



Performance Evaluation

SICKLECHECKTM

Rapid test for simultaneous detection of
Hb S and Hb A in human whole blood.

Foreword

Sicklecheck™ is an innovative point of care test (POCT) developed for the detection and differentiation of Sickle cell disease and trait, by the leading IVD manufacturer Tulip Diagnostics (P) Limited, India.

Sickle cell disease is an inherited blood condition which is most common among people of African, Arabian and Indian origin.

The most common diagnostic test methods for Sickle cell disease and trait are screening tests such as complete blood count, peripheral blood smears, sickling test, that may lack adequate sensitivity or specificity, confirmatory tests such as hemoglobin separation techniques, electrophoresis and HPLC; and genetic tests, which are more expensive and need to be done in centralized labs by highly skilled personnel.

The introduction of Point of care testing (POCT) has created a paradigm shift in recent years by offering rapid tests with performance characteristics comparable to the confirmatory tests for detection and differentiation of sickle cell anaemia and trait.

POCT test method has its advantages as it can enable near-patient testing, can be performed in field settings, gives faster results/diagnosis, faster therapeutic intervention, reduced preanalytical errors and smaller specimen volume requirements.

Sicklecheck™ has been evaluated and compared with the gold standard methods as electrophoresis and HPLC in the highly prevalent areas of India and Africa.

We are presenting a summary of all the evaluations performed in form of this small booklet.

Happy Reading!

CONTENTS

Evaluation reports from India **1-7**

- Internal evaluation from Tulip Diagnostics, Goa, India 1
- M.K.C.G Medical College, Behrampur, Odisha, India 2
- All India Institute of Medical Sciences, Nagpur, India 3
- ICMR, Odisha, India 4
- Christian Hospital, Odisha, India 5
- Phulo- Jhano Medical College & Hospital, Jharkhand, India 6
- Valsad Raktadan Kendra, Gujarat, India 7

Evaluation reports from Africa **8-11**

- Laboratoire d' Analyse Biomedicale, Cameroon, Africa 8
- Bungoma County Referral Hospital, Kenya, Africa 9
- Muhimbili Hospital, Dar-es-Salaam, Tanzania, Africa 10
- Laboratoire Prima Sarl, Yaounde, Africa 11

Evaluation reports from India

In-house Evaluation Site: **Tulip Diagnostics (P) Ltd, Verna, Goa**

Sample Type	Samples tested	Results
Sickle cell disease	5 Nos	Sensitivity : 100%
Sickle cell trait	45 Nos	Specificity : 100%
Normal	75 Nos	Correlation with Competitor RDT: 100%

Conclusion

Study was conducted for simultaneous detection of Hb S and Hb A in Human whole blood with in-house developed RDT (**Sicklecheck™**) in comparison with commercially available kit.

Based on the above evaluation all the results are found to be in 100% co relation with both the assays i.e. In-house developed assay:

- **Sicklecheck™** (Rapid test for simultaneous detection of Hb S and Hb A in Human whole blood and Commercially available assay:
- Hemotype SC™ (Rapid test for detection of Haemoglobin A, S and C).

Evaluation reports from India

Evaluating Body: **M.K.C. G. Medical College, Behrampur, Odisha, India**

Sample Type	Samples tested	Results in comparison with HPLC method
Sickle cell disease	48 Nos	Sensitivity : 97.92% } Sickle cell disease Specificity : 100%
Sickle cell trait	107 Nos	
Normal	204 Nos	Sensitivity : 99.07% } Sickle cell trait Specificity : 98.81%

Study Protocol

The study samples have been recruited from 31st March 2023 to 30th May 2023.

- A total of 400 unknown samples have been analyzed
- All the three investigations i.e. ITLC (Variant-II, Bio-Rad), **Sicklecheck™** (manufactured by Tulip Diagnostics Pvt. Ltd. India) and HemoTypeSC (manufactured by Silver Lake Research, California, USA) were run simultaneously for all the samples.
- The results were compared between HPLC Vs **Sicklecheck™**; and HPLC Vs HemoType SC separately considering HPLC as gold standard.

For the sensitivity and specificity calculation, only 359 cases were considered.

Inferences:

- **Sicklecheck™** was found to have a high sensitivity and specificity of >98% making it suitable for screening purposes for sickle cell disorders.

Comments:

- Readability of result in **Sicklecheck™** test kit is easy and clear.
- Clear and dark colour bands should be considered in **Sicklecheck™** test for diagnosis, while appearance of any faint/light bands should go for HPLC.
- The intensity of bands in HemoType SC need to be optimised.

