SICKLE-TEST
(Hb-S Solubility Screening Test Kit)

IVD CE

PRODUCT CODE
CS012

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 PREPARATION
Add content of reagent 2 "Sodium dithionite" to reagent 1 "Sickling buffer", or alternatively dissolve 0.1g Sodium dithionite in 10 ml of buffer (1.0 %) just prior to use.

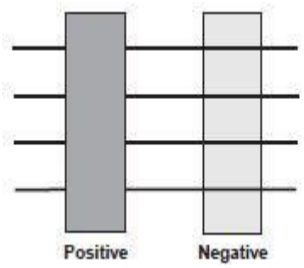
REAGENT STORAGE AND STABILITY
The reagents are stable throughout the expiration date when stored tightly capped at 2 - 8° C.
The working reagent is stable for 30 days at 2-8° C.

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

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

PROCEDURE
1- Take 2 ml of the reconstituted sickling solution to a 75X12 mm glass tube.
2- Add 20 ul of blood
3- Mix thoroughly and allow standing for at least 5 minutes.
4- Examine tube for insoluble Hb by holding the tube against newsprint. If the print is clearly visible, the test is presumed negative for Hb-S.
5- If the print is not clearly visible, the test is repeated by adding 100 ul of blood to 2 ml sickling solution in a 75 x12 glass tube.
6- Mix thoroughly and centrifuge at 1200 g for 5 minutes.
7- Allow the centrifuge to stop without breaking and carefully remove the tube without disturbing the contents.
8- Examine the tube.

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.

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