched
118.	SS	Sickle cell	+	1-	+		Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
119.	SS	Sickle cell	+	+-	+	1-	Sickle	cell	Both HPLC and POC
110.		.disease	1				disease	0011	card results matched
120.	AA	Normal	+	+	1-	+	Normal		Both HPLC and POC
120.	1,0,	Normal	ļ .	1			Nomia		card results matched
121.	AA	Normal	+	+	+-	† <u> </u>	Normal		Both HPLC and POC
121.	/**	Tromia		1			Homia		card results matched
122.	AA	Normal	+	+	 -	+	Normal		Both HPLC and POC
122.	~~	Normal	'	1.	-		Ivoliliai		card results matched
123.	AA	Normal	+	+	+ -	+	Normal		Both HPLC and POC
125.	~~	Noma	'	1.	-	-	Noma		card results matched
101		Normal	_	1			Normal		Both HPLC and POC
124.	AA	Normal	*	*	-	-	INOITIAI		card results matched
		,							(Faint line on S band)
405		O'alda asil	├ .		+.		Cialda	11	
125.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
100		disease		-	+	-	disease		card results matched
126.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
127.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
100		disease		1	1		disease		card results matched
128.	AS	Sickle cell trait	+	+	+	1-1	Sickle	cell	Both HPLC and POC
100							trait		card results matched
129.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
				1			trait		card results matched
130.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched



131.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
132.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
133.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
		0.11			-	-	trait		card results matched
134.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
		0:11111	-	-	 		trait	11	card results matched
135.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
		0:11:	-		+		trait		card results matched
136.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
407		disease	-		+.		disease	11	card results matched
137.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC card results matched
400		disease	.	-	+.		disease Sickle	اامو	Both HPLC and POC
138.	SS	Sickle cell	+	-	+	-		cell	l .
400	100	disease		+	+		disease	11	card results matched
139.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
		0:11 111 11		+	+		trait	11	card results matched
140.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
		0:11			1		0:11	11	(Faint band on A)
141.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease		1		-	disease		card results matched
142.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
143.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
144.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				1	disease		card results matched (S
		<u> </u>							line seen on C band)
145.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease		1		1	disease		card results matched
146.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
147.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease		-		+	disease		card results matched
148.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
149.	AA	Normal	+	+	-	1 -	Normal		Both HPLC and POC
									card results matched
150.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
151.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
152.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
153.	SS	Sickle cell	+	-	+		Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
154.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
155.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
156.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
				\perp			trait		card results matched
157.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC

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							trait		card results matched
450	AS	Sickle cell trait	+	+	+	+-	Sickle	cell	Both HPLC and POC
158.	AS	Sickle cell trait	"	'	1.		trait	0011	card results matched
450	100	Cialda aall trait	+	+	+	+	Sickle	cell	Both HPLC and POC
159.	AS	Sickle cell trait	T	*	1	-	trait	OOII	card results matched
		Olabla sall trait	ļ.,	+	+		Sickle	cell	Both HPLC and POC
160.	AS	Sickle cell trait	+	+	*	-	trait	Cell	card results matched
		0.11	-		-		Sickle	cell	Both HPLC and POC
161.	SS	Sickle cell	+	-	+	-		Cell	card results matched
		disease	_				disease	اامم	
162.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease	11	card results matched
163.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
164.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
165.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
166.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
167.	AS	Sickle cell trait	+	+	+	T -	Sickle	cell	Both HPLC and POC
							trait		card results matched
168.	SS	Sickle cell	+	T -	+	-	Sickle	cell	Both HPLC and POC
100.	55	disease				İ	disease		card results matched
169.	SS	Sickle cell	+	1-	+	T-	Sickle	cell	Both HPLC and POC
100.	00	disease			'		disease	00	card results matched
		diocaso					aloodoo		(Faint line on S band)
170.	SS	Sickle cell	+	+	+	+_	Sickle	cell	Both HPLC and POC
170.	33	disease	"	-	"	-	disease	COII	card results matched
171.	SS	Sickle cell	+	+	+	+	Sickle	cell	Both HPLC and POC
171.	33		T	-	"	-	disease	Cell	card results matched
470		disease	- -		+.			المم	Both HPLC and POC
172.	SS	Sickle cell	+	-	+	-	Sickle	cell	1
470	- 00	disease	 		.		disease	11	card results matched
173.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
4=4		disease	.				disease		card results matched
174.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
175.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
176.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
177.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
178.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
179.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease		1			disease	•••	card results matched
180.	SS	Sickle cell	+	1_	+	-	Sickle	cell	Both HPLC and POC
	55	disease			'		disease	OOII	card results matched
181.	AS	Sickle cell trait	+	+	+	+_	Sickle	cell	Both HPLC and POC
	/10	Cloric con trait	1		'	-	trait	COII	card results matched
182.	AS	Sickle cell trait	+	+	+		Sickle	coll	Both HPLC and POC
102.	^0	Olonie Gell trait	'	"	"	-		cell	card results matched
							trait		
183.	AS	Sickle cell trait	+	+	+.		Cioldo	ocli	(Faint line on S band)
100.	AS	Sickle cell frait	T	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched

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			1	T					(Faint line on A band)
184.	AS	Sickle cell trait	+	+	+	+_	Sickle	cell	Both HPLC and POC
104.	40	Olokie celi trait	'	1.	'		trait	OOII	card results matched
185.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
100.	10	Olokie celi trait	'	'	'		trait	OOII	card results matched
186.	SS	Sickle cell	+	<u> </u>	+	-	Sickle	cell	Both HPLC and POC
100.	33	disease	Ι΄.	-	'	-	disease	OGII	card results matched
187.	SS	Sickle cell	+	+	+	-	Sickle	cell	Both HPLC and POC
107.	33	disease	'		'		disease	OCII	card results matched
188.	SS	Sickle cell	+	 - - - - - - - - - - - - -	+	-	Sickle	cell	Both HPLC and POC
100.	00	disease	'		'		disease	0011	card results matched
189.	AS	Sickle cell trait	+	+	+	T-	Sickle	cell	Both HPLC and POC
100.	7.0	Ciolas con trait					trait	0011	card results matched
190.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
100.	,						trait		card results matched
									(Faint line on S band)
191.	SS	Sickle cell	+	-	+	1-	Sickle	cell	Both HPLC and POC
1011	55	disease					disease		card results matched
	-								(Faint line on S band)
192.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
102.							trait		card results matched
193.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
100.	55	disease					disease		card results matched
194.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				1	disease		card results matched
195.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
	55	disease				1	disease		card results matched
196.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
197.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
198.	SS	Sickle cell	+	-	+	1-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
199.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
					~				card results matched
200.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC
									card results matched
201.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				1	disease		card results matched
									(Faint line on A band)
202.	SS	Sickle cell	+	-	+	T -	Sickle	cell	Both HPLC and POC
		disease				-	disease		card results matched
203.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
204.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease				1	disease		card results matched
205.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
206.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
207.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
208.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
209.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC

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			T -	_			T		card results matched
210.	AA	Normal	+	+	+	+	Normal		Both HPLC and POC
210.	~~	INOITIIAI	*	· •	-	-	Nonnai		
211.	SS	Sickle cell	+	-	+	_	Cialda	!!	card results matched
211.	33		*	-	*	-	Sickle	cell	Both HPLC and POC
212.	SS	disease Sickle cell	·		+	_	disease	!!	card results matched
212.	55		+	-	+	-	Sickle	cell	Both HPLC and POC
213.		disease	ļ.,	-	+.	_	disease		card results matched
213.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
24.4		disease			+.		disease		card results matched
214.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
045		disease	·		+		disease	11	card results matched
215.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
040	100	disease		+	 		disease		card results matched
216.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
247		0:11 "11 "1		-			trait		card results matched
217.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait		card results matched
									(Faint line on S band)
218.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
219.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
220.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
221.	AA	Normal	+	+	-	-	Normal	-	Both HPLC and POC
		, '				~			card results matched
222.	AA	Normal	+	+	- 7	-	Normal		Both HPLC and POC
				1		ì			card results matched
223.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease	*				disease		card results matched
224.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
225.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
226.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched
227.	SS	Sickle cell	+	1-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease	00	card results matched
228.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
							trait	0011	card results matched
		,					l didit		odia rosalis maisnea
				1	1				
220	10	Oialda a III () 'I		+	+	-	0: 1:		
229.	AS	Sickle cell trait	+	+	+	-	Sickle	cell	Both HPLC and POC
		[11	trait		card results matched
									(Faint line on S band)
		,							
230.	SS	Sickle cell	+	-	+	-	Sickle	cell	Both HPLC and POC
		disease					disease		card results matched

Theran

Interpretation: All samples tested with the POC of MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd kit show 100% sensitivity, 100% specificity and 100% accuracy for all the haemoglobinopathies tested. (Band Intensity of 12/230 (5.2%) samples showed low intensity)

Conclusion: The Indian Council of Medical Research (ICMR- CRMCH, Chandrapur) under ICMR- National Institute of Immunohematology, Mumbai tested 230 normal (AA) and sickle cell samples (AS and SS pattern) on MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd as per instructions and compared it to HPLC results. MyLab Sickle cell Rapid Test Kit of MyLab Discovery Solutions Pvt. Ltd and HPLC as technology provided 100% accurate results as compared to the GOLD STANDARD (Biorad Variant II HPLC). The band intensities needs to be improved.

Dr. Manisha Madkaikar

Director

निदेशक / Director आईसीएमआर-राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान ICMR - National Institute of Immunohaematology 13वीं मजिल, नई बहुमंजिली ईमारत, के इ एम अस्पताल परिसर, परेल, मुंबई-४०००१२. 13th Floor, New Multistoreyed Building, KEM Hospital Campus Parel, Mumbai - 400 012. Dr. Prabhakar S. Kedar, Ph.D.
Scientist 'E', (Dy. Director)
ICMR National Institutre of Immunohacmatology
13th Floor, New Multistoreyed Bldg.,
KEM Hospital Campus, Parel,
Mumbai 400 012.

Jula

Dr. Prabhakar Kedar

HOD Haematogenetics





आई सी एम आर - राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

ICMR-National Institute of Immunohaematology

Department of Health Research, Ministry of Health and Family Welfare, Government of India.

Date:02/02/2024

VALIDATION REPORT OF TRIVITRON HEALTHCARE BIOCARD SICKLE CELL RAPID TEST

ICMR-NIIH Mumbai and CRMCH Chandrapur evaluated Trivitron healthcare Biocard sickle cell rapid test card by testing normal, sickle cell trait and sickle cell disease individuals (adults) with HPLC results on 290 samples.

Following are the details of the batches used for the evaluation from Trivitron Healthcare Pvt. Ltd.

	TRIVITRON HEALTH	ICARE BIOCARD SICKLE CEL	L RAPID TEST CARD
Product Name			
Product Code	MFG/TL/IVD/2023/000393	MFG/TL/IVD/2023/000393	MFG/TL/IVD/2023/000393
Lot No	RDSCR23004	RDSCR23005	RDSCR23006
Mfg. Date	July - 2023	July - 2023	July - 2023
Exp. Date	June - 2025	June - 2025	June - 2025
Total Test	100	100	100
Testing Start			
Date	18/01/2024	Completion Date:	31/01/2024

Details of Gold Standard test:

Prodct Code	Variant II β - thalassemia (HPLC) Kit
Product Made	Biorad
Lot No:	64536704
Mfg. Date	7/3/2023
Ex. Date	13/11/2025

Name of the Institute: ICMR-NIIH, Mumbai

Name of the Director: Dr. Manisha Madkaikar, ICMR-NIIH, Mumbai Phone No: 09892472552, Email ID: madkaikarmanisha@gmail.com

Name of the HOD: Dr. Prabhakar S Kedar, Scientist E, Dept. of Haematogenetics, ICMR-NIIH, Mumbai.

