iLAB™ αTHAL

IC Strip Test for Alpha Thalassemia Detection

PRINCIPLE

The i+LAB αTHAL IC Strip Test is a qualitative, lateral flow immunoassay for the screening of various types of alpha(α) thalassemia trait in whole blood. As the blood test sample diffuses through the absorbent test strip, the labeled antibody-dye conjugate binds to the Hb Bart's in the specimen forming an antibody-antigen complex. This complex binds to the anti Hb Bart's antibody in the test line and expresses a colored band. The absence of a colored band in the test region indicates a negative result. The reaction mixture continues flowing through the absorbent device past the test and control lines. Unbound conjugate binds to the reagents in the control line, producing a pink color band, demonstrating that the reagents and test strip are functioning correctly.

KIT CONTENTS**

96 Alpha Thalassemia IC Strip Tests
1 Instruction Sheet Insert

STORAGE CONDITION

1. The test strip must be stored at room temperature 4°C to 30°C (40°F to 86°F) until expiration date.
2. To ensure accurate results, the strip test should remain in the sealed pouch until used.
3. The test strip is stable until expiration date when handled and stored as directed.

SPECIMEN COLLECTION AND PREPARATION

1. i+LAB αTHAL IC Strip Test can be performed using whole blood specimen in EDTA tube.
2. Hemolysis of blood sample by mixing 100 µl of EDTA blood sample with 100 µl of Lysis buffer in a well plate.

LIMITATION

1. i+LAB αTHAL IC Strip Test is for *in vitro* diagnostic use only. This test is recommended for the detection of Hb Bart's protein in a human whole blood specimen. Other body fluids or pooled specimens may not give accurate results.
2. i+LAB αTHAL IC Strip Test will only indicate the presence of *alpha thal 1 trait, HbH (alpha thal1/alpha thal2), HbH-CS (alpha thal1/Hb ConstantSpring), AEBart's (Hb H disease + Hb E trait), homozygous alpha thal 2.*
3. i+LAB αTHAL IC Strip Test will give **negative results** in the *alpha thal 2 trait, beta thal trait, Hb E trait and normal persons.*
4. As with all diagnostic tests, all results must be considered along with other clinical information available to the physician.

Distributed by:

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**Specification and design are subject to change without notice due to product improvement

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The World's First Alpha Thalassemia Immunochromatographic Strip Test

iLAB™ αTHAL

IC Strip Test for Alpha Thalassemia Detection

EASY, QUICK & COST-EFFECTIVE
HIGH SENSITIVITY & SPECIFICITY
NO EQUIPMENT NECESSARY

"A severe condition of Alpha(α) thalassemia, Hb Bart's hydrops fetalis, die in the womb or shortly after birth. Moreover, pregnant woman may become edema with high blood pressure and proteinuria known as toxemia of pregnancy."

Alpha(α) thalassemia is commonly found in Southeast Asia, Southern China, India, the Middle East and in the Mediterranean region.

The alpha(α) thalassemia traits combine in different ways to produce blood disorders that range from mild to severe in their effect on the human body.

A blood test is highly recommended in couples planning to have a baby, or a woman that is already pregnant, to determine if either parent is a carrier of the alpha(α) thalassemia trait. Early and aggressive birth screening and genetic counseling is recommended to determine if a person(s) has the alpha(α) thalassemia trait.

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i LAB αTHAL

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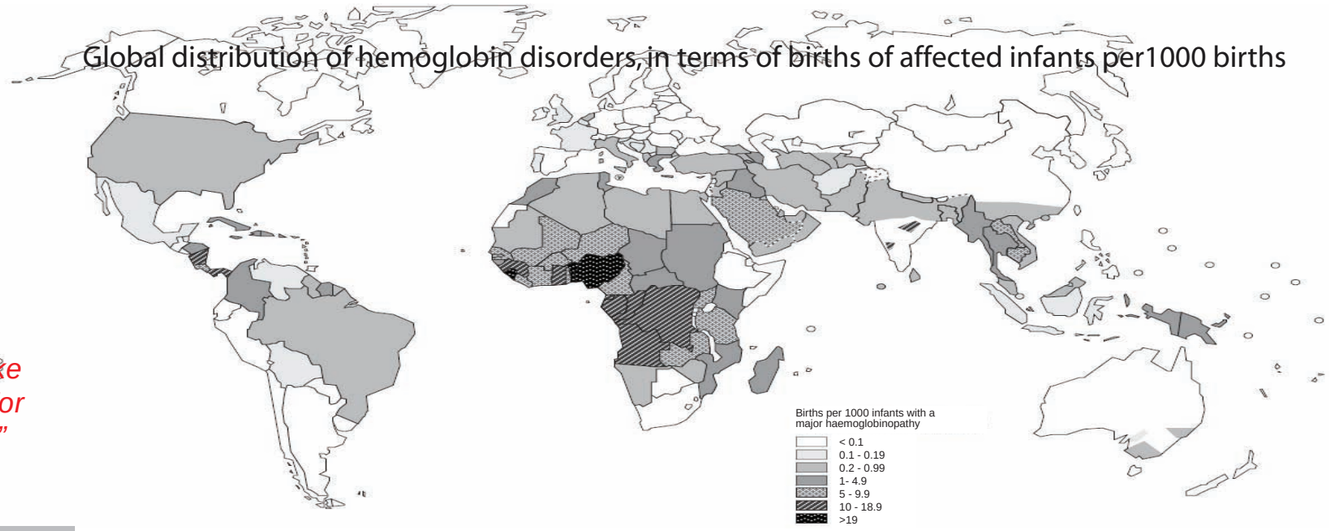
What is alpha(α) thalassemia?

