

### Rapid Test for Sick Cell Anemia – Device

(Rapid immunochromatographic assay for simultaneous detection and differentiation of Sick Hemoglobin (HbS) and Normal Hemoglobin (HbA) from human whole blood)

**For In-Vitro Diagnostic Use Only**

**Store at 2°C to 40°C**

#### INTRODUCTION

Sickle Cell Anemia is a group of inherited disorders that affect hemoglobin, the major protein that carries oxygen in red blood cells. Normally, red blood cells are disc-shaped and flexible so they can move easily through the blood vessels. In sickle cell disease, red blood cells are typically "sickle"-shaped due to a gene mutation. Sick Hemoglobin (HbS) which is different from the normal Hemoglobin (HbA). They differ at the 6th amino acid position, where HbA has glutamic acid, and HbS has valine. These sickle-shaped cells cause blockages in the blood flow.

#### INTENDED USE

The product is intended for Simultaneous detection and differentiation of Sick Hemoglobin (HbS) and Normal Hemoglobin (HbA) from human whole blood.

The product is for professional IVD use only.

#### PRINCIPLE

After addition of the diluted whole blood sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with PAN Hb specific Antibodies and Rabbit IgG. If the sample contains detectable levels of the Sick Cell Anemia (HbS) specific Hb, it reacts with the gold conjugated PAN Hb Specific Antibodies to form a complex. This complex moves further and reacts with Anti-HbS Antibody coated as a separate test line on the nitrocellulose membrane to form colored band. The normal Hb (HbA) also binds to gold conjugated PAN Hb Specific Antibodies to form a complex. This complex moves further and reacts with Anti-HbA Antibody coated as a separate test line on the nitrocellulose membrane to form colored band. The formation of colored line at HbA denotes presence of normal Hb. While, the formation of colored line at HbS denotes presence of Sick Cell Anemia Hb (HbS).

The unbound complex & Rabbit IgG conjugated colloidal gold particles move further to the goat anti-Rabbit IgG coated control area to form a colored band (Control line).

Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

#### CONTENTS OF KIT

1. Test Device with desiccant and plastic dropper in individual pouch
2. Sample Extraction tube (prefilled with dilution Buffer)
3. Plastic dropper for Blood sample collection
4. Plastic dropper for Adding diluted sample into device
5. Package Insert

#### OPTIONAL MATERIAL REQUIRED

1. Timer
2. Blood Sample container/collection tube
3. Micro pipette
4. Lancet
5. Alcohol swab
6. Disposable Gloves

#### PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use the product after expiry date, the expiry date is printed on the foil pouch and packing of product.

3. Store in the sealed pouch in a dry place in between temperature 2°C to 30°C. Do not freeze.

4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

#### WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the used test components hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

#### SAMPLE COLLECTION AND PREPARATION:

1. Collect finger prick fresh blood or EDTA fresh blood for testing.
2. Blood collected in EDTA tube can be used within 3 days of collection if stored 2 to 8 °C till testing or during transportation.
3. Aspirate fresh finger prick /EDTA fresh blood sample using 10 µl dropper provided with the kit (Plastic dropper for Blood sample collection).
4. Add 1 drop of whole blood (10µl) in to the sample preparation tube containing dilution buffer.
5. Mix and use this diluted sample for testing as per given test procedure.
6. Do not keep this diluted sample at room temperature for prolonged period.
7. Use the diluted sample immediately or use with in 3 hours provided the tube is capped and stored at room temperature or 2 to 8 °C.

#### TEST PROCEDURE

1. Dilute the sample as per sample preparation procedure.
2. Allow the test device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
3. Remove the test device, desiccant and plastic dropper from the pouch and use it as early as possible.
4. Put the device on plain surface and add 3 drops (Approx. 70 - 80 µl) of diluted blood sample in sample well using the provided Plastic dropper for Adding diluted sample into device
5. Start the timer.
6. Read the result at 15 minutes. Do not read the result after 20 minutes.

#### RESULT INTERPRETATION

C: Control line  
A: HbA line (HA)  
S: HbS line (HS)

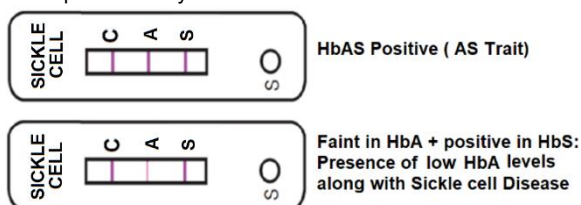
**Negative for Sick cell disease (Presence of normal Hemoglobin HbA):** Colored line observed at control region C and HbA region (A) and Absence of colored line HbS region (S).



**Positive for Sick cell disease (Presence of Hemoglobin HbS):** Colored line observed at control region C and HbS region (A) and Absence of colored line HbA region (S).

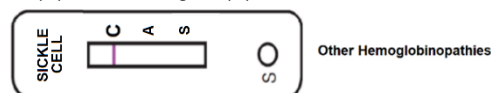


**Positive for both Hemoglobin HbS and Hemoglobin HbA:** Colored line observed at control region C and HbS region (S) and HbA region (A). Presence of faint clearly visible line at respective region denotes presence of traces of respective analyte.



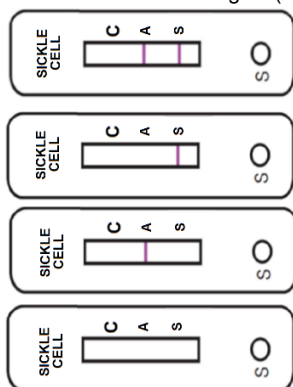
#### Positive for other hemoglobinopathies or thalassemia:

Colored line observed at control region C and absence of colored line at HbS region (S) and HbA region (A).



#### Invalid:

Colored line absents at control region C and in either presence or absence of colored line at HbS region (S) or/and HbA region (S).



#### LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

#### PERFORMANCE CHARACTERISTICS

##### INTERNAL EVALUATION

Total 185 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (60/60) and relative specificity was found 100% (125/125).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with RF, Pregnancy, High Hemoglobin, Malaria, SLE, ANA, Psoriasis, HIV positive samples.

| Sample           | SCA Test |          | Reference |          | Sensitivity (%)              | Specificity (%) | PPV (%) | NPV (%) |
|------------------|----------|----------|-----------|----------|------------------------------|-----------------|---------|---------|
|                  | Positive | Negative | Positive  | Negative |                              |                 |         |         |
| Positive         | 60       | -        | 60        | -        | 100                          | -               | 100     | -       |
| Negative         | -        | 100      | -         | 100      | -                            | 100             | -       | 100     |
| Cross reactivity | -        | 25       | -         | 25       | No cross reactivity observed |                 |         |         |
| Total            | 60       | 125      | 60        | 125      | -                            |                 |         |         |

#### EXTERNAL EVALUATION

The product is evaluated by ICMR-NIIH, government of India. 100 % sensitivity and 100 % specificity were found in external evaluation.

#### REFERENCES

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11. Sickle Cell Disease: Pathophysiology, Diagnosis, and Management. Westport: Praeger; 1992. p. 201-20.

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|  | In Vitro Diagnostic Use            |
|  | Manufacturer                       |
|  | Manufacturing Date                 |
|  | Expiry Date                        |
|  | Lot Number                         |
|  | Store at 2°C to 40°C               |
|  | Single Use                         |
|  | Number of tests in the pack        |
|  | Do not use if pouch or kit damaged |
|  | This side Up                       |
|  | Read package insert before use     |



#### MANUFACTURED BY

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