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

Date: 15.03.2024



२ भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIAN COUNCIL OF MEDICAL RESEARCH

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

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

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

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



आई सी एम आर - राष्टीय प्रतिरक्षा रुधिर विज्ञान संस्थान

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

ICMR-National Institute of Immunohaematology

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

Date: 05/03/2024

VALIDATION REPORT OF BioSci True-Detect Sickle Cell Rapid Test Device

ICMR-NIIH Mumbai evaluated the <u>BioSci True-Detect Sickle Cell Rapid Test Device</u> by testing normal, sickle cell trait and sickle cell disease individuals (adults) with HPLC results on 300 samples. Following are the details of the batches used for the evaluation from the <u>BioSci True-Detect Sickle Cell Rapid Test Device</u>

Product Name	BioSci True-Detect Sickle Cell Rapid Test Device									
LIC. No.	MFG/TL/IVD/2022/000746	MFG/TL/IVD/2022/000746 MFG/TL/IVD/2022/000746 MFG/TL/IVD/2022/000746								
Lot No	SCK2301	SCK2302	SCK2303							
Mfg. Date	DEC- 2023	DEC- 2023	DEC- 2023							
Exp. Date	NOV - 2025	NOV - 2025	NOV - 2025							
Total Test	100	100	100							
Testing Start Date 22/02/2024 Completion Date: 05/03/2024										

Details of Gold Standard test:

Product Code	Variant II β - thalassemia (HPLC) Kit
Product Made	Biorad
Lot No:	0064AA
Mfg. Date	13/01/2023
Ex. Date	13/01/2025

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, Scientist E, CRMCH, Chandrapur. 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:

Sample	Gold	Standard	BioSci Test Do	True-Detec	ct Sickle	Cell Rapid	Inference
ID	Test	- ·	1				
	HPLC	Diagnosis		eveloped in	Card	Diagnosis	
	Test		С	НА	HS		
1.	SS	Sickle cell	+		+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
2.	SS	Sickle cell	+	•	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
3.	SS	Sickle cell	+		+	Sickle cell	Both HPLC and POC card
		disease	alan a			disease	results matched
4.	SS	Sickle cell	+	1-	+	Sickle cell	Both HPLC and POC card
		disease			(Faint)	disease	results matched
5.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
6.	AA	Normal	+	+ (Faint)	-	Normal	Both HPLC and POC card
							results matched
7.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
8.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
						1	results matched
9.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
10.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
-		trait				trait	results matched
11.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
12.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait			(Faint)	trait	results matched
13.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
14.	AA	Normal	+	+	-	Normal	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.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
						er .	results matched
18.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease			(Faint)	disease	results matched
19.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease			1	disease	results matched
20.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease			(Faint)	disease	results matched
21.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
22.	SS	Sickle cell	+	-	Ť	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
23.	AA	Normal	+	+	-	Normal	Both HPLC and PQC card
23.		- 4	, '			(,)	results matched

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24.	AS	Sickle cell	+	+ (Faint)	+	1	Both HPLC and POC card
		trait			(Faint)	trait	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	+	+ (Faint)	-	Normal	Both HPLC and POC card results matched
28.	AA	Normal	+	+	-	Normal	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	+	+ (Faint)	+ (Faint)	Sickle cell trait	Both HPLC and POC card results matched
31.	SS	Sickle cell disease	+	-	+ (Faint)	Sickle cell disease	Both HPLC and POC card results matched
32.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
33.	AA	Normal	+	+	-	Normal	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.	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.	AS	Sickle cell trait	+	+ (Faint)	+ (Faint)	Sickle cell trait	Both HPLC and POC card results matched
41.	SS	Sickle cell disease	+	-	+	Sickle cell disease	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.	ВТМ	Beta thal Major	+	-	-	Thal Major	Both HPLC and POC card results matched
46.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
47.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
48.	SS	Sickle cell disease	+	-	+ (Faint)	Sickle cell disease	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	+	-	+ (Faint)	Sickle cell disease	Both HPLC and POC card results matched



51	. AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
52	. AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
53	. SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
54	. SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
55		Normal	+	+	-	Normal	Both HPLC and POC card results matched
56		Beta thal Major	+	-	-	Thal Major	Both HPLC and POC card results matched
57.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
58.		Beta thal Major	+	-	-	Thal Major	Both HPLC and POC card results matched
59.	AA	Normal	+ 1	+	-	Normal	Both HPLC and POC card results matched
60.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
61.		Sickle cell disease	+	-	+ (Faint)	Sickle cell disease	Both HPLC and POC card results matched
62.		Sickle cell disease	+	+	+	Sickle cell disease	Both HPLC and POC card results matched
63.	SS	Sickle cell disease	+	+	+	Sickle cell disease	Both HPLC and POC card results matched
64.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
65.	AA	Normal	+	+ :	-	Normal	Both HPLC and POC card results matched
66.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
67.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
68.	SS	Sickle cell disease	+	-	+ (Faint)	Sickle cell disease	Both HPLC and POC card results matched
69.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
	AA	Normal	+	+ (Faint)	-	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.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
75.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
76.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
77.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched



78	. AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
79	. AS	Sickle cell trait	+	+ (Faint)	+ (Faint)	Sickle cell trait	Both HPLC and POC card results matched
80		Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
81.		Sickle cell trait	+	+ (Faint)	+ (Faint)	Sickle cell trait	Both HPLC and POC card results matched
82.		Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
83.		Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
84.		Beta thal Major	+	-	-	Thal Major	Both HPLC and POC card results matched
85.		Normal	+	+	-	Normal	Both HPLC and POC card results matched
86.		Normal	+	+	-	Normal	Both HPLC and POC card results matched
87.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
88.		Normal	+	+	-	Normal	Both HPLC and POC card results matched
89.		Sickle cell trait	+	+ (Faint)	+ (Faint)	Sickle cell trait	Both HPLC and POC card results matched
90.	AS	Sickle cell trait	+	+	+ (Faint)	Sickle cell trait	Both HPLC and POC card results matched
91.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
92.	SS	Sickle cell disease	+	-	+ (Faint)	Sickle cell disease	Both HPLC and POC card results matched
93.	SS	Sickle cell disease	+	-	+	Sickle cell disease	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.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
	AA	Normal	+	+ (Faint)	-	Normal	Both HPLC and POC card results matched
98.		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.	AS	Sickle cell trait	+	+ (Faint)	+ (Faint)	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.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched



106. AA Normal +	105	.l aa	Normal	l +	l +	1.	Normal	Both HPLC and POC card
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107. AA Normal	106.	. AA	Normal	+	+	-	Normal	Both HPLC and POC card
108. AA Normal + + - Normal Both HPLC and POC card results matched								results matched
108. AA Normal + + - Normal Both HPLC and POC card results matched Both HPLC and POC card results match	107.	. AA	Normal	+	+	-	Normal	Both HPLC and POC card
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disease disease results matched 122. AA Normal +								
122. AA Normal + + - Normal Both HPLC and POC card results matched 123. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched 124. SS Sickle cell + - + Sickle cell Both HPLC and POC card disease results matched 125. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched 126. AA Normal + + - Normal Both HPLC and POC card results matched 127. AA Normal + + - Normal Both HPLC and POC card results matched 128. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched	121.	SS		+	-	+		
123. AS Sickle cell + + + + Sickle cell Both HPLC and POC card results matched 124. SS Sickle cell + - + Sickle cell disease 125. AS Sickle cell + + + + Sickle cell Both HPLC and POC card results matched 126. AA Normal + + - Normal Both HPLC and POC card results matched 127. AA Normal + + - Normal Both HPLC and POC card results matched 128. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched 128. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched			disease				disease	
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trait results matched 124. SS Sickle cell + - + Sickle cell Both HPLC and POC card disease 125. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched 126. AA Normal + + - Normal Both HPLC and POC card results matched 127. AA Normal + + - Normal Both HPLC and POC card results matched 128. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched 128. AS Sickle cell + + + Sickle cell Both HPLC and POC card results matched								
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disease disease results matched 125. AS Sickle cell +	404	00						TOTAL THATALE
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127. AA Normal + + - Normal Both HPLC and POC card results matched 128. AS Sickle cell + + + Sickle cell Both HPLC and POC card trait results matched	120.	///	Nomia				Ittorina	
128. AS Sickle cell + + + Sickle cell Both HPLC and POC card trait results matched	127.	AA	Normal	+	+	-	Normal	
trait trait results matched								results matched
	128.	AS	Sickle cell	+	+	+	Sickle cell	
400 00 01-11								results matched
	129.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
disease disease results matched			disease				disease	results matched
	130.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
131. SS Sickle cell + - + Sickle cell Both HPLC and POC card disease results matched					-		disease	Both HPLC and POC card results matched Both HPLC and POC card

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132.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
133.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
133.	AS		"	T	T		
404	00	trait				trait	results matched
134.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
135.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
136.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
137.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
138.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
139.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
	.,	trait				trait	results matched
140.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
110.	/ 1.0	trait				trait	results matched
141.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
141.	٨٥	trait	•	·	•	trait	results matched
142.	SS	Sickle cell	+		+	Sickle cell	Both HPLC and POC card
142.	55		Τ	-	т	5 5 5 5 5	
440	00	disease				disease	results matched
143.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
144.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
145.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
146.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
147.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
148.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait		_		trait	results matched
149.	SS	Sickle cell	+		+	Sickle cell	Both HPLC and POC card
1101		disease				disease	results matched
150.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
150.	٨٥	trait	•		·	trait	results matched
151	۸۸		+	+		Normal	Both HPLC and POC card
151.	AA	Normal	T	т	-	INUITIAI	results matched
450	ΛΛ	Marrael				Normal	Both HPLC and POC card
152.	AA	Normal	+	+	-	Normal	
450		0.11		_		0:11	results matched
153.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
154.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
155.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
156.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
157.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
158.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
100.		trait	~	`		trait	results matched
						uit	

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		T					
159.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
100		disease				disease	results matched
160.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
161.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
162.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
163.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
164.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
165.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
166.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
167.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
168.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
169.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
170.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
171.	SS	Sickle cell	+		+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
172.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
173.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
174.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease		7		disease	results matched
175.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
176.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
177.	AA	Normal	+	+	<u>-</u>	Normal	Both HPLC and POC card
					1.		results matched
178.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
179.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
180.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
	-	disease				disease	results matched
181.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
182.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait	-			trait	results matched
183.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
,55.		trait	•	-	<i>'</i>	trait	results matched
184.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
101.	-	disease		-	'	disease	results matched
185.	AS	Sickle cell	+	+	+	Sickle cell	
100.	/.0	trait		•	ſ		Both HPLC and POC card
		uuit				trait	results matched

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186.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
187.	100	Sickle cell	+	+	+	Sickle cell	
107.	AS	trait	T	T	7	trait	Both HPLC and POC card
400	100				 . 		results matched
188.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
189.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
190.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
191.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
192.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
193.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
100.		disease				disease	results matched
194.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
134.	00	disease	,			disease	results matched
195.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
195.	33	disease	'	-	T	disease	results matched
400	00	Sickle cell					
196.	SS		+	-	+	Sickle cell	Both HPLC and POC card
407	00	disease			_	disease	results matched
197.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease		2		disease	results matched
198.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
199.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
200.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
201.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
202.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
203.	AA	Normal	+	+	_	Normal	Both HPLC and POC card
200.	77	Noma	.	·	_	Ivoliliai	results matched
204.	A.C.	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
204.	AS		T	т .	T		
005	••	trait				trait	results matched
205.	AS	Sickle cell	+	+	+	0.0	Both HPLC and POC card
		trait				trait	results matched
206.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
207.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
208.	AS	Sickle cell	+	+	+	Sicklé cell	Both HPLC and POC card
		trait				trait	results matched
209.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
210.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
211.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait			-	trait	results matched
212.	AS		+	+	+	Sickle cell	Both HPLC and POC card
212.	,	trait	·	.	.	trait	results matched
		uait				uaii	ICOURS MARCHEU

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213.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
214.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
215.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
040	00	disease				disease	results matched
216.	55	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
217.	AA	Normal	+	+	_	Normal	Both HPLC and POC card
	' ' '					TTOTTICAL	results matched
218.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
219.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
220.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
204	00	disease				disease	results matched
221.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
222	00	disease				disease	results matched
222.	SS	Sickle cell disease	+	-	+	Sickle cell	Both HPLC and POC card
223.	SS	Sickle cell	+		+	disease Sickle cell	results matched
223.	33	disease	•	_	Т	disease	Both HPLC and POC card results matched
224.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
		disease	•		•	disease	results matched
225.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
226.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
227.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
228.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
229.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
000	40	trait	_	_		trait	results matched
230.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
231.	SS	trait Sickle cell				trait Sickle cell	results matched
231.	ડ ડ	disease	+	-	+	disease	Both HPLC and POC card results matched
232.	۸۸	Normal	+	+		Normal	Both HPLC and POC card
202.	747	Noma		•	-	Noma	results matched
233.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
200.	7.0	trait		·	·	trait	results matched
234.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
	,	trait				trait	results matched
235.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
236.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
237.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
238.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
239.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched

Gream

240.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
241.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
242.	AA	Normal	+	+	-	Normal	Both HPLC and POC car
							results matched
243.	AA	Normal	+	+	-	Normal	Both HPLC and POC can
							results matched
244.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
245.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC car
210.	00	disease			·	disease	
246.	SS	Sickle cell	+	_	+	Sickle cell	results matched
240.	33		Т	-	Τ		Both HPLC and POC car
247.	00	disease				disease	results matched
247.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
248.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
249.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
250.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
251.	SS	Sickle cell	+	_	+	Sickle cell	
	-	disease		-	•		Both HPLC and POC car
252.	SS	Sickle cell	+			disease	results matched
202.	55		Т	-	+	Sickle cell	Both HPLC and POC car
252	Λ Λ	disease				disease	results matched
253.	AA	Normal	+	+	-	Normal	Both HPLC and POC car
2=4							results matched
254.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC car
		trait				trait	results matched
255.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC car
		disease				disease	results matched
256.	AA	Normal	+	+	_	Normal	Both HPLC and POC car
						Homai	results matched
257.	AS	Sickle cell	+	+	+	Sickle cell	
		trait		•	T	W 101	Both HPLC and POC car
258.	ΔS	Sickle cell	+	+		trait	results matched
200.	7.0	trait	T	"	+	Sickle cell	Both HPLC and POC car
259.	۸۸	Normal				trait	results matched
255.	^^	Normai	+	+	-	Normal	Both HPLC and POC car
000	40						results matched
260.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC care
- (trait				trait	results matched
261.	AS	Sickle cell	+	+	+	Sickle cell	Both HPIC and POC car
			+	+	+	Sickle cell trait	Both HPLC and POC car
261. 262.		Sickle cell trait	+	+		trait	results matched
		Sickle cell trait Sickle cell			+	trait Sickle cell	results matched Both HPLC and POC care
262.	AS	Sickle cell trait Sickle cell trait	+	+	+	trait Sickle cell trait	Both HPLC and POC car results matched
	AS	Sickle cell trait Sickle cell trait Sickle cell				trait Sickle cell trait Sickle cell	results matched Both HPLC and POC carresults matched Both HPLC and POC carr
262. 263.	AS	Sickle cell trait Sickle cell trait Sickle cell disease	+	+	+	trait Sickle cell trait Sickle cell disease	results matched Both HPLC and POC car results matched Both HPLC and POC car results matched
262.	AS	Sickle cell trait Sickle cell trait Sickle cell disease Sickle cell	+	+	+	trait Sickle cell trait Sickle cell disease Sickle cell	results matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched
262. 263. 264.	AS SS SS	Sickle cell trait Sickle cell trait Sickle cell disease Sickle cell disease	+ + +	+	+	trait Sickle cell trait Sickle cell disease Sickle cell disease	results matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched
262. 263.	AS SS SS	Sickle cell trait Sickle cell trait Sickle cell disease Sickle cell disease Sickle cell	+	+	+	trait Sickle cell trait Sickle cell disease Sickle cell	results matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched
262. 263. 264. 265.	AS SS SS SS	Sickle cell trait Sickle cell trait Sickle cell disease Sickle cell disease Sickle cell disease	+ + + + + +	-	+ + +	trait Sickle cell trait Sickle cell disease Sickle cell disease	results matched Both HPLC and POC carresults matched
262. 263. 264.	AS SS SS SS	Sickle cell trait Sickle cell trait Sickle cell disease Sickle cell disease Sickle cell	+ + +	-	+ + +	trait Sickle cell trait Sickle cell disease Sickle cell disease Sickle cell	results matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched Both HPLC and POC carresults matched



267.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
268.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
200.		disease				disease	results matched
269.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
270.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
271.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
272.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
273.	AS	Sickle cell	+	+	+	Sickle cell	results matched Both HPLC and POC card
213.	AS	trait	Τ	T	т	trait	results matched
274.	SS	Sickle cell	+	_	+	Sickle cell	Both HPLC and POC card
214.		disease				disease	results matched
275.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
276.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
277.	AA	Normal	+	+	-	Normal	Both HPLC and POC card
							results matched
278.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
070	00	trait				trait	results matched
279.	55	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
280.	00	disease Sickle cell	+			disease Sickle cell	results matched Both HPLC and POC card
200.	33	disease	Т	-	+	disease	results matched
281.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease			·	disease	results matched
282.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
283.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
284.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched
285.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
2000	00	trait				trait	results matched
286.	55		+	-	+	disease	Both HPLC and POC card results matched
287.	AS	disease Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
201.	A0	trait		•	•	trait	results matched
288.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
200.	,,,	trait				trait	results matched
289.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
290.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
291.	AS	Sickle cell	+	+	+	Sickle cell	Both HPLC and POC card
		trait				trait	results matched
292.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
200		disease				disease	results matched
293.	SS	Sickle cell	+	-	+	Sickle cell	Both HPLC and POC card
		disease				disease	results matched



294.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
295.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
296.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
297.	AA	Normal	+	+	-	Normal	Both HPLC and POC card results matched
298.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched
299.	SS	Sickle cell disease	+	-	+	Sickle cell disease	Both HPLC and POC card results matched
300.	AS	Sickle cell trait	+	+	+	Sickle cell trait	Both HPLC and POC card results matched

Interpretation: All samples tested [(Normal (AA): 89 cases, Sickle cell trait (AS): 96 cases, Sickle cell disease (SS): 111cases and Beta thal Major (BTM): 4 cases)] with the POC of BioSci True-Detect Sickle Cell Rapid Test Device showed 100% sensitivity, 100% specificity and 100% accuracy for all the tested hemoglobinopathies.

Remark: However, 7.66% of samples [23/300 (five cases of AA, nine cases of AS and 9 cases of SS samples)] showed a faint band.

<u>Conclusion:</u> The Indian Council of Medical Research (ICMR)-National Institute of Immunohematology, Mumbai have tested 120 samples [Normal (AA), AS (sickle cell trait), SS (sickle cell anaemia) and Beta thal Major (BTM) BioSci True-Detect Sickle Cell Rapid Test Device kit as per the kit instructions and compared it with HPLC results. BioSci True-Detect Sickle Cell Rapid Test Device showed a satisfactory match with the HPLC gold standard results (Biorad Variant II). Needs improvement as 19.16% of cases showed faint band intensities which can give false negative or false positive interpretations.

Mmy3/24 Dr. Manisha Madkaikar

Director

ोबा मडकईकर / Br. Manisha Madkaikar

ান্থাক / Director

ईसीएमआर-राष्ट्रीय त्रतिरक्षा रुधिर विज्ञान संस्थान

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Parel, Mumbai - 400 012.

Dr. Prabhakar Kedar **HOD Haematogenetics**

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Mumbai 400 012.



आई सी एम आर - राष्टीय 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: 21/02/2024

VALIDATION REPORT OF Vimek SUPERVELOCE SICKLE CELL RAPID TEST KIT

ICMR-NIIH Mumbai evaluated <u>Vimek SUPERVELOCE sickle cell rapid test card (Vimek Bioconcept PVT. LTD.)</u> by testing normal, sickle cell trait and sickle cell disease individuals (adults) with HPLC results on 300 samples.

Following are the details of the batches used for the evaluation from <u>Vimek SUPERVELOCE sickle cell rapid</u> test card (Vimek Bioconcept PVT. LTD.)

