SICKLE-TEST (24Test)

(Hb-S Solubility Screening Test Kit)

IVD CE

PACKAGE SIZE
CS013

INTENDED USE
SICKLE-TEST is intended for in vitro qualitative solubility screening test for the determination of sickle hemoglobin (Hb-S) in human blood.

CLINICAL SIGNIFICANCE AND PRINCIPLE
Sickle cell disease is an inherited condition characterized by the presence of Hemoglobin S (Hb-S). Hb-S exists in a homozygous state (S/S) known as Sickle Cell Anemia or in a heterozygous state (A/S) known as Sickle Cell Trait. Homozygous individuals (S/S) commonly exhibit symptoms of severe hemolytic anemia and/or vascular occlusions. Heterozygous individuals (A/S) are usually asymptomatic. Hb-S may be present with other hemoglobins, such as Hemoglobin A, C or D, or with thalassemia, a condition that interferes with the synthesis of normal hemoglobin.

Under conditions of low oxygen tension, the heterozygous (A/S) form can cause erythrocytes to form the characteristic sickle-shaped tactoids. The formation of these irreversibly sickled red blood cells causes the onset of the acute symptoms. Detection of both the homozygous and heterozygous condition is important so high-risk individuals can be identified and their symptoms reduced.

Deoxygenated Hb-S is insoluble in the presence of a concentrated phosphate buffer solution and forms a turbid suspension that can be easily visualized. Normal Hemoglobin A and other hemoglobins remain in solution under these conditions. These different qualitative outcomes allow for the detection of sickle cell disease and its traits.

Saponin in the phosphate buffer lyses the red blood cells. Sodium dithionite then reduces the released hemoglobin. Reduced Hb-S is insoluble in the concentrated phosphate buffer and forms a cloudy, -turbid suspension.

REAGENT COMPOSITION
Reagent -1(Buffer (pH 7.1))

KH2PO4	1 mol/L
K2HPO4	1.36 mol/L
Saponin	0.5 g/L

Reagent-2 (Sodium dithionite)

REAGENT STORAGE AND STABILITY
Sickle cell reagent tubes and buffer are stable throughout the expiration date when stored tightly capped at 2 - 8° C. Reconstituted sickle cell reagent tubes must be used in the same day.

SPECIMEN
Whole blood EDTA, Heparin or oxalate anti-Coagulant.

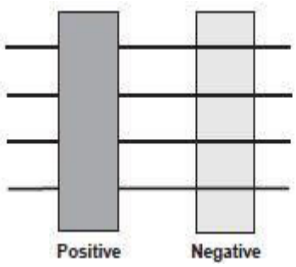
PRECAUTION
Reagents should never be frozen.
To avoid contamination, use clean laboratory wares.

REAGENT PREPARATION
1- If the sickle cell buffer and Tubes are refrigerated, remove it from the refrigerator and allow it to come to room temperature.
2- Remove only as many sickle cell reaction tubes as necessary.
3- Gently tap reaction tubes in order to remove any residual Powder that may have adhered to the cap during shipment or storage. Remove top cap from tubes carefully to avoid breakage.
4- Into each reaction tube, add 4ml of Reagent 1 (buffer) and mix. Sickle cell reaction tubes are now ready for the addition of the blood sample as outlined in the Test procedure section of this insert.
5- Reaction tubes are now ready for use

NOTE:
Reaction tubes should be prepared not more than 15 minutes before analysis of sample is begun. This not only insures fresh reagents, but the reducing agent in sickle cell is not stable for long period in an aqueous form.

TEST PROCEDURE
1- Using the Sickle cell reagent tubes prepared as per the directions in reagent preparation section of the insert, add 40 µl (0.04ml) of blood to Sickle cell reaction tube, label accordingly.
2- Using the cap or a piece of Para film, cover and then invert each tube several times to insure mixing of reagents and hemolysis of sample.
3- Wait at least 5 minutes, and then examine each tube in the sickle cell observation rack.

RESULTS
1-The reaction is read macroscopically by looking through the test tube at black lines or against a newsprint
2-A POSITIVE test for sickling hemoglobin (HbS) is indicated by a cloudy , turbid suspension through which the black tube rack lines or newsprint are NOT VISIBLE
3-A NEGATIVE test for sickling hemoglobin is indicated by a transparent suspension through which the black tube rack lines or newsprint are CLEARLY VISIBLE



QUALITY CONTROL
Known positive and negative controls should be run in parallel with the test samples.

NORMAL RANGE
Negative

NOTES
All positive results must be confirmed by hemoglobin electrophoresis.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBILOGRAPHY
1- Bunn HF (1997) pathogenesis and of sickle cell disease N Engl J Med 337: 762-769.
2- Begue P (1999) Infection and sickle cell anemia. Pathol Biol 47:19-25.

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany