

# Study on HemoTypeSC™ test for the rapid screening of sickle cell disease patients in Government Medical College and Hospital, Ambikapur



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## ABSTRACT

**Background:** Sickle cell disease (SCD), also known as sickle cell anemia, is a dangerous disease in which the body produces an abnormal form of hemoglobin, the protein in red blood cells that transport oxygen throughout the body. The body produces sickle- or crescent-shaped red blood cells as a result of this genetic change. **Aims and Objectives:** This study aims to study on HemoTypeSC™ test for the rapid screening of SCD patients in Government Medical College and Hospital, Ambikapur. **Materials and Methods:** Fifty patients have been diagnosed as sickle cell anemia by sickle cell solubility test at Govt. Medical College, Ambikapur, Chhattisgarh, India. All the patients were admitted in the Department of Medicine at Govt. Medical College, Ambikapur, Chhattisgarh, India, from April 1, 2021, to June 1, 2021. **Results:** The study group (HbSS patients) comprised 22 (42%) males and 28 (58%) females. The ages ranged from 1 to 45 years; these 50 patients have been diagnosed as sickle cell anemia by sickle cell solubility test positive at Govt. Medical College, Ambikapur, Chhattisgarh, India. **Conclusion:** Sickle cell illness can be counted and observed in a variety of ways. Experience includes things such as electrophoresis and hand counting. HemoTypeSC™ is a blood test kit that determines hemoglobin type in whole blood in a short amount of time. At the point of care, this test detects the hemoglobin phenotype HbAA (normal), HbSS and HbSC (SCD), HbCC (hemoglobin C illness), and HbAS and HbAC (carrier or trait). Monoclonal antibodies are highly specific and sensitive to hemoglobin's A, S, and C. The fetal hemoglobin has no effect. There are no liquid buffer components or requirements for refrigeration. In high temperatures, it remains stable and the test takes only 10 min to complete.

**Key words:** Phenotype HbAA; Phenotype HbAS; Phenotype SC; Sickle cell disease

## INTRODUCTION

Sickle cell disease (SCD), also known as sickle cell anemia, is a dangerous disease in which the body produces an abnormal form of hemoglobin, the protein in red blood cells that transport oxygen throughout the body. The body produces sickle- or crescent-shaped red blood cells as a result of this genetic change.<sup>1</sup> Unlike normal red blood cells, which flow freely through blood channels,

sickle cells are stiff and sticky, and they tend to cluster together, obstructing blood flow. As a result, there are bouts of excruciating agony (referred to as “crises”), as well as chronic damage to essential organs. SCD is a genetic condition. SCD is caused by the inheritance of two copies of the sickle cell gene.<sup>2</sup>

At different stages, these hemoglobins are expressed as follows:

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### In the embryo

- Gower 1 ( $\xi_2\varepsilon_2$ )
- Gower 2 ( $\alpha_2\varepsilon_2$ )<sup>3</sup>
- Hemoglobin Portland

### In the fetus

- Hemoglobin F ( $\alpha_2\gamma_2$ )<sup>4</sup>

### In adults

- Hemoglobin A ( $\alpha_2\beta_2$ )<sup>5</sup>—The most common type.
- Hemoglobin A2 ( $\alpha_2\delta_2$ ) — $\delta$  chain synthesis begins late in the third trimester and in adults, it has a normal level of 2.5%.
- Hemoglobin F ( $\alpha_2\gamma_2$ ) — In adults, hemoglobin F is restricted to a limited population of red cells called F-cells.
- Hemoglobinopathies - Abnormal hemoglobin is a leading cause of genetic diseases in India. HbS is one of the hundreds of distinct hemoglobin types found in red blood cells. Many tribal people in India are known to carry the sickle cell allele, or HbS, and that the frequency of HbS is much higher among tribes than among castes.<sup>6</sup>

### Abnormal hemoglobin<sup>7</sup>

Hemoglobin S ( $\alpha_2\beta^S_2$ ) is a kind of hemoglobin present in SCD patients. A mutation in the chain gene causes a change in the characteristics of hemoglobin, resulting in red blood cell sickling.

Another form is hemoglobin C ( $\alpha_2\beta^C_2$ ) which is caused by a mutation in the chain gene. Mild chronic hemolytic anemia is caused by this variation.

More than 5% of the world's population carries the sickle cell disease gene but is otherwise healthy. In some locations, carriers account for more than 25% of the population. Every year more than 5 million children's are born with sickle cell trait, with over 400,000 developing SCD. Newborn screening is not prevalent in low-resource settings and without proper treatment, SCD can kill up to 80% of children. When newborn screening is combined with easily available, low-cost treatment, SCD mortality is dramatically decreased (Figure 1).<sup>8</sup>

Sickle cell anemia is the most frequent of a series of hereditary hemoglobinopathies in which normal adult hemoglobin (HbA) is replaced in part or whole by defective sickle cell hemoglobin (HbS) (Figure 1). Sickle cell anemia, hemolytic anemia, and acute and chronic tissue damage caused by vascular blockage caused by trapped aberrant red blood cells are all symptoms of SCD.<sup>9,10</sup>

HbS is caused by a single amino acid glutamic acid which is replaced by valine due to a change in base from "A" to

"T" at the beta-globulin gene's sixth codon. As a result, whereas chain function is normal in SCD, chain function is aberrant.<sup>11</sup>

### Aims and objectives

1. Study on HemoTypeSC™ test for the rapid screening of sickle cell disease patients in Government Medical College and Hospital, Ambikapur.

## MATERIALS AND METHODS

HemoTypeSC™ is a fast blood test kit that determines hemoglobin type in whole blood. This test detects the hemoglobin phenotypes HbAA (normal), HbSS and HbSC (SCD), HbCC (hemoglobin C disease), and HbAS and HbAC at the point of care (carrier or trait).

HemoTypeSC™ is a fast blood test kit that determines hemoglobin type in whole blood. This test detects the hemoglobin phenotypes HbAA (normal), HbSS and HbSC (SCD), HbCC (hemoglobin C disease), and HbAS and HbAC at the point of care (carrier or trait) at the Govt. Medical College in Ambikapur, Chhattisgarh, India, 50 patients were diagnosed with sickle cell anemia after undergoing a sickle cell solubility test positive from April 1, 2021, to June 1, 2021. All patients were admitted at the Department of Medicine at the Govt. Medical College in Ambikapur, Chhattisgarh, India. Ethical Clearance No.: No.IEC/GMC/2376A/2021.

## RESULTS

There were 22 (42%) males and 28 (58%) females in the study group (HbSS patients).

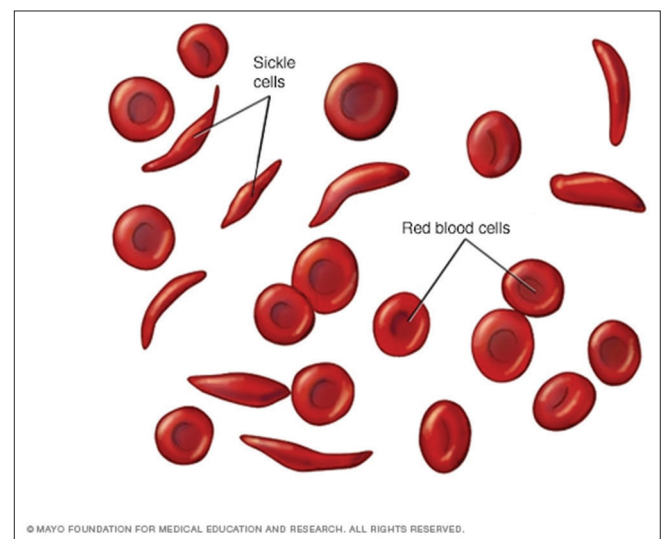


Figure 1: Sickle and normal red blood cells

These 50 patients varied in age from 1 to 45yearsold and were diagnosed with sickle cell anemia after a positive sickle cell solubility test at Govt.Medical College at Ambikapur, Chhattisgarh, India, from April 1, 2021, to June 1, 2021, all patients were admitted to the Department of Medicine at the Govt. Medical College in Ambikapur, Chhattisgarh, India.

Patients who had no clinical or laboratory evidence of diabetes mellitus, liver disease, lupus nephritis, acute sickness, or respiratory disorders were excluded from the study. None of the patient had previously taken antioxidant supplements.

Sickle cell anemia: Persons with hemoglobin genotype SS (HbSS).

Sickle cell anemia (Carrier): Persons with hemoglobin genotype AS (HbAS).

Normal individuals: Persons with hemoglobin genotype AA (HbAA).

### Sickle cell crisis

In patients with SCA, the term “crisis” refers to episodes of acute sickness induced by the sickling phenomenon, in which patients who were previously in a stable condition have a dramatic worsening of symptoms and signs. This can include pain or a vaso-occlusive crisis, aplastic crisis, acute sequestration crisis, or hemolytic crisis<sup>11</sup> (Table 1).

### HemoTypeSC™

HemoTypeSC™ is a quick test kit that identifies hemoglobin A, S, and C in whole blood and capillary blood (and optionally EDTA blood). The kit can be used for *in vitro* diagnostic reasons by health professionals. To evaluate the presence of hemoglobins A, S, and C, this test uses monoclonal antibodies in a competitive lateral flow immunoassay. HemoTypeSC™ can swiftly detect the hemoglobin phenotypes HbAA, HbSS, HbSC, HbCC, HbAS, and HbAC.

1. HemoTypeSC™ results are unaffected by fetal hemoglobin (Figure 2).
2. The HbS/0-thalassemia phenotype has the same HemoTypeSC™ result as the HbSS phenotype.
3. Other hemoglobin variations (for example, HbD and HbE) will yield the same HemoTypeSC™ result as HbA.

### Features

Monoclonal antibodies for hemoglobins A, S, and C that are highly specific and ultrasensitive:

