



भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIAN COUNCIL OF MEDICAL RESEARCH

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Date: 06.02.2024

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

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

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



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INDIAN COUNCIL OF
MEDICAL RESEARCH

NIIH
NATIONAL INSTITUTE OF
IMMUNOHAEMATOLOGY



आई सी एम आर - राष्ट्रीय प्रतिरक्षा रूधिर 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
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:

Product 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 ID	Gold Standard Test		ErbaQik SICKLE POC Card					Inference
	HPLC Test	Diagnosis	Band developed in Card				Diagnosis	
			C	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 diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
4.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
5.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC 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	+	+	-	-	Normal	Both HPLC and POC card results matched
9.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
10.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
11.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
12.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC 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 card results matched
17.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
18.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
19.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
20.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
21.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
22.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
23.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
24.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched

Mesary

25.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC 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 card results matched
29.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
30.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	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.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
34.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
35.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
36.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
37.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
38.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card 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 cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
42.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
43.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
44.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
45.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
46.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	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.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
50.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
51.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
52.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched

		diseases					diseases	card results matched
53.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
54.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	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	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
57.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
58.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC 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	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
66.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
67.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
68.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
69.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC 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.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
74.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
75.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
76.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
77.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
78.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
79.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched

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 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	+	+	-	-	Normal	Both HPLC and POC 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 card results matched
90.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	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.	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	+	+	-	-	Normal	Both HPLC and POC card 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 trait	+	-	-	-	Sickle cell trait	Both HPLC and POC 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

								card results matched
108.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
109.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
110.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
111.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card 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 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 diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
119.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
120.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
121.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
122.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
123.	AS	Sickle cell trait	+	-	-	-	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 diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
126.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
127.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
128.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	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 cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
132.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
133.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
134.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched

135.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
136.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
137.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
138.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases 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 cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
142.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
143.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	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 diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
147.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
148.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
149.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
150.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC 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 diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
154.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
155.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
156.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
157.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
158.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
159.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
160.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
161.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched
162.	SS	Sickle diseases cell	+	-	+	-	Sickle diseases cell	Both HPLC and POC card results matched

		diseases					diseases	card results matched
163.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
164.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
165.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
166.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
167.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
168.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
169.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
170.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
171.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
172.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
173.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
174.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
175.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
176.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
177.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
178.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
179.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
180.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
181.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
182.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
183.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
184.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
185.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
186.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC 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

190.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
191.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC 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 diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
196.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
197.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
198.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
199.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
200.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
201.	SS	Sickle disease	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
202.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
203.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
204.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
205.	AA	Normal	+	-	+	-	Normal	Both HPLC and POC card results matched
206.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
207.	AA	Normal	+	-	+	-	Normal	Both HPLC and POC card results matched
208.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
209.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
210.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
211.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
212.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
213.	SS	Sickle disease cell	+	+	-	-	Sickle cell disease	Both HPLC and POC card results matched
214.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
215.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC 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

		disease					disease	card results matched
218.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
219.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
220.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
221.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
222.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
223.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
224.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
225.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
226.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
227.	SS	Sickle disease cell					Sickle disease cell	Both HPLC and POC card results matched
228.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
229.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
230.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	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 disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
235.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
236.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
237.	AA	Normal	+	-	+	-	Normal	Both HPLC and POC card results matched
238.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
239.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC card results matched
240.	AS	Sickle cell trait	+	-	-	-	Sickle cell trait	Both HPLC and POC card results matched
241.	SS	Sickle disease cell	+	+	-	-	Sickle disease cell	Both HPLC and POC 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 रूधिर विज्ञान संस्थान
ICMR - National Institute of Immunohaematology

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INDIAN COUNCIL OF
MEDICAL RESEARCH

NIIH
NATIONAL INSTITUTE OF
IMMUNOHAEMATOLOGY



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 230 samples.