Evaluation reports from India

Evaluating Body: **All India Institute of Medical Sciences, Nagpur, India**

Sample Type	Samples tested	Results in comparison with HPLC method
Sickle cell disease	17 Nos	Sensitivity : 100% Specificity : 99.7% } Sickle cell disease
Sickle cell trait	85 Nos	
Normal	398 Nos	Sensitivity : 96.5% Specificity : 99.5% } Sickle cell trait

Study Design

Site of the study: All India Institute of Medical Sciences Nagpur

Period of the study: The study samples have been recruited from October 2023 to February 2024.

A total of 550 unknown samples have been analyzed after excluding post transfusion sample and patient with age less than 1 year.

Both the investigations i.e. HPLC (Variant-II, Bio-Rad) and **Sicklecheck™** (Manufactured by Tulip Diagnostics Pvt. Ltd. India) were run simultaneously for all the samples. In our lab HPLC is run in batches. So, samples were collected throughout the week and stored at 2 to 6 degrees in refrigerator. Batch of sample was processed at the end of a week for both the tests.

For the sensitivity and specificity calculation, only 500 cases detected as Normal, sickle cell trait (AS) and sickle cell anemia (SS) by HPLC were considered.

The results were compared between HPLC V/s **Sicklecheck™** considering HPLC as gold standard.

Evaluation reports from India

Evaluating Body: **Indian Council of Medical Research (ICMR), Odisha, India**

Sample Type	Samples tested	Results in comparison with HPLC method
Sickle cell disease	63 Nos	Sensitivity : 98.14%
Sickle cell trait	95 Nos	Specificity : 99.03%
Normal	305 Nos	Positive Predictive Value : 98.10%
		Negative Predictive Value : 99.02%

Highlights

A total of 463 whole blood samples were collected from participants across state of Odisha in the month of May 2023, this included 135 children and 328 adults.

The point of care tests was done by the field teams and data recorded using online forms.

The samples were run independently by the lab team who were blinded to the results of the POC tests.

All samples were tested by High Performance Liquid Chromatography (HPLC) method at ICMR-RMRC, Bhubaneswar, Odisha, which was gold standard.

Evaluation reports from India

Evaluating Body: **Christian Hospital, Bissamcuttack, Odisha, India**

Sample Type	Samples tested	Results in comparison with HPLC method
Sickle cell disease	17 Nos	Sensitivity : 95.7% Specificity : 100%
Sickle cell trait	30 Nos	
Normal	55 Nos	

Observation

All the above results are 98% co-related with both the methods i.e. **Sicklecheck™** — rapid point of care test and HPLC method.

Conclusion

Based on the above evaluation, it can be concluded that **Sicklecheck™**- Rapid point of care test can be used as alternative of standard HPLC test in limited resource setup where HPLC test are not available.

Evaluation reports from India

Evaluating Body: **Phulo- Jhano Medical College & Hospital, Jharkhand, India**

Sample Type	Samples tested	Results in comparison with Licensed competitor method
Sickle cell disease	2 Nos	Sensitivity : 100% Specificity : 100%
Sickle cell trait	6 Nos	Evaluation included 38 infant samples indicating results unaffected by fetal hemoglobin
Normal	227 Nos	

Findings

The results of **Sicklecheck™** and Hemotype SC have been well correlated and **Sicklecheck™** results have shown 100% sensitivity and 100% specificity in comparison to HemoType SC as reference test.

Sicklecheck™ rapid test can be carried out by anyone without previous experience with a nominal training (Non-pathology person like nurse).

Readability of results interpretation is easier in **Sicklecheck™** as visible band intensity of **Sicklecheck™** is better than HemoType SC.

Biohazard exposure risk during test is less in **Sicklecheck™** as it is a test card, the test system covered in plastic housing; where as HemoType SC is a open test strip.

Conclusion

We have found indigenously developed test **Sicklecheck™** appropriate for use for detection of Sickle cell disorder in point of care setup as well as laboratory setup. The performance of **Sicklecheck™** is well correlated with imported test kit HemoType SC.