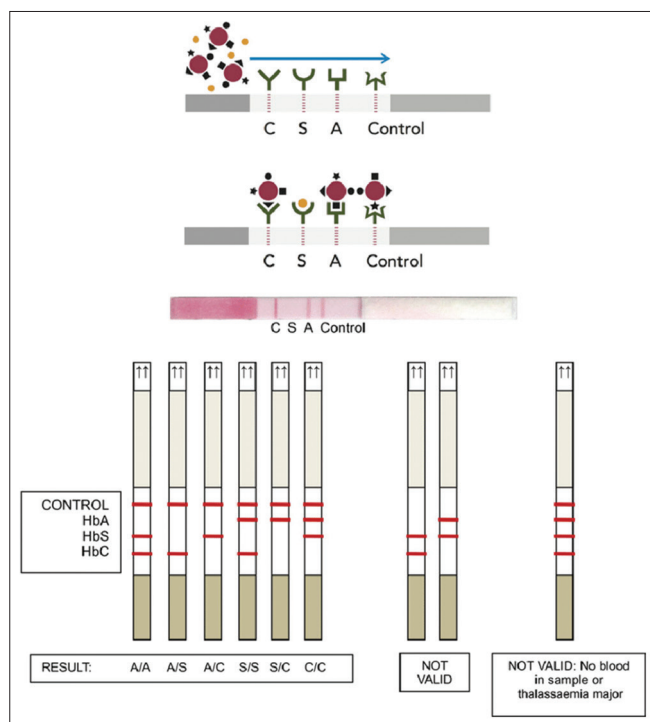


Figure 2: Sickling results

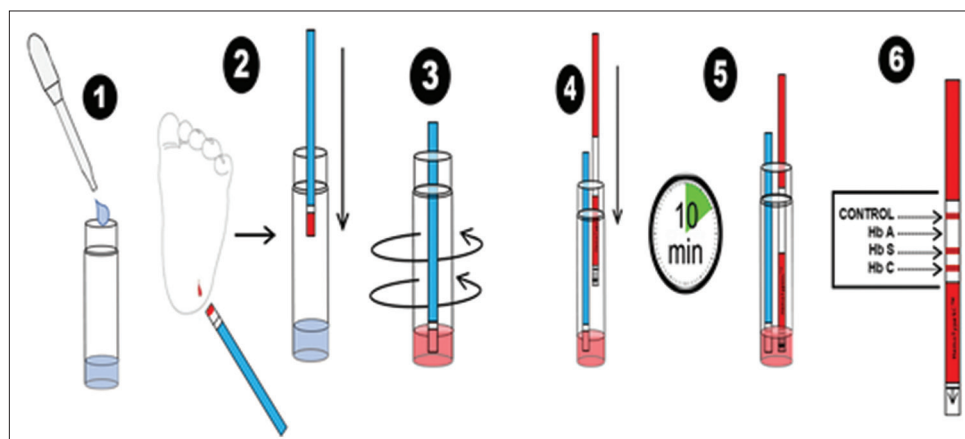


Figure 3: HemoTypeSC™ test procedure

**Table 1: Shows the Patients solubility and Hemotype SC test results**

S.No.	NAME	AGE	SEX	Solubility test	HemoTypeSC™result
1.	Rajini Das	40	F.	Yes	A.S.
2.	Poonam	20	F.	Yes	S.S.
3.	Anjali Das	18	F.	Yes	A.S.
4.	Vimala	40	F.	Yes	A.S.
5.	Lucky s/o Ramesh	9	M.	Yes	S.S.
6.	Sudhawpo Ramesh	30	F.	Yes	A.S.
7.	Ramesh	35	M.	Yes	A.A.
8.	Nishant S/O KamlesSingh	9	M.	Yes	S.S.
9.	KamlesS/O Manilal	28	M.	Yes	A.S.
10.	Devendra das S/Osona Das	19	M.	Yes	S.S.
11.	Devti DAS W/O Sana Das	46	F.	Yes	A.S.
12.	Dr. Salma D/O Subhani	32	F.	Yes	A.A.
13.	Jahid S/O Ali Husain	10	M.	Yes	S.S.
14.	Ruksana W/O Ali Husain	30	M.	Yes	A.S.
15.	Ali Husain	32	M.	Yes	A.S.
16.	Sadhana D/O Sobin	26	F.	Yes	S.S.
17.	Akbhar Ram Nayak S/O JokhuRam Nayak	32	M.	Yes	A.S.
18.	Sourya	7	M.	Yes	A.A.
19.	Sanadan Ram	28	M.	Yes	A.A.
20.	Roshani	12	F.	Yes	A.S.
21.	Dhana Pati	31	F.	Yes	A.S.
22.	Anish Ramnayak	6	M.	Yes	A.A.
23.	Manish Ramnayak	8	M.	Yes	S.S.
24.	VishnaviNayak	10	F.	Yes	S.S.
25.	ShithalYadha	60	M.	Yes	A.S.
26.	ApsanaParveen	15	F.	Yes	A.S.
27.	Fakruniskha	32	F.	Yes	A.S.
28.	Vikas Das	24	M.	Yes	S.S.
29.	Subhasa	35	F.	Yes	A.S.
30.	Surendra	25	M.	Yes	S.S.
31.	Seema w/o Mukesh	21	F.	Yes	A.A.
32.	Dev Kumari	34	F.	Yes	A.A.
33.	Ramdass	50	M.	Yes	A.S.
34.	Suresh	22	M.	Yes	A.A.
35.	Sneha D/Omadhan	20	F.	Yes	A.A.
36.	Aastha	1	F.	Yes	A.A.
37.	Aasha	5	F.	Yes	A.A.
38.	Chiraf	16	M.	Yes	A.S.
39.	Savitri	34	F.	Yes	A.S.
40.	Babi	22	F.	Yes	A.S.
41.	Mukesh D/O Varun	24	M.	Yes	S.S.
42.	Varun	42	M.	Yes	S.S.
43.	Ahilya w/o	40	F.	Yes	S.S.
44.	Rajesh	30	M.	Yes	S.S.
45.	Pranjal	20	F.	Yes	A.A.
46.	Anju	32	F.	Yes	A.A.
47.	RAJU	35	M.	Yes	A.S.
48.	Alisa	12	F.	YES	S.S.
49.	Khajahusain	42	M.	Yes	A.S.
50.	Ruksana	36	F.	Yes	A.S.