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.	
Product Code	135339	
Lot No	AG00046-D-1022001E, 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:

Product 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 Standard Test		My Lab SICKLE POC Card					Inference
	HPLC Test	Diagnosis	Band developed in Card				Diagnosis	
			C	A	S	C		
1.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
2.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC 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 card results matched
6.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
7.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
8.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
9.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
10.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
11.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
12.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC 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 disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
16.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
17.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
18.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
19.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
20.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
21.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
22.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
23.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
24.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC

Nedra

		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 cell trait	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 cell trait	Both HPLC and POC card results matched
34.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	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 cell trait	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 cell trait	Both HPLC and POC card results matched
46.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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 cell trait	Both HPLC and POC card results matched

51.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
52.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
53.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
54.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
55.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
56.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
57.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
58.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC 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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
66.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
67.	SS	Sickle cell diseases	+	-	+	-	Sickle cell diseases	Both HPLC and POC card results matched
68.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
69.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC 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	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
74.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
75.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
76.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
77.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched

78.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC 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 card results matched
82.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
83.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
84.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
85.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
86.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
87.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
88.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
89.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC 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 disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
94.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
95.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
96.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
97.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
98.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
99.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
100.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
101.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
102.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
103.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC 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 card results matched
108.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
109.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
110.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
111.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
112.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
113.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
114.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
115.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
119.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
120.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
121.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
122.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
123.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
124.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched (Faint line on S band)
125.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
126.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
127.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
128.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
129.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
130.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched

131.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
132.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
133.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
134.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
135.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
136.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
137.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
138.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
139.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
140.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched (Faint band on A)
141.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
142.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
143.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
144.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched (S line seen on C band)
145.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
146.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
147.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
148.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
149.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
150.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
151.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
152.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
153.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
154.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
155.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
156.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
157.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched

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							trait	card results matched
158.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
159.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
160.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
161.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
162.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
163.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
164.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
165.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
166.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
167.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
168.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
169.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched (Faint line on S band)
170.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
171.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
172.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
173.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
177.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
178.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
179.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
180.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
181.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
182.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched (Faint line on S band)
183.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched

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								(Faint line on A band)
184.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
185.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
186.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
187.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
188.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
189.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
190.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched (Faint line on S band)
191.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched (Faint line on S band)
192.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
193.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
194.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
195.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
196.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
197.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
198.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched (Faint line on A band)
202.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
203.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
204.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
205.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
206.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
207.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
208.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
209.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC

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									card results matched
210.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
211.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
212.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
213.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
214.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
215.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
216.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait		Both HPLC and POC card results matched
217.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait		Both HPLC and POC card results matched (Faint line on S band)
218.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
219.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
220.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
221.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
222.	AA	Normal	+	+	-	-	Normal		Both HPLC and POC card results matched
223.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
224.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
225.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
226.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
227.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched
228.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait		Both HPLC and POC card results matched
229.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait		Both HPLC and POC card results matched (Faint line on S band)
230.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease		Both HPLC and POC card results matched


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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 Immunohaematology, 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 रक्षित विज्ञान संस्थान
ICMR - National Institute of Immunohaematology
13वीं मजिल, नई बहुमंजिली ईमारत, के इ एम अस्पताल परिसर,
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Dr. Prabhakar Kedar
HOD Haematogenetics

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INDIAN COUNCIL OF
MEDICAL RESEARCH

NIIH
NATIONAL INSTITUTE OF
IMMUNOHAEMATOLOGY



आई सी एम आर - राष्ट्रीय प्रतिरक्षा रूधिर 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 Triviron 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 Triviron Healthcare Pvt. Ltd.

Product Name	TRIVITRON HEALTHCARE BIOCARD SICKLE CELL RAPID TEST CARD		
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:

Product 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 ID	Gold Standard Test		Trivitron SICKLE POC Card				Inference
	HPLC Test	Diagnosis	Band developed in Card			Diagnosis	
			C	HA	HS		
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.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
5.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC 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	+	+	-	Normal	Both HPLC and POC card results matched
9.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
10.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
11.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
12.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC 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 card results matched
17.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
18.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
19.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched*
20.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
21.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
22.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched

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23.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
24.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
25.	SS	Sickle cell diseases	+	-	+	Sickle cell diseases	Both HPLC and POC card results matched
26.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
27.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
28.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
29.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
30.	SS	Sickle cell disease	+	-	+	Sickle cell disease	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.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
34.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
35.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
36.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
37.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
38.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card 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 cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
42.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
43.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
44.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
45.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
46.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
47.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched

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48.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
49.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
50.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
51.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
52.	SS	Sickle cell diseases	+	-	+	Sickle cell diseases	Both HPLC and POC card results matched
53.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
54.	AS	Sickle cell trait	+	+	+	Sickle cell trait	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	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
57.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
58.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC 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.	SS	Sickle cell diseases	+	-	+	Sickle cell diseases	Both HPLC and POC card results matched
64.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
65.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
66.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
67.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
68.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
69.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC 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.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
74.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
75.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
76.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
77.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched*
78.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
79.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
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 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	+	+	-	Normal	Both HPLC and POC 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 card results matched
90.	AS	Sickle cell trait	+	+	+	Sickle cell trait	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.	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	+	+	-	Normal	Both HPLC and POC card 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 trait	+	+	+	Sickle cell trait	Both HPLC and POC 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 card results matched
108.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
109.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
110.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
111.	AA	Normal	+	+	-	Normal	Both HPLC and POC card 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 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 disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
119.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
120.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
121.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
122.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched

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123.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
124.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
125.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
126.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
127.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
128.	SS	Sickle disease	cell	+	-	+	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 disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
132.	SS	Sickle diseases	cell	+	-	+	Sickle diseases	cell	Both HPLC and POC card results matched
133.	SS	Sickle diseases	cell	+	-	+	Sickle diseases	cell	Both HPLC and POC card results matched
134.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
135.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
136.	SS	Sickle diseases	cell	+	-	+	Sickle diseases	cell	Both HPLC and POC card results matched
137.	SS	Sickle disease	cell	+	-	+	Sickle disea	cell	Both HPLC and POC card results matched
138.	SS	Sickle disease	cell	+	-	+	Sickle disease	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 trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
142.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
143.	AS	Sickle trait	cell	+	+	+	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 disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
147.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched

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148.	SS	Sickle cell disease	+	-	+	Sickle cell diseases	Both HPLC and POC card results matched
149.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
150.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC 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 diseases	+	-	+	Sickle cell diseases	Both HPLC and POC card results matched*
154.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
155.	SS	Sickle cell diseases	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
156.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
157.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
158.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
159.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
160.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
161.	SS	Sickle cell diseases	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
162.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
163.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
164.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
165.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
166.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
167.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
168.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
169.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
170.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
171.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
172.	SS	Sickle cell disease	+	-	+	Sickle cell disease	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.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
176.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
177.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
178.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
179.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
180.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
181.	SS	Sickle cell diseases	+	-	+	Sickle cell diseases	Both HPLC and POC card results matched
182.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
183.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
184.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
185.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
186.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC 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
190.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
191.	AA	Normal	+	+	-	Normal	Both HPLC and POC 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 disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
196.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched*
197.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched*

198.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
199.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
200.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
201.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
202.	AS	Sickle trait cell	+	+	+	Sickle trait cell	Both HPLC and POC card results matched
203.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
204.	AS	Sickle trait cell	+	+	+	Sickle trait cell	Both HPLC and POC card results matched
205.	AS	Sickle trait cell	+	+	+	Sickle trait cell	Both HPLC and POC card results matched
206.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
207.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
208.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
209.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
210.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
211.	AS	Sickle trait cell	+	+	+	Sickle trait cell	Both HPLC and POC card results matched
212.	AS	Sickle trait cell	+	+	+	Sickle trait cell	Both HPLC and POC card results matched
213.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
214.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
215.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
216.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
217.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
218.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
219.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
220.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
221.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched
222.	SS	Sickle disease cell	+	-	+	Sickle disease cell	Both HPLC and POC card results matched

223.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
224.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
225.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
226.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
227.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
228.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
229.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
230.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
231.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
232.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
233.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
234.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
235.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
236.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
237.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
238.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
239.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
240.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
241.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
242.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
243.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
244.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
245.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
246.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
247.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched

248.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
249.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
250.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
251.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
252.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
253.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
254.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
255.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
256.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
257.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
258.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
259.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
260.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
261.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
262.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
263.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
264.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
265.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
266.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
267.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
268.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
269.	AA	Normal		+	+	-	Normal		Both HPLC and POC card results matched
270.	SS	Sickle disease	cell	+	-	+	Sickle disease	cell	Both HPLC and POC card results matched
271.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched
272.	AS	Sickle trait	cell	+	+	+	Sickle trait	cell	Both HPLC and POC card results matched

273.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
274.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
275.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
276.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
277.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
278.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
279.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
280.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
281.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
282.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
283.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
284.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
285.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
286.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
287.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
288.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
289.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
290.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card 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
Dr. Manisha Madkaikar
Director

निदेशक / Director

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icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

NIIH
NATIONAL INSTITUTE OF
IMMUNOHAEMATOLOGY



आई सी एम आर - राष्ट्रीय प्रतिरक्षा रूधिर 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.)**

Product Name	ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.)		
Ref. Code	135339	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:

Product 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

Handwritten signature

Results: ICMR-NIIH and CRMCH validated 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 Standard Test		ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.)				Inference
	HPLC Test	Diagnosis	Band developed in Card			Diagnosis	
			C	S	A		
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

Healer

							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 disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
28.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
29.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 diseases	+	+	-	Sickle cell diseases	Both HPLC and POC 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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
36.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
37.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	+	-	Sickle cell disease	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.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
44.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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

		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	+	-	-	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	+	-	-	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

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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
77.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
78.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
79.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
80.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
81.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
82.	AS	Sickle cell trait	+	-	-	Sickle cell trait	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	+	-	+	Normal	Both HPLC and POC card results matched
88.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
89.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
90.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
91.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
92.	AS	Sickle cell trait	+	-	-	Sickle cell trait	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

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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	+	-	+	Normal	Both HPLC and POC card results matched
99.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 card results matched
102.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
103.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
104.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
105.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
106.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
107.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
108.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
109.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
110.	AA	Normal	+	-	+	Normal	Both HPLC and POC 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 card results matched
119.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
120.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched

121.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
122.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
123.	AS	Sickle cell trait	+	-	-	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.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
126.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
127.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
128.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
129.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
130.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
134.	SS	Sickle cell diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
135.	SS	Sickle cell diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
136.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
137.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
138.	SS	Sickle cell diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
139.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
140.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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	+	-	-	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

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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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
149.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
150.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
151.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
152.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
153.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
154.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
155.	SS	Sickle cell disease	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
156.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
157.	SS	Sickle cell diseases	+	+	-	Sickle cell diseases	Both HPLC and POC card results matched
158.	SS	Sickle cell disease	+	+	-	Sickle cell disea	Both HPLC and POC card results matched
159.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
168.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
169.	SS	Sickle cell disease	+	+	-	Sickle cell diseas	Both HPLC and POC 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 card results matched
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	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
195.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched

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196.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
197.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
198.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
199.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
200.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
201.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
202.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
203.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
204.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
205.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
206.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
207.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
208.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
209.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
210.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
211.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
212.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
213.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
214.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
215.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
216.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
217.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
218.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
219.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
220.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched

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 card results matched
223.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
224.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
225.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
226.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched
227.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
228.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
229.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
235.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC card results matched
236.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC 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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
242.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
243.	SS	Sickle cell disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
244.	AS	Sickle cell trait	+	-	-	Sickle cell trait	Both HPLC and POC 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 disease	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
250.	AA	Normal	+	-	+	Normal	Both HPLC and POC card results matched

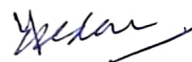
Interpretation: All samples tested with the POC of ErbaQik sickle cell rapid test card (TRANSASIA DIAGNOSTICS Pvt. Ltd.) showed 100% sensitivity, 100% specificity and 100% accuracy for all the hemoglobinopathy samples tested.

Conclusion: 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.



Dr. Manisha Madkaikar
Director

निदेशक / Director
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