Product Name	Vimek SUPERVELOC	E sickle cell rapid test card (Vimek Bioconcept PVT. LTD.)
Lot No	SCD24021	SCD24022	SCD24023
Mfg. Date	FEB - 2024	FEB - 2024	FEB - 2024
Exp. Date	JAN - 2026	JAN - 2026	JAN - 2026
Total Test	100	100	100
Testing Start			
Date	16/02/2024	Completion Date:	05/03/2024

Details of Gold Standard test:

Prodct Code	Variant II β - thalassemia (HPLC) Kit
Product Made	Biorad
Lot No:	0064AA
Mfg. Date	13/01/2023
Ex. Date	13/01/2025

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

Meden

<u>Results</u> | CMR-NIIH and | ICMR-CRMCH validated | Vimek | SUPERVELOCE | sickle | cell | rapid | of | Vimek | BoConcept | PVT | test | card. | LTD. | by testing | normal, | sickle | cell | trait | and | sickle | cell | disease | individuals | and | sample | status | was | confirmed | with | HPLC | Test

Sample No.	Gold	Standard Test			rapio	l test o		Inference
		1		Vimek				
	HPLC	Diagnosis	The	band		ped	Diagnosis	
	Test			in C				
			С	T1 HA	T2 HS	T3 HC		
1.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
2.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
3.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
4.	ВТМ	Beta thal Major	+	-	-	-	Thalassemia Major	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
10.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
11.	ВТМ	Beta thal Major	+	-	-	-	Thalassemia Major	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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
16.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
17.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
21.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC 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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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
27.	AA	Normal	+	+	-	-	Normal	card results matched 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	+	-	+	-	Sickle cell	Both HPLC and POC
23.		disease		_	Ľ.		disease	card results matched
30.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
31.	SS	Sickle cell	+	-	+	_	Sickle cell	Both HPLC and POC
		disease			,		disease	card results matched
32.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
33.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
24	00	Cialda asti	<u> </u>	_		_	0:11 "	card results matched
34.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
35.	SS	disease	<u> </u>	_	<u> </u>		disease	card results matched
35.	55	Sickle cell disease	+	-	+	-	Sickle cell	Both HPLC and POC
36.	AA		- -	<u> </u>			disease	card results matched
30.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
37.	AA	Nomed	<u> </u>	<u> </u>		<u> </u>		card results matched
37.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
38.	SS	Cialda asti		_			0.11	card results matched
30.	55	Sickle cell disease	+	-	+	-	Sickle cell	Both HPLC and POC
39.	AA		-				disease	card results matched
39.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
40.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
								card results matched
41.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
42.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
43.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
44	• • • • • • • • • • • • • • • • • • • •	.						card results matched
44.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
45	DTM	5						card results matched
45.	ВТМ	Beta thal Major	+	-	-	-	Thalassemia	Both HPLC and POC
40							Disorder	card results matched
46.	SS	Sickle cell disease	+] -	+	-	Sickle cell	Both HPLC and POC
47.	SS		- -	-	-		disease	card results matched
"'	33	Sickle cell disease	+	-	+	-	Sickle cell	Both HPLC and POC
48.	SS	Sickle cell	 		-		disease	card results matched
	00	disease	+	-	+	-	Sickle cell	Both HPLC and POC
49.	AA	Normal	+	١.			disease	card results matched
		Nomai	*	+	-	-	Normal	Both HPLC and POC card results matched
50.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
51.	A A	.						card results matched
51,	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
52.	AA	Normal	+	+	-	-	Normal	card results matched
		, tomai	້	"	-	-	Normal	Both HPLC and POC card results matched
						_		L cara results matched