- No interference from fetal hemoglobin
- Test strip dimensions: 4mm × 75mm
- No liquid buffer components and no refrigeration required
- Stable in high temperatures

According to prior studies in low-resource and laboratory settings, the total sensitivity and specificity for detecting sickle cell anemia illness is >99 percent, with 100 percent accuracy.<sup>6,8,9</sup>

#### Procedure

1. Fill test vial with six droplets of water (about 250 microliters) using dropper pipette. Place the test vial in a rack that is compatible with it.
2. Remove one blood sampling device from the vial of blood sampling devices and seal the vial. Obtain a blood sample – only a few drops will suffice (1–2 microliters). Touch the blood sample to the white pad of the blood sampling device until the white pad absorbs the blood droplet. If you're using whole

blood, be sure the blood sampling instrument is not submerged in the tube of blood. Make sure the white pad is completely red.

3. Swirl the blood sampling device in the test vial water to mix it in.
  - a) Enough spinning is required for adequate blood transfer into the test vial.
  - b) Visually inspect the water to see if it has turned pink or light red in hue.
  - c) After swirling, leave the blood sampling device in the test vial.
4. Remove one test strip from the vial of test strips and seal the vial. With the arrows pointing down, place the HemoTypeSC™ test strip into the test vial.
5. Wait for 10 min.
6. Remove the HemoTypeSC™ test strip from the test vial and examine the results. For reference, compare the test strip to the results chart on the reverse side of this paper (Figure 3).

## DISCUSSION

In India, the symptoms of sickle cell anemia appear to be milder than in Africa and Jamaica.<sup>7</sup> SCD can cause mild-to-severe liver dysfunction, as well as clinical crises with significant hyperbilirubinemia and liver failure. Ischemia, transfusion-related viral hepatitis, iron overload, and gallstones are some of the factors that can contribute to the pathogenesis of liver disease.<sup>12</sup> Alkaline phosphatase levels may be raised as a result of delayed growth and bone deterioration.

Xandra et al.<sup>13</sup> “The rate and extent of reversible and permanent damage to organs caused by the SCD process, culminating in disability necessitating medical intervention,” according to the definition. Researchers have tried several times to develop a universally accepted system for grading disease severity in SCA patients, including the Cooperative Study of SCD and Bayesian Network Modeling (developed by Boston Medical Centre).

### Limitations of the study

1. HemoTypeSC™ results are unaffected by fetal hemoglobin.
2. The HbS/0-thalassemia phenotype has the same HemoTypeSC™ result as the HbSS phenotype.
3. Other hemoglobin variations (for example, HbD and HbE) will yield the same HemoTypeSC™ result as HbA.

## CONCLUSION

Counting and observing SCD can be done in a variety of ways. Electrophoresis and manual counting are examples of experience. HemoTypeSC™ is a fast blood test kit that determines hemoglobin type in whole blood. This test detects the hemoglobin phenotypes HbAA (normal), HbSS and HbSC (SCD), HbCC (hemoglobin C disease), and HbAS and HbAC at the point of care (carrier or trait). In HemoTypeSC™ test there are no liquid buffer components or refrigeration requirements. In high temperatures, it remains stable. The test takes only 10 min to complete.

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**Authors' Contributions:**

**SM**- Concept and Planning of the study; **OG**- Preparation of manuscript; **RKS**- Statistical analysis and preparation of Manuscript and Reviewing the Study and study results; **RM,PA and RCA**- Reviewed literature and Manuscript.

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