Evaluation reports from India

Evaluating Body: **Valsad Raktadan Kendra, Gujarat, India**

Sample Type	Samples tested	Results in comparison with HPLC method
Sickle cell disease	28 Nos	Sensitivity : 100% Specificity : 100%
Sickle cell trait	112 Nos	
Normal	60 Nos	

Conclusion

200 samples screened by **Sicklecheck™** - Sickle Cell Rapid Test were analysed by HPLC and confirmed Sickle gene detection showing 100 % specificity and sensitivity. **Sicklecheck™** - Sickle Cell Rapid Test gave perfect result within 15 minutes.

Test can be carried out by anyone without previous experience (Non technical persons like nurses etc.)

Reports can available immediately in case of emergency for counselling and treatment.

Sicklecheck™ - Sickle Cell Rapid Test is a handy test which does not required power supply and has not shown any impact of temperature and storage conditions.

Sicklecheck™ - Sickle Cell Rapid Test can be used by any laboratory to define Sickle Cell gene with accuracy.

This **Sicklecheck™**- Sickle Cell Rapid Test is being evaluated and validated as per protocol and found appropriate for use in the field base screening program as well as bed side (Point of Care) testing in emergency for Sickle Cell Detection.

Evaluation reports from Africa

Evaluating Body: **Laboratoire d' Analyse Biomedicale, Cameroon, Africa**

Sample Type	Samples tested	Results in comparison with Electrophoresis method
Sickle cell disease	40 Nos	Sensitivity for Sickle cell disease : 95%
Sickle cell trait	60 Nos	Sensitivity for Sickle cell trait : 100%
Normal	110 Nos	Sensitivity for Normal (HBAA) : 98.2%

Study method

A total of 210 blood samples were run on RAL Scanion electrophoresis system and were simultaneously run on **Sicklecheck™** test.

Name of the centre: Toxilogly Institute for Analysis and Risk Assessment

Duration of the study: 2nd October 2023 to 31st October 2023

Sample type involved: EDTA whole blood samples

Age group: 2 years to 70 years

Conclusion

Based on this evaluation results, we can recommend **Sicklecheck™** as an alternative and cheaper test for Hb electrophoresis especially in low income communities.

Evaluation reports from Africa

Evaluating Body: **Bungoma County Referral Hospital, Kenya, Africa**

Sample Type	Samples tested	Results in comparison with HPLC method
Sickle cell disease	95 Nos	Sensitivity : 99.14% Specificity : 97.44%
Sickle cell trait	21 Nos	
Normal	78 Nos	

Study design

The **Sicklecheck™** was tested on 194 children, including 95 known sickle cell disease positive (Hb SS), 21 known sickle trait (Hb AS), and 78 sickle cell negative (Hb AA) children.

Sample type : Whole blood

Comparator method :Bio-Rad High Performance Liquid Chromatography (HPLC)

Duration of the study: 8/11/2023 to 22/01/2024

Age group of participants : 10 wks – 15 years

Sample size : – 194

Conclusion

The **Sicklecheck™** displayed good sensitivity and specificity when compared to the Bio-Rad high performance liquid chromatography as a standard, required a small sample amount, did not require a sophisticated instrument, did not require electricity, required little training, and provided results promptly. Therefore **Sicklecheck™** use as a rapid point of care testing based on the current findings is feasible.

Evaluation reports from Africa

Evaluating Body: Muhimbili Hospital, Dar-es-Salaam, Tanzania

Sample Type	Samples tested	Results in comparison with a Licensed competitor RDT
Sickle cell disease	350 Nos	Sensitivity > 99% Specificity > 90%

Study Design

Site of the study: Muhimbili National Hospital, Dar-es-Salaam, Tanzania

No. of tests: 350 tests

Sample: Whole blood

Report date: 23 May 2023

Licensed competitor RDT: Hemotype SC and Sickle Scan

Highlights

MORE ACCURATE ON THE RESULT INTERPRETATION, CLEAR VISIBILITY OF LINES.

Evaluation reports from Africa

Evaluating Body: **Laboratoire Prima Sarl, Yaounde, Africa**

Sample Type	Samples tested	Results in comparison with Electrophoresis method
Sickle cell disease	5 Nos	Sensitivity : 100% Specificity : 100%
Sickle cell trait	42 Nos	
Normal	120 Nos	

Study Design

Site of the study: Laboratoire Prima Sarl, Yaounde, Africa

Period of the study: 6/10 2023- 20/12/2023

Electrophoresis method : Helena Sas Vitresi (technique su gel d' agarose).

For the use of Registered Medical Practitioners and Laboratories only

For Faster, Reliable and
Large Scale Screening

SICKLECHECK™



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