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SS			1 0.11	1		1 .		1 0.11 "	
SS	53.	SS		*	-	+	-		
		00		-	-				
Select S	54.	88	I	*	-	*	-		
Select S	55.	AA	Normal	+	+		-	Normal	Both HPLC and POC
	56.	BTM	Beta thal Major	+	T -	-	-	Thalassemia	
57. AA Normal + + - - Normal Both HPLC and POC card results matched			,		1				
S8. AA Normal + + - Normal Both HPLC and POC card results matched	57.	AA	Normal	+	+	-	_		
58. AA Normal + + - Normal Both HPLC and POC card results matched both HPLC and POC card results matched both HPLC and POC card results matched disease 60. SS Sickle cell disease + - + - Sickle cell Both HPLC and POC card results matched disease 61. SS Sickle cell trait + - + - Sickle cell Both HPLC and POC card results matched disease 62. AS Sickle cell trait + + - - Sickle cell trait both HPLC and POC card results matched disease 63. AA Normal + + - - Normal Both HPLC and POC card results matched disease 64. SS Sickle cell disease - + - Sickle cell Both HPLC and POC card results matched disease 65. AA Normal + + - Normal Both HPLC and POC card results matched disease 66. AA Normal + + - Normal Both HPLC and POC card results matched disease 67. AA Normal + <t< td=""><td> "</td><td></td><td>1.0</td><td></td><td></td><td></td><td></td><td>1.10</td><td></td></t<>	"		1.0					1.10	
Second S	58.	AA	Normal	+	+	-	-	Normal	
59. BTM			110111101					, roman	
	59.	BTM	Beta thal Major	+	-	-	-	Thalassemia	
60. SS Sickle cell + - + - Sickle cell disease 61. SS Sickle cell disease + - + - Sickle cell disease 62. AS Sickle cell trait + + + - Sickle cell Sickle cell disease 63. AA Normal + + - Normal Soth HPLC and POC card results matched 64. SS Sickle cell + - + - Sickle cell Soth HPLC and POC card results matched 65. AA Normal + + - - Normal Soth HPLC and POC card results matched 66. AA Normal + + - - Normal Soth HPLC and POC card results matched 66. AA Normal + + - - Normal Soth HPLC and POC card results matched 67. AA Normal + + - - Normal Soth HPLC and POC card results matched 68. SS Sickle cell + - + - Sickle cell Soth HPLC and POC card results matched Gasease + - - Normal Soth HPLC and POC card results matched Gasease + - - Sickle cell Soth HPLC and POC card results matched Gasease + - - Sickle cell Soth HPLC and POC Card results matched Gasease + - - Sickle cell Soth HPLC and POC Card results matched Gasease + - - Normal Soth HPLC and POC Card results matched Gasease + - - Normal Soth HPLC and POC Card results matched Gasease + - - Normal Soth HPLC and POC Card results matched Gasease - - Normal Soth HPLC and POC Card results matched Gasease - - - Normal Soth HPLC and POC Card results matched Gasease - - - Sickle cell Soth HPLC and POC Card results matched Gasease - - - Normal Soth HPLC and POC Card results matched Gasease - - - Normal Soth HPLC and POC Card results matched Gasease - - - Normal Soth HPLC and POC Card results matched Soth HPLC and POC Card								Not the second of the second	
	60.	SS	Sickle cell	+	-	+	-		Both HPLC and POC
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62. AS Sickle cell trait			1						
63. AA Normal + + + - Normal Soth HPLC and POC Card results matched Gard re	62.	AS		+	+	+	-		
63.		1.05							
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68. SS Sickle cell disease	67.	AA	Normal	+	+	-	-	Normal	
68. SS Sickle cell disease			11011111					Tionna.	
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72. SS Sickle cell disease							1		
72. SS Sickle cell disease	71.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
72. SS Sickle cell disease									card results matched
disease disease card results matched 73.	72.	SS	Sickle cell	+	-	+	-	Sickle cell	
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74. AA Normal + + Normal Both HPLC and POC card results matched 75. BTM Beta thal Major + Thalassemia Disorder Card results matched 76. AA Normal + + Normal Both HPLC and POC card results matched 77. AA Normal + + Normal Both HPLC and POC card results matched 78. AA Normal + + Normal 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. SS Sickle cell + - + - Sickle cell Both HPLC and POC									
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77. AA Normal + + Normal Both HPLC and POC card results matched 78. AA Normal + + Normal 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. SS Sickle cell + - + - Sickle cell Both HPLC and POC	76.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
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78. AA Normal + + Normal 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. SS Sickle cell + - + - Sickle cell Both HPLC and POC	77.	AA	Normal	+	+	-	-	Normal	
78. AA Normal + + Normal 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. SS Sickle cell + - + - Sickle cell Both HPLC and POC									I =
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. SS Sickle cell + - + - Sickle cell Both HPLC and POC	78.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
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. SS Sickle cell + - + - Sickle cell Both HPLC and POC									card results matched
80. AS Sickle cell trait + + + - Sickle cell trait Both HPLC and POC card results matched 81. SS Sickle cell + - + - Sickle cell Both HPLC and POC	79.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	
80. AS Sickle cell trait + + + - Sickle cell trait Both HPLC and POC card results matched 81. SS Sickle cell + - + - Sickle cell Both HPLC and POC									
81. SS Sickle cell + - + - Sickle cell Both HPLC and POC	80.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
John Son Dourth 25 and 1 65									
disease disease card results matched	81.	SS		+	-	+	-	Sickle cell	Both HPLC and POC
aleeded card results middled			disease					disease	card results matched



82.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
83.	AS	Sickle cell trait		ļ.,	<u> </u>		Ciable call took	card results matched
65.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
84.	втм	Beta thal Major	+	-	-	-	Thalassemia	Both HPLC and POC
							Disorder	card results matched
85.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
86.	AA	Normal	+	+			Name	card results matched
00.	AA	Normal	*	†	-	-	Normal	Both HPLC and POC card results matched
87.	втм	Beta thal Major	+	-	-	-	Thalassemia	Both HPLC and POC
						1	Disorder	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
90.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	card results matched Both HPLC and POC
	7.0	Olokie celi tiait		"	"	-	Sickle cell trait	card results matched
91.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
								card results matched
92.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
- 00		disease					disease	card results matched
93.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
94.	AA	disease Normal	<u> </u>				disease	card results matched
34.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
95.	AA	Normal	+	+	-	_	Normal	card results matched Both HPLC and POC
							Noma	card results matched
96.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
97.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
98.	AS	Sickle cell trait	 				0:11 11 11	card results matched
30.	AO	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
99.	SS	Sickle cell	+	-	+	-	Sickle cell	card results matched Both HPLC and POC
		disease					disease	card results matched
100.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
101.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
102.	SS	Cielde sell						card results matched
102.	33	Sickle cell disease	+	-	+	-	Sickle cell	Both HPLC and POC
103.	AS	Sickle cell trait	+	+	+	_	disease Sickle cell trait	card results matched Both HPLC and POC
		Oronio con trait	'			-	Sickle cell trait	card results matched
104.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
105.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
106.		disease					disease	card results matched
100.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
107.	AS	Sickle cell trait	+	+	+		Sickle cell trait	card results matched
	7.0	Clorid och trait	Ι΄.		'	-	Sickle cell trait	Both HPLC and POC card results matched
108.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
100								card results matched
109.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
110.	۸۸	NI						card results matched
110.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
			L	L				card results matched