Phone No: 9969007500, Email ID: kedarps2002@yahoo.com

Name of the Operator: Mrs. Pratibha Sawant (Technical Officer) and Mrs. Manju Gorivale (Technician)

Name of the Institute: ICMR-CRMCH, Mumbai

Name of OIC: Dr. Anand Bodade

Contact Details: 8080889764, Email ID: anand.bodade@icmr.gov.in

Name of Operator: Mr. Umesh Dhumne (Technical Officer, ICMR-CRMCH) Contact: 9822569572

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Results: ICMR-NIIH and ICMR CRMCH validated Trivitron healthcare Biocard sickle cell rapid test card by testing normal, sickle cell trait, and sickle cell disease individuals and sample status was confirmed with HPLC Test

Sample	Gold S	tandard Te	st	Trivitron \$	SICKLE P	OC Card			Inference
ID	HPLC	Diagnos	is	Band deve	eloped in C	ard	Diagnos	is	1
	Test			С	HA	HS			
1.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
2.	AA	Normal		+	+	,-	Normal		Both HPLC and POC card
3.	SS	Sickle	cell	+	-	+	Sickle	cell	results matched Both HPLC and POC card
		disease					disease		results matched
4.	SS	Sickle disease	cell	+	,-	+	Sickle disease	cell	Both HPLC and POC card results matched
5.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
6.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
7.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
8.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
9.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
10.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
44	00	disease	11				disease		results matched
11.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
12.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
12.	00	disease	CCII	·	_	1	disease	CCII	results matched
13.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
14.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
15.	AA	Normal		+ ,	+	-	Normal		Both HPLC and POC card
		ļ					ļ., .		results matched
16.	AA ·	Normal		+	+	-	Normal		Both HPLC and POC card
47	00	Cialda	!!				Cialda	11	results matched
17.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
18.	SS	disease Sickle	cell	+		+	disease Sickle	cell	results matched Both HPLC and POC card
10.	00	disease	ceii	7	-	*	disease	ceii	results matched
19.	SS	Sickle	cell	+	y_	+	Sickle	cell	Both HPLC and POC card
13.	30	disease	Cell	r	_	"	disease	Cell	results matched*
20.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
	/	trait	0011	-			trait	0011	results matched
21.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait	55	results matched
22.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched

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						T		Dath UDLC and DOC cord
23.	AA	Normal	+	+	-	Normal		Both HPLC and POC card results matched
						Normal		Both HPLC and POC card
24.	AA	Normal	+	+	-	Normai		results matched
						Sickle	cell	Both HPLC and POC card
25.	SS	Sickle ce	ell +	-	+	diseases		results matched
		diseases	, .		+	Sickle	cell	Both HPLC and POC card
26.	SS	Sickle ce	+	-	"	disease	Cell	results matched
		disease	11 +		+	Sickle	cell	Both HPLC and POC card
27.	SS	Sickle ce	SII T	-	'	disease	OCII	results matched
	AC	disease Sickle ce	11 +	+	+	Sickle	cell	Both HPLC and POC card
28.	AS	trait	" '	'		trait	0011	results matched
20	AS	Sickle ce	11 +	+	+	Sickle	cell	Both HPLC and POC card
29.	AS	trait	" '			trait		results matched
20	SS	Sickle ce	11 +		+	Sickle	cell	Both HPLC and POC card
30.	33	disease	"			disease		results matched
31.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
31.	1	Normal						results matched
32.	AA	Normal	+	+	_	Normal		Both HPLC and POC card
32.	7	Noma						results matched
33.	SS	Sickle ce	+		+	Sickle	cell	Both HPLC and POC card
55.	00	disease	"			disease		results matched
34.	SS	Sickle ce	II +	_	+	Sickle	cell	Both HPLC and POC card
JT.	00	disease	"			disease		results matched
35.	SS	Sickle ce	11 +	_	+	Sickle	cell	Both HPLC and POC card
5 0.		disease	.			disease		results matched
36.	AS	Sickle ce	+	+	+	Sickle	cell	Both HPLC and POC card
00.	1	trait				trait		results matched
37.	AS	Sickle ce	+	+	+	Sickle	cell	Both HPLC and POC card
• • • • • • • • • • • • • • • • • • • •		trait				trait		results matched
38.	SS	Sickle ce	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched*
39.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
40.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
41.	SS	Sickle ce	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
42.	SS	Sickle ce	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
43.	AS	Sickle ce	+	+	+	Sickle	cell	Both HPLC and POC card
		trait				trait		results matched
44.	SS	Sickle ce	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
45.	AS	Sickle ce	+	+	+	Sickle	cell	Both HPLC and POC card
		trait				trait		results matched
46.	SS	Sickle ce	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
47.	AA	Normal	+,	+	-	Normal		Both HPLC and POC card
								results matched

Mesas

48.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
49.	SS	Sickle ce	+	-	+		results matched Both HPLC and POC card
		disease				disease	results matched
50.	SS	Sickle ce	∥ +	-	+		ell Both HPLC and POC card
		disease				disease	results matched
51.	AS	Sickle ce	N	+	+	1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	ell Both HPLC and POC card
		trait				trait	results matched
52.	SS	Sickle ce	∥ +	-	+	4.4	ell Both HPLC and POC card
		diseases				diseases	results matched
53.	AS	Sickle ce trait	+	+	+	Sickle contrait	ell Both HPLC and POC card results matched
54.	AS	Sickle ce	+	+	+	Sickle c	ell Both HPLC and POC card
		trait				trait	results matched
55.	AS	Sickle ce	+	+	+		ell Both HPLC and POC card
		trait				trait	results matched
56.	AS	Sickle ce	+	+	+		ell Both HPLC and POC card
		trait				trait	results matched
57.	SS	Sickle ce	ll +	-	+		ell Both HPLC and POC card
• • •		disease	"			disease	results matched
58.	SS	Sickle ce	+		+		ell Both HPLC and POC card
00.		disease	" '		-	disease	results matched
59.	AA	Normal	+	+		Normal	Both HPLC and POC card
00.	/**	Normal		'	_	Normal	results matched
60.	AA	Normal	+	+		Normal	Both HPLC and POC card
00.	^^	Normal	'	-	_	Nomai	results matched
61.	AA	Normal	+	+	<u> </u>	Normal	Both HPLC and POC card
01.	1	Noma		'	_	Nomia	results matched
62.	AA	Normal	+	+		Normal	Both HPLC and POC card
UZ.	1	Nomiai	•	'	-	INOIIIIai	results matched
63.	SS	Sickle ce	+	-	+	Sickle ce	
		diseases	_			diseases	results matched
64.	SS	Sickle ce	11 +	_	+	Sickle ce	
•		disease	-			disease	results matched
65.	AS	Sickle ce	+	+	+	Sickle co	
	/	trait	"			trait	results matched
66.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
	1751	11077711011	•			11011110	results matched
67.	AS	Sickle ce	+	+	+	Sickle ce	ell Both HPLC and POC card
	7.0	trait	.			trait	results matched
68.	AS	Sickle ce	+	+	+ -		ell Both HPLC and POC card
	/.0	trait				trait	results matched
69.	AS	Sickle ce	+	+	+		ell Both HPLC and POC card
		trait				trait	results matched
70.	AA	Normal	+	+	_	Normal	Both HPLC and POC card
		110///				110111101	results matched
71.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
72.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched

Denon

73.	AA	Normal	+	+	Τ -	Normal		Both HPLC and POC card
								results matched
74.	SS	Sickle cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
75.	SS	Sickle cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
76.	SS	Sickle cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
77.	SS	Sickle cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched*
78.	SS	Sickle cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease				disease		results matched
79.	AS	Sickle cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait				trait		results matched
80.	AS	Sickle cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait				trait		results matched
81.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
		•						results matched
82.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
83.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
84.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
85.	AA	Normal	+	+	-	Normal	,	Both HPLC and POC card
								results matched
86.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
87.	AA	Normal	+	+	1-1	Normal		Both HPLC and POC card
								results matched
88.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
89.	AS	Sickle cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait				trait		results matched
90.	AS	Sickle cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait		4		trait		results matched
91.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
92.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
93.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
94.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
95.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
96.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched
97.	AA	Normal	+	+	-	Normal		Both HPLC and POC card
								results matched



98.	AA	Normal		+	+	Τ.	Normal		Both HPLC and POC card
J0.	1	Nonna		'	'		Indinial		results matched
99.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
100.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
101.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
102.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
103.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
104.	AA	Normal	l	+	+	-	Normal		Both HPLC and POC card
405	-	- N					No.		results matched
105.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
400		Named		+	+		Normal		results matched Both HPLC and POC card
106.	AA	Normal		+	T	-	Normal		
107	AA	Normal		+	+		Normal		results matched Both HPLC and POC card
107.	AA	Normal		т	T	-	Normal		results matched
108.	AA	Normal		+	+		Normal		Both HPLC and POC card
100.	AA	Nomai		т	"	-	Nomiai		results matched
109.	AA	Normal		+	+		Normal		Both HPLC and POC card
109.	~~	Nomai		т		_	Nomai		results matched
110.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
110.	10	trait		•			trait	CCII	results matched
111.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
	/ 0 (- Nomiai					Ittorina		results matched
112.	AA	Normal		+	+	_	Normal		Both HPLC and POC card
									results matched
113.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
114.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
115.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
116.	AS	1	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
117.	AS	1	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
118.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
440		disease	0		-		disease	11	results matched
119.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
400	- 00	disease	!!				disease	aall	results matched
120.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card results matched
121.	AS	disease Sickle	coll	+	+	+	disease Sickle	cell	Both HPLC and POC card
121.	AS	trait	cell	7	*	*	trait	cell	results matched
122.	AS	_	cell	+	+	+	Sickle	cell	Both HPLC and POC card
122.	70	trait	CEII	r	"	, r	trait	Cell	results matched
		uait			L		llail		าธอนแอ เแตเบเซน

General

123.	AS	Sickle o	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
124.	AS		cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
125.	SS		ell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
126.	SS		cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
127.	AS		ell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
128.	SS	_	ell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
129.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
130.	AA	Normal		+	+	_	Normal		Both HPLC and POC card results matched
131.	SS	Sickle c	ell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
132.	SS		ell	+	-	+	Sickle diseases	cell	Both HPLC and POC card results matched
133.	SS		ell	+	-	+	Sickle diseases	cell	Both HPLC and POC card results matched
134.	SS		ell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
135.	SS		ell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
136.	SS		cell	+	-	+	Sickle diseases	cell	Both HPLC and POC card results matched
137.	SS		cell	+	-	+	Sickle disea	cell	Both HPLC and POC card results matched
138.	SS		ell	+	-	+		cell	Both HPLC and POC card results matched
139.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
140.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
141.	AS	Sickle c	ell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
142.	AS	_	ell	+	+	+		cell	Both HPLC and POC card results matched
143.	AS		ell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
144.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
145.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
146.	SS	Sickle c	æll	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
147.	SS		æll	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched

year

148.	SS	Sickle	cell	.1	1		Olat-I-		D. II. LIDLO 1 DOO 1
		disease		+	-	+	Sickle diseas	cell	Both HPLC and POC card results matched
149.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
150.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
151.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
152.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
150									results matched
153.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
454		disease	11				diseases		results matched*
154.	SS	Sickle	cell	+		+	Sickle	cell	Both HPLC and POC card
155.	SS	disease	المم				disease		results matched
100.	33	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
156.	SS	diseases Sickle	aall				disease	11	results matched
150.	33	disease	cell	+	-	+	Sickle	cell	Both HPLC and POC card
157.	AS	Sickle	aall	+		<u> </u>	disease		results matched
137.	AS	trait	cell	+	+	+	Sickle	cell	Both HPLC and POC card
158.	AS	Sickle	cell	+	+	—	trait Sickle	!!	results matched
130.	7.5	trait	cell	т	+	+		cell	Both HPLC and POC card
159.	AS	Sickle	cell	+	+	+	trait Sickle	aall	results matched Both HPLC and POC card
100.	70	trait	Cell	т	"	T	trait	cell	
160.	AA	Normal		+	+		Normal		results matched Both HPLC and POC card
100.	7	Noma		т	T	-	Nomai		results matched
161.	SS	Sickle	cell	+	_	+	Sickle	cell	Both HPLC and POC card
101.		diseas			_		disease	CEII	results matched
162.	SS	Sickle	cell	+	_	+	Sickle	cell	Both HPLC and POC card
102.		disease		•			disease	CCII	results matched
163.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
164.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
	(40)								results matched
165.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
166.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
167.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
168.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
169.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
170.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
171.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
172.	SS	I	cell	+		+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched*



173.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
174.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
175.	AA	Normal		+	+		Normal		Both HPLC and POC card
									results matched
176.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
							0		results matched
177.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
178.	AS	2 2 2	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
179.	AS	1	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
180.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
181.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		diseases					diseases		results matched
182.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
183.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
184.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
185.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
186.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
187.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
188.	AS		cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
189.	AS		cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
190.	SS	1	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
191.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
192.	AS	I	cell	+	+	+		cell	Both HPLC and POC card
		trait					trait		results matched
193.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
194.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
195.	SS	1	cell	+	-	+		cell	Both HPLC and POC card
		disease					disease		results matched
196.	SS		cell	+	-	+		cell	Both HPLC and POC card
		disease					disease		results matched*
197 <i>.</i>	SS		cell	+	-	+		cell	Both HPLC and POC card
		disease					disease		results matched*