111.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
110		0:11 ": "					0.11 #4 #	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
114.	SS	Sickle cell	+	-	+	_	Sickle cell	card results matched Both HPLC and POC
114.	00	disease	'	_	,	-	disease	card results matched
115.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
''		disease					disease	card results matched
116.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
117.	BTM	Beta thal Major	+	-	-	-	Thalassemia	Both HPLC and POC
							Disorder	card results matched
118.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
119.	AA	Normal		<u> </u>			Nemal	card results matched
119.	AA	INOTTIAL	+	+	-	-	Normal	Both HPLC and POC
120.	SS	Sickle cell	+	 	+	-	Sickle cell	card results matched Both HPLC and POC
120.	00	disease	, T	-	Т	-	disease	card results matched
121.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
""	7.0	Olokie deli trait	١.	l '		_	Sickle cell trait	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.	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
400	40	0:11 11 11	-37					card results matched
126.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
127.	AA	Normal	+	+	_	-	Normal	card results matched Both HPLC and POC
		Tronna.	'	l .			Noma	card results matched
128.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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
404		0.11						card results matched
131.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
132.	AC	Cialda aall taa't	<u> </u>	_				card results matched
152.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
133.	AS	Sickle cell trait	+	+	+	 	Sickle cell trait	card results matched
	7.0	Cloric och 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
100								card results matched
136.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
137.	ВТМ	Poto that Main		-				card results matched
107.	DIN	Beta thal Major	+	-	-	-	Thalassemia	Both HPLC and POC
138.	AS	Sickle cell trait	+	-		_	Disorder	card results matched
	7.0	Jone Cell trait		†	+	-	Sickle cell trait	Both HPLC and POC card results matched
139.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
							John John Hall	card results matched
				-				

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140.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
141.	SS	Sickle cell	+	-	+	-	Sickle cell	card results matched Both HPLC and POC
		disease				1	disease	card results matched
142.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
		disease					disease	card results matched
143.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
140.	00	disease	Ι΄.	-	Ι΄.	-	disease	card results matched
144.	AS	Sickle cell trait	- .	_	· .			
144.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
445	A A	N1	-				Mariani	card results matched
145.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
	10	0111	_			_	01.11	card results matched
146.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
								card results matched
147.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
								card results matched
148.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
								card results matched
149.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
					l			card results matched
150.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
100.	ΛO	Olonie Cell tiait	Ι'.	١.	Ι΄.	-	Olckie celi ti alt	card results matched
			_	-		_		
151.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
151.								card results matched
		0:11					0:11 "	D. (I. LIDI O I. DOO
450	SS	Sickle cell	+	_	+	_	Sickle cell	Both HPLC and POC
152.		disease					disease	card results matched
		T. E. servizosas, se						D (I UDI O 1 DOO
450	AS	Sickle cell trait	+	+	+	_	Sickle cell trait	Both HPLC and POC
153.								card results matched
								D # 11D1 0 1 D00
154.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
104.								card results matched
								D-#- UDI O I DOO
155	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
155.								card results matched
								Dati LIDLO - LDOO
450	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
156.								card results matched
		-		-				D # 11010 1000
457	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC
157.								card results matched
		Sickle cell		-			0:-11	D (1 11D) 0 1 D00
150	SS		+	-	+	-	Sickle cell	Both HPLC and POC
158.		disease					disease	card results matched
		Cialda aall					0:11	D (1 1 1 D) O 1 DOO
159.	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
159.		disease					disease	card results matched
			-		-	_		Dath LIDI C and DOO
160.	AS	Sickle cell trait	+	+	-	-	Sickle cell trait	Both HPLC and POC
100.								card results matched
		Ciakla aall	-	-		-	Ciakle sell	Both HPLC and POC
161.	SS	Sickle cell	+	-	+	-	Sickle cell	
101.		disease		1			disease	card results matched
					_	-		Both HPLC and POC
162.	AA	Normal	+	+	-	-	Normal	card results matched
102.								Caru IDSUIS MAIGHEU
			1		L			L



		,						
163.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
164.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	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.	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 disease	Both HPLC and POC card results matched
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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
176.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
177.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
178.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	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.	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.	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.	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
191.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
192.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
197.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
198.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
199.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
200.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
201.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
202.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched

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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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
206.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
210.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
211.	AA	Normal	+	+	-	-	Normal	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 cell disease	+	-	+	-	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
216.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
217.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
222.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched

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		T	Γ					Both HPLC and POC
223.	AA	Normal	+	+	-	-	Normal	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.	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.	SS	Sickle cell disease	+	+	+	-	Sickle cell trait	Both HPLC and POC card results Not matched
229.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
230.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
231.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	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.	AA	Normal	+	+	-	-	Normal	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.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
240.	SS	Sickle cell disease	+	+	+	-	Sickle cell disease	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