198.	SS	Sickle	cell	+	_	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
199.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
200.	AA	Normal		+	+	-	Normal		Both HPLC and POC card
									results matched
201.	SS		cell	+	_	+	Sickle	cell	Both HPLC and POC card
		disease		<u> </u>			disease		results matched
202.	AS	10.00	cell	+	+	+	Sickle	cell	Both HPLC and POC card
LUL.		trait					trait		results matched
203.	SS		cell	+	_	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
204.	AS	1	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
205.	AS		cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
206.	SS		cell	+	_	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
207.	AA	Normal		+	+	_	Normal		Both HPLC and POC card
									results matched
208.	SS	1	cell	+	_	+	Sickle	cell	Both HPLC and POC card
	-	disease					disease		results matched
209.	AA	Normal		+	+	_	Normal		Both HPLC and POC card
	1								results matched
210.	SS		cell	+	_	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
211.	AS		cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
212.	AS		cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait	II	results matched
213.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease	!!				disease	11	results matched
214.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease	!!				disease	11	results matched
215.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease	11				disease	II	results matched
216.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease	!!				disease		results matched
217.	SS		cell	+	_	+	Sickle	cell	Both HPLC and POC card
		disease	II				disease	11	results matched
218.	SS	4.0	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease	!!				disease	11	results matched
219.	SS	- A.S.	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease	!!	results matched
220.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease	المما	results matched
221.	SS	1 20	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease	"				disease	00	results matched
222.	SS		cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched

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		Cialda	المم	1	T		Sickle	cell	Poth UDLC and DOC card
223.	AS	Sickle trait	cell	+	+	+	trait	cell	Both HPLC and POC card results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
224.	AS	trait	Cell	+	+	+	trait	Cell	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
225.	AS	trait	Cell	+	+	+	trait	CEII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
226.	SS	disease	Cell	+	-	+	disease	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
227.	AS	trait	CCII	+	+	+	trait	OCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
228.	AS	trait	OOII	+	+	+	trait	00	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
229.	SS	disease	OCII	+	-	+	disease	0011	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POv C
230.	SS	disease	OOII	+	-	+	disease	00	card results matched
	1	Sickle	cell	5 26			Sickle	cell	Both HPLC and POC card
231.	SS	disease	OCII	+	-	+	disease	00	results matched
	+	Sickle	cell				Sickle	cell	Both HPLC and POC card
232.	AS	trait	CCII	+	+	+	trait	00	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
233.	SS	disease	OCII	+	-	+	disease	0011	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
234.	AS	trait	OCII	+	+	+	trait	00	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
235.	AS	trait	OC!I	+	+	+	trait	00	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
236.	SS	disease	00	+	-	+ -	disease		results matched
									Both HPLC and POC card
237.	AA	Normal		+	+	-	Normal		results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
238.	SS	disease		+	-	+	disease		results matched
	1			_					Both HPLC and POC card
239.	AA	Normal		+	+	-	Normal		results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
240.	SS	disease		+	-	+	disease		results matched
	1	Sickle	cell		2		Sickle	cell	Both HPLC and POC card
241.	AS	trait		+	+	+	trait		results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
242.	AS	trait		+	+	+	trait		results matched
		Sickle	cell	7.			Sickle	cell	Both HPLC and POC card
243.	SS	disease		+	-	+	disease		results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
244.	SS	disease		+	-	+	disease		results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
245.	SS	disease		+	-	+	disease		results matched
212		Sickle	cell				Sickle	cell	Both HPLC and POC card
246.	SS	disease		+	-	+	disease		results matched
0.17		Sickle	cell				Sickle	cell	Both HPLC and POC card
247.	SS	disease		+	-	+	disease		results matched



		Cioldo	acli				Cialda	ocli	Both UDI C and DOC sord
248.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
		Sickle	aall				Sickle	aall	Both HPLC and POC card
249.	SS	disease	cell	+	-	+	disease	cell	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
250.	SS	disease	Cell	+	-	+	disease	Cell	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
251.	SS	disease	Cell	+	-	+	disease	Cell	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
252.	SS	disease	CEII	+	-	+	disease	Cell	results matched
	-	Sickle	cell				Sickle	cell	Both HPLC and POC card
253.	AS	trait	CCII	+	+	+	trait	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
254.	AS	trait	CCII	+	+	+	trait	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
255.	AS	trait	CGII	+	+	+	trait	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
256.	SS	disease	CEII	+	-	+	disease	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
257.	AS	trait	CEII	+	+	+	trait	CEII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
258.	AS	trait	CEII	+	+	+	trait	CEII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
259.	SS	disease	CEII	+	-	+	disease	CEII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
260.	SS	disease	CEII	+	-	+	disease	CEII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
261.	SS	disease	CCII	+	-	+	disease	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
262.	AS	trait	CCII	+	+	+	trait	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
263.	SS	disease	0011	+	-	+	disease	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
264.	AS	trait	0011	+	+	+	trait	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
265.	AS	trait	0011	+	+	+	trait	CCII	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
266.	SS	disease	0011	+	-	+	disease	CCII	results matched
									Both HPLC and POC card
267.	AA	Normal		+	+	-	Normal		results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
268.	SS	disease		+	-	+	disease	CEII	results matched
	+						uiscasc		Both HPLC and POC card
269.	AA	Normal		+	+	-	Normal		results matched
7 - 7		Sickle	cell				Sickle	cell	Both HPLC and POC card
270.	SS	disease	CCII	+	,-	+	disease	Cell	results matched
		Sickle	cell				Sickle	cell	Both HPLC and POC card
271.	AS	trait	OGII	+	+	+	trait	CEII	results matched
	1	Sickle	cell				Sickle	cell	Both HPLC and POC card
272.	AS	trait	Cell	+	+	+	trait	cell	results matched
		uait					แสแ		results matched



273.	SS	Sickle	cell				Sickle	cell	Both HPLC and POC card
213.	33	disease		+	-	+	disease		results matched
274.	SS	Sickle	cell	cell +	-	+	Sickle	cell	Both HPLC and POC card
	33	disease					disease		results matched
275.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
	33	disease					disease		results matched
276.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
	00	disease		T			disease		results matched
277.	ss	Sickle	cell	cell +	-	+	Sickle	cell	Both HPLC and POC card
	00	disease					disease		results matched
278.	SS	Sickle	cell	ell +	-	+	Sickle	cell	Both HPLC and POC card
	00	disease					disease		results matched
279.	SS	Sickle	cell	cell +	-	+	Sickle	cell	Both HPLC and POC card
	- 00	disease					disease		results matched
280.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease		T .			disease		results matched
281.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
	100	disease		•			disease		results matched
282.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
283.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
284.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait		<u>'</u>	•	•	trait		results matched
285.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
286.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
287.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait					trait		results matched
288.	AS	Sickle	cell	+	+	+	Sickle	cell	Both HPLC and POC card
		trait	2				trait		results matched
289.	SS	Sickle	cell	+	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched
290.	SS	Sickle	cell	cell +	-	+	Sickle	cell	Both HPLC and POC card
		disease					disease		results matched

Interpretation: All samples tested with the POC of Trivitron healthcare Biocard sickle cell rapid test card show 100% sensitivity, specificity and 100% accuracy for all the haemoglobinopathies tested. * 2.41% (7/290) of the sickle cell anemia patients showed faint band in HA (Adult Hb) position. This might be due to Transfused/ Haemolyzed sample.

Conclusion: The Indian Council of Medical Research (ICMR-NIIH Mumbai and CRMCH, Chandrapur) tested 290 normal (AA) and sickle cell samples (AS and SS pattern) on Trivitron healthcare Biocard sickle cell rapid test card as per instructions and compared it to HPLC results. Trivitron healthcare Biocard sickle cell rapid test card and HPLC as technology provided 100% accurate results as compared to the GOLD STANDARD (Biorad Variant II HPLC). The band intensities were found to be satisfactory as visible and clear to the naked eye.

Dr. Manisha Madkaikar

Director

निदेशक / Director आईसीएमआर-राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान ICMR - National Institute of Immunohaematology 13वीं मजिल, नई बहुमंजिली ईमारत, के इ एम अस्पताल परिसर, परेल, मुंबई-४०० ०१२. 13th Floor, New Multistoreyed Building, KEM Hospital Campus Farel, Mumbai - 400 012. Dr. Prabhakar Kedar HOD Haematogenetics

Dr. Prabhakar S. Kedar, Ph.D. Scientist 'E', (Dy. Director)
ICMR National Institutre of Immunohaematology
13th Floor, New Multistoreyed Bldg.,
KEM Hospital (France, Parel,
Mumbai 400 012.

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आई सी एम आर - राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

ICMR-National Institute of Immunohaematology

Department of Health Research, Ministry of Health and Family Welfare, Government of India.

Date:05/02/2024

VALIDATION REPORT OF ErbaQik SICKLE CELL RAPID TEST

ICMR-NIIH Mumbai and CRMCH Chandrapur evaluated ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.) by testing normal, sickle cell trait and sickle cell disease individuals (adults) with HPLC results on 250 samples.

Following are the details of the batches used for the evaluation from ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.)

Desduct Name	E-b-Oik sickle sol	I rapid test card (TRANSASIA [DIAGNOSTICS Pvt td.)	
Product Name			135339	
Ref. Code	135339	135339		
Lot No	VRSCF2301	VRSCF2302	VRSCF2303	
Mfg. Date	Sep - 2023	Sep - 2023	Sep - 2023	
Exp. Date	Aug - 2025	Aug - 2025	Aug - 2025	
Total Test	100	100	100	
Testing Start				
Date	18/01/2024	Completion Date:	31/01/2024	

Details of Gold Standard test:

Details of Cold Ctails	
Prodct Code	Variant II β - thalassemia (HPLC) Kit
Product Made	Biorad
Lot No:	64536704
Mfg. Date	7/3/2023
Ex. Date	13/11/2025

Name of the Institute: ICMR-NIIH, Mumbai

Name of the Director: Dr. Manisha Madkaikar, ICMR-NIIH, Mumbai Phone No: 09892472552, Email ID: madkaikarmanisha@gmail.com

Name of the HOD: Dr. Prabhakar S Kedar, Scientist E, Dept. of Haematogenetics, ICMR-NIIH, Mumbai.

Phone No: 9969007500, Email ID: kedarps2002@yahoo.com

Name of the Operator: Mrs. Pratibha Sawant (Technical Officer) and Mrs. Manju Gorivale (Technician)

Name of the Institute: ICMR-CRMCH, Mumbai

Name of OIC: Dr. Anand Bodade

Contact Details: 8080889764, Email ID: anand.bodade@icmr.gov.in

Name of Operator: Mr. Umesh Dhumne (Technical Officer, ICMR-CRMCH) Contact: 9822569572

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<u>Results: ICMR-NIIH and CRMCH validated</u> ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.) by testing normal , sickle cell trait, and Sickle cell disease individuals and sample status was confirm with HPLC test.

Sample ID	Gold Stand			cell rapid	test card CS Pvt. Ltd.)	Inference		
	HPLC Test	Diagnosis	Band developed in Card			Diagnosis		
			С	S	Α			
1.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
2.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
3.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched	
4.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
5.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched	
6.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched	
7.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched	
8.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched	
9.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched	
10.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
11.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
12.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched	
13.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched	
14.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched	
15.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
16.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched	
17.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
18.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
19.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched	
20.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched	
21.	AA	Normal	+	-	+	Normal	Both HPLC and POC	

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			1				
							card results matched
22.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
23.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
24.	SS	Sickle cell	+	+	j-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
25.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
26.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
27.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		diseases				diseases	card results matched
28.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
29.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
30.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
31.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
32.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		diseases				diseases	card results matched
33.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
34.	AA	Normal	+	-	+	Normal	Both HPLC and POC
					-		card results matched
35.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
36.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
37.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
38.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
39.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
40.	SS	Sickle cell	+	+	1-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
41.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
42.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
43.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
44.	SS		+	+	-	Sickle cell	Both HPLC and POC
	1.2	disease				disease	card results matched
45.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
46.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC

Willer

		disease				disease	card results matched
47.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
48.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
49.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
50.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
51.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
52.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
53.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
54.	SS	Sickle cell diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
55.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
56.	AS	Sickle cell trait	+	-	ļ -	Sickle cell trait	Both HPLC and POC card results matched
57.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
58.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
59.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
60.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
61.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
62.	AA	Normal	+		+	Normal	Both HPLC and POC card results matched
63.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
64.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
65.	SS	Sickle cell diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
66.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
67.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
68.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
69.	AS	Sickle cell trait	+	-	1-	Sickle cell trait	Both HPLC and POC card results matched
70.	AS	Sickle cell trait	+	-	-,,	Sickle cell trait	Both HPLC and POC card results matched

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			,				
71.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
72.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
73.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
74.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
75.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
76.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC card results matched
77.	SS	disease Sickle cell	+	+	-	disease Sickle cell	Both HPLC and POC
78.	SS	disease Sickle cell	+	+	-	disease Sickle cell	card results matched Both HPLC and POC
79.	SS	disease Sickle cell	+	+	-	disease Sickle cell	Both HPLC and POC
80.	SS	disease Sickle cell	+	+	-	disease Sickle cell	Both HPLC and POC
81.	AS	disease Sickle cell trait	+	-	-	disease Sickle cell trait	Both HPLC and POC
82.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
83.	AA	Normal	+	-	+	Normal	Both HPLC and POC
84.	AA	Normal	+	-	+	Normal	card results matched Both HPLC and POC
85.	AA	Normal	+	-	+	Normal	Both HPLC and POC
86.	AA	Normal	+	-	+	Normal	Both HPLC and POC
87.	AA	Normal	+	-	+	Normal	Both HPLC and POC
88.	AA	Normal	+	-	+	Normal	Both HPLC and POC
89.	AA	Normal	+	-	+	Normal	Both HPLC and POC
90.	AA	Normal	+	-	+	Normal	Both HPLC and POC
91.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
92.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
93.	AA	Normal	+	-	+	Normal	Both HPLC and POC
94.	AA	Normal	+	-	+	Normal	Both HPLC and POC
95.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched



96.	AA	Normal	+	-	+	Normal	Both HPLC and POC
97.	AA	Normal	+		+	Normal	card results matched Both HPLC and POC
	' ' '	, riomai				, voimai	card results matched
98.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
99.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
100.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
101.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
400						0.11	card results matched
102.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
400	10	O'cliber of Harris	ļ.,			0:11	card results matched
103.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
101		Cialda aall				Oistals sall	card results matched
104.	SS	Sickle cell	+	1+	-	Sickle cell	Both HPLC and POC
105.	SS	disease Sickle cell	+	+		disease	card results matched Both HPLC and POC
105.	00	Sickle cell disease	•	+	-	Sickle cell	
106.	AS	Sickle cell trait	+			disease Sickle cell trait	card results matched Both HPLC and POC
100.	AS	Sickle Cell trait	•	-	-	Sickle cell trait	card results matched
107.	SS	Sickle cell	+	+		Sickle cell	Both HPLC and POC
107.	00	disease	'	1	-	disease	card results matched
108.	AA	Normal	+		+	Normal	Both HPLC and POC
100.	7.5	Normal	·	-	'	Noma	card results matched
109.	AA	Normal	+	-	+	Normal	Both HPLC and POC
100.	""	Noma	-		'	Noma	card results matched
110.	AA	Normal	+	-	+	Normal	Both HPLC and POC
						1101111011	card results matched
111.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
112.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
113.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
114.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
115.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
116.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
117.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
118.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
440	100	0:11				0:11	card results matched
119.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
400	00	Cialda "				O'alla "	card results matched
120.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched

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191							
121.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
400	+	disease				disease	card results matched
122.	SS	Sickle cell	+	+		Sickle cell	Both HPLC and POC card results matched
100	100	disease				disease Sickle cell trait	Both HPLC and POC
123.	AS	Sickle cell trait	+	-	-	Sickle cell trait	
404	10	0:11	ļ. —			Cialda aall trait	card results matched
124.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
405	1.0	0:11 "11"				Oishis sall tasit	card results matched
125.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
400	10	01-1-1				Cialda a all taait	card results matched
126.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC
407		0:11		+.		Olabla and	card results matched
127.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
100		disease				disease	card results matched
128.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
129.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
130.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
131.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
132.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
133.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
134.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		diseases				diseases	card results matched
135.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		diseases				diseases	card results matched
136.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
137.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
138.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		diseases				diseases	card results matched
139.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disea	card results matched
140.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
141.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
142.	AA	Normal	+		+	Normal	Both HPLC and POC
							card results matched
143.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
144.	AS	Sickle cell trait	+	-1	-	Sickle cell trait	Both HPLC and POC
							card results matched
145.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched



146.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
147.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
148.	SS	Sickle cell	+	+	-	Sickle cell	
140.	33	disease	Ι τ	"	-	disease	card results matched
149.	SS		+	+	-		Both HPLC and POC
149.	55	Sickle cell disease	*	*	1.5	Sickle cell disease	
150			+	+	-	*****	Both HPLC and POC
150.	SS	Sickle cell	T	"	-	Sickle cell disease	
151.	SS	disease Sickle cell	+	+	_		Both HPLC and POC
151.	55		•	*	-		
150		disease	+	+		disease Sickle cell	card results matched
152.	SS	Sickle cell	Τ.	+	-	2004 35.7 cm 10.35 50.1	Both HPLC and POC
150	A A	disease	 . 			disease	card results matched
153.	AA	Normal	+	-	+	Normal	Both HPLC and POC
454	-	Name of				NI	card results matched
154.	AA	Normal	+	-	+	Normal	Both HPLC and POC
455	100	0:11					card results matched
155.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				diseases	card results matched
156.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
157.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		diseases				diseases	card results matched
158.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disea	card results matched
159.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
160.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
161.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
162.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
163.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
164.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
165.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
166.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
167.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
168.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
169.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				diseas	card results matched
170.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched



171.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
172.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
173.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
174.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
175.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
176.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
177.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
178.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
179.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
180.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
181.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
182.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
183.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
184.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
185.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
186.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
187.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
188.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
189.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
190.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
191.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
192.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
193.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
194.	AS	Sickle cell trait	+	1-	-	Sickle cell trait	Both HPLC and POC card results matched
195.	AS	Sickle cell trait	+	7-2	-	Sickle cell trait	Both HPLC and POC card results matched



AA	Normal	+	-	+	Normal	Both HPLC and POC
						card results matched
SS		+	+	-		Both HPLC and POC card results matched
22		+	+			Both HPLC and POC
33		'	,		disease	card results matched
SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
	disease				disease	card results matched
SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
	disease				disease	card results matched
SS		+	+	-	7.0	Both HPLC and POC
	disease					card results matched
AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
						card results matched
AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
						card results matched
AA	Normal	+	-	+	Normal	Both HPLC and POC
			1			card results matched
SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
	disease				disease	card results matched
AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
						card results matched
SS	Sickle cell	+	+	-		Both HPLC and POC
						card results matched
AA	Normal	+	-	+	Normal	Both HPLC and POC
						card results matched
AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
AS	Sickle cell trait	+	-	1-	Sickle cell trait	Both HPLC and POC
						card results matched
AA	Normal	+	-	+	Normal	Both HPLC and POC
						card results matched
SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
	disease				disease	card results matched
SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
	disease				disease	card results matched
SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
,	disease	<u> </u>			disease	card results matched
AS	Sickle cell trait	+	-	1-	Sickle cell trait	Both HPLC and POC
						card results matched
AA	Normal	+	-	+	Normal	Both HPLC and POC
	.					card results matched
AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
CC	Cioklo oc!!		1		Cioklo ocil	Both HPLC and POC
33		т	T	-		
	dispase		1	1	dicasce	cam regulity maichen
SS	disease Sickle cell	+	+	-	disease Sickle cell	card results matched Both HPLC and POC
	SS	SS Sickle cell disease AA Normal AS Sickle cell trait AA Normal SS Sickle cell trait SS Sickle cell disease AA Normal SS Sickle cell trait AA Normal SS Sickle cell trait AA Normal SS Sickle cell trait AA Normal	SS Sickle cell + disease SS Sickle cell trait + AS Sickle cell trait + AS Sickle cell trait + AA Normal + SS Sickle cell trait + SS Sickle cell trait + AS Sickle cell trait + SS Sickle cell trait + AS Sickle cell trait + AA Normal +	SS Sickle disease + + + + disease + + disease + + disease SS Sickle cell cell disease + + disease Sickle cell trait + + disease + + disease + + disease Sickle cell trait + + disease + + disease Sickle cell trait + + disease Sickle cell trait + + disease Sickle cell trait + - disease Sickle cell trait + - disease AS Sickle cell trait + - disease AS Sickle cell trait + - disease AS Sickle cell trait + - disease disease AS Sickle cell trait + - disease disease disease AS Sickle cell trait disease disease disease	SS Sickle cell disease + + + - disease SS Sickle cell disease + + + - disease SS Sickle cell disease + + - disease SS Sickle cell disease + + - disease SS Sickle cell trait + disease AA Normal + disease AA Normal + disease AS Sickle cell trait + disease AS Sickle cell trait + disease AA Normal + disease AA Normal + disease Sickle cell trait + disease SS Sickle cell trait +	SS



204	00	Olable s-II		1.		Cialda a-II	Doth UDIC and DOO
221.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
222.	AS	Sickle cell trait	+	-		Sickle cell trait	Both HPLC and POC
222.	AS	Sickle cell trait	•	-	-	Sickle cell trait	card results matched
223.	AS	Sickle cell trait	+	_	4	Sickle cell trait	Both HPLC and POC
223.	AS	Sickle cell trait	'	-		Olokie deli trait	card results matched
224.	AS	Sickle cell trait	+	_	_	Sickle cell trait	Both HPLC and POC
224.	7.0	Olokie deli trait	'			Cloric con trait	card results matched
225.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
220.	10	Cioldo don trait				Ciolilo con trait	card results matched
226.	AA	Normal	+	-	+	Normal	Both HPLC and POC
	' ' ' '	1101111011					card results matched
227.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
	1.0		1				card results matched
228.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
229.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
230.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
231.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
232.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
233.	AA	Normal	+	-	+	Normal	Both HPLC and POC
		· [card results matched
234.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease		,		disease	card results matched
235.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
236.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
237.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
238.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
239.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
240.	AA	Normal	+		+	Normal	Both HPLC and POC
							card results matched
241.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
0.10		disease				disease	card results matched
242.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
040	00	disease				disease	card results matched
243.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
244	A.C.	disease				disease	card results matched
244.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
245	AC	Cialda as II 4 = 14				Olal I a a " 4 "	card results matched
245.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched



246.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched
247.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
248.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC
							card results matched
249.	SS	Sickle cell	+	+	-	Sickle cell	Both HPLC and POC
		disease				disease	card results matched
250.	AA	Normal	+	-	+	Normal	Both HPLC and POC
							card results matched

Interpretation: All samples tested with the POC of ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.) showed 100% sensitivity, 100% specificity and 100% accuracy for all the hemoglobinopathy samples tested.

<u>Conclusion:</u> The Indian Council of Medical Research (ICMR-CRMCH, Chandrapur) under ICMR-National Institute of Immunohaematology, Mumbai have tested 250 samples [Normal (AA), AS (sickle cell trait) and SS (sickle cell anemia)] on ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.) kit as per the kit instructions and compared it with HPLC results. ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.) showed satisfactory match with the HPLC gold standard results (Biorad Variant II). Band intensities were found to be satisfactory as visible and clear to the naked eye.

White Manisha Madkaikar

Director

निदेशक / Director आईसीएमआर-राष्ट्रीय प्रतिरक्षा रुधिर विज्ञान संस्थान ICMR - National Institute of Immunohaematology 13वीं मजिल, नई बहुमंजिली ईमारत, के इ एम अस्पताल परिसर, परेल, पुंबई-४०० ०१२. 13th Floor, New Multistoreyed Building, KEM Hespital Campus Parel, Mumbai - 400 012. Dr. Prabhakar Kedar Scientist E and HOD Haematogenetics

Dr. Prabhakar S. Kedar, Ph.D.
Scientist 'E', (Dy. Director)

JCMR National Institutre of Immunolaematology
13th Floor, New Multistoreyed Bldg.,
KEM Hospital Campus, Parel,
Mumbai 400 012.