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040	SS	Sickle cell	+	_	+	_	Sickle cell	Both HPLC and POC
243.		disease			'		disease	card results matched
		Sickle cell					Sickle cell	Both HPLC and POC
244.	SS	disease	+	-	+	-	disease	card results matched
	SS	Sickle cell	+	_	+	_	Sickle cell	Both HPLC and POC
245.	00	disease					disease	card results matched
								Both HPLC and POC
246.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	card results matched
240.								oura results materiou
	AS	Sickle cell trait	+	+	+	_	Sickle cell trait	Both HPLC and POC
247.	AO	Sickle Cell trait	'	'	١.	-	Sione cell trait	card results matched
								Dath LIDLO and DOO
248.	AS	Sickle cell trait	+	-	+	-	Sickle cell trait	Both HPLC and POC card results matched
240.								card results matched
							0'-1111111	Both HPLC and POC
249.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	card results matched
	SS	Sickle cell	+	+	+	_	Sickle cell	Both HPLC and POC
250.	00	disease					trait	card results Not matched
		Sickle cell			-	-	Sickle cell	Both HPLC and POC
251.	SS	disease	+	-	+	-	disease	card results matched
		discase					diodado	dara rocano materioa
	SS	Sickle cell	+	+	+	_	Sickle cell	Both HPLC and POC
252.	33	disease	, T	-	"	-	disease	card results matched
		0:11 "					0:-1:111	Dath LIDLC and DOC
253.	SS	Sickle cell	+	+	+	-	Sickle cell disease	Both HPLC and POC card results matched
255.		disease					uisease	Card results matched
	20	Sickle cell					Sickle cell	Both HPLC and POC
254.	SS	disease	+	-	+	-	disease	card results matched
055	SS	Sickle cell	+	-	+	-	Sickle cell	Both HPLC and POC
255.		disease					disease	card results matched
		Sickle cell					Sickle cell	Both HPLC and POC
256.	SS	disease	+	-	+	-	disease	card results matched
	AS	Sickle cell trait	+	+	+	_	Sickle cell trait	Both HPLC and POC
257.	AO	Cionic och dan					Cionio con trait	card results matched
								Both HPLC and POC
258.	AA	Normal	+	+	-	-	Normal	card results matched
200.								oura roouno matema
	۸۸	Normal					Normal	Both HPLC and POC
259.	AA	Normal	+	+	-	-	Normai	card results matched
								Dath LIDI C and DOC
260.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
200,								บลเน เชอนแอ เแสเบเเซน
	00	Sickle cell					Sickle cell	Both HPLC and POC
261.	SS	disease	+	-	+	-	disease	card results matched
								D # 11D1 0 1500
060	AA	Normal	+	+	-	-	Normal	Both HPLC and POC
262.								card results matched
ı I								



			,	,				
263.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
264.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
265.	SS	Sickle cell disease	+	+	+	-	Sickle cell trait	Both HPLC and POC card results Not matched
266.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
267.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
268.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
269.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
270.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
271.	AS	Sickle cell trait	+	+	+	v	Sickle cell trait	Both HPLC and POC card results matched
272.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
273.	AS	Sickle cell trait	+	-	+	-	Sickle cell trait	Both HPLC and POC card results matched
274.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	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.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched



283.	AA	Normal	+	+	-	-	Normal	Both HPLC and POC card results matched
284.	AA	Normal	+	+	-	-	Normal	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.	AA	Normal	+	+	-	-	Normal	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 trait	Both HPLC and POC card results Not matched
291.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
292.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
293.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
294.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
295.	SS	Sickle cell disease	+	-	+	-	Sickle cell disease	Both HPLC and POC card results matched
296.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
297.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
298.	AS	Sickle cell trait	+	-	+	-	Sickle cell trait	Both HPLC and POC card results matched
299.	AS	Sickle cell trait	+	+	+	-	Sickle cell trait	Both HPLC and POC card results matched
300.	SS	Sickle cell disease	+	+	+	-	Sickle cell disease	Both HPLC and POC card results matched

Interpretation: All samples tested for the POC of Vimek SUPERVELOCE sickle cell rapid test card (Vimek Bioconcept PVT. LTD.) showed 96.67% sensitivity, 100% specificity and 98.6% accuracy for all the tested hemoglobinopathies.

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Conclusion: The Indian Council of Medical Research (ICMR)-National Institute of Immunohematology, Mumbai have tested 300 samples [Normal (AA), AS (sickle cell trait), SS (sickle cell anemia) and Beta thal Major (BTM) on Vimek SUPERVELOCE sickle cell rapid test card (Vimek Bioconcept PVT. LTD.) kit as per the kit instructions and compared it with HPLC results. Vimek SUPERVELOCE sickle cell rapid test card (Vimek Bioconcept PVT. LTD.) showed 98.6% satisfactory match with the HPLC gold standard results (Biorad Variant II). Needs to improve band intensities of T1 (HbA) and T2 (HbS) position as they were found to very faint.

Dr. Manisha Madkaikar

Director

डॉ. मनीषा सडकईकर / Dr. Manisha Madkaikar

निदेशक / Director

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