Thalassemia is a recessive inherited disorder of the red blood cells that affect the hemoglobin production. Hemoglobin is a protein in the blood that carries oxygen throughout our bodies. The thalassemia gene is genetically passed from parent to child. Genes carry information about human characteristics such as eye color, hair color and hemoglobin.

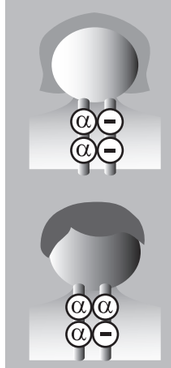
"Physicians often mistake alpha thalassemia trait for iron deficiency anemia"



Global distribution of hemoglobin disorders, in terms of births of affected infants per1000 births

Source: http://www.who.int/genomics/public/Maphaemoglobin.pdf

"The alpha thalassemia traits combine in different ways to produce blood disorders that range from mild to severe in their effect on the human body."

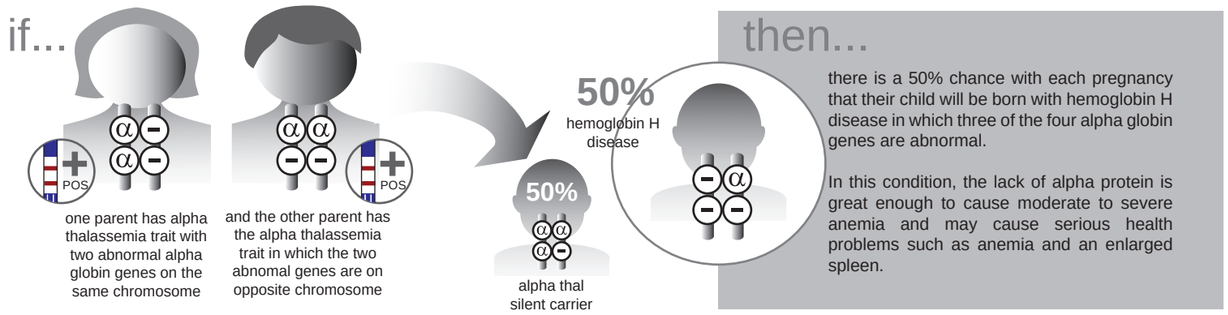


Severe Alpha Thalassemia Trait
(Alpha Thalassemia1 or Alpha° Thalassemia Trait)
In this condition, in which two of the four alpha globin genes are missing or defective, the lack of alpha globin protein is somewhat greater.

Both abnormal alpha globin genes is on the same chromosome (cis position).

Mild Alpha Thalassemia Trait
(Alpha Thalassemia2 or Alpha+ Thalassemia Trait).
One alpha globin gene is missing in this condition. Homozygote of this condition, homozygous α-thalassemia2, has one intact alpha globin gene on each chromosome

Patients with this condition have smaller red blood cells and a mild anemia, although they do not experience symptoms



one parent has alpha thalassemia trait with two abnormal alpha globin genes on the same chromosome

and the other parent has the alpha thalassemia trait in which the two abnomal genes are on opposite chromosome

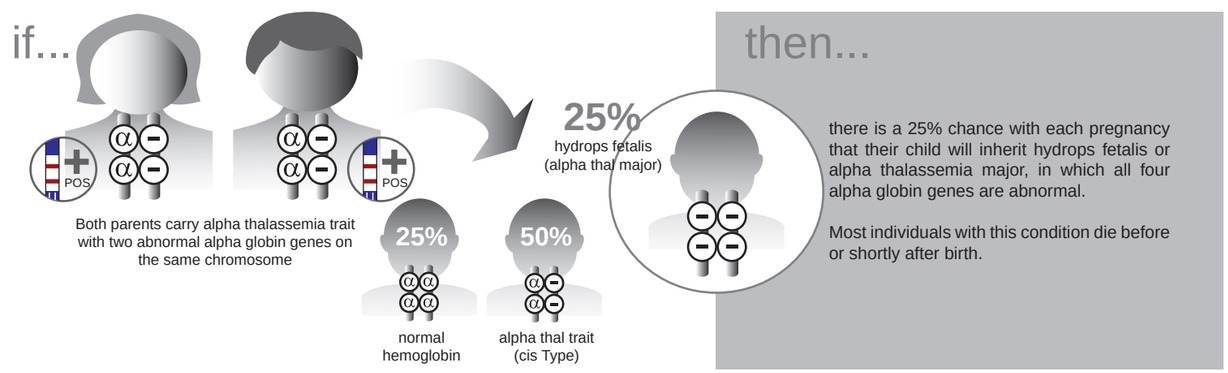
hemoglobin H disease

alpha thal silent carrier

then...

there is a 50% chance with each pregnancy that their child will be born with hemoglobin H disease in which three of the four alpha globin genes are abnormal.

In this condition, the lack of alpha protein is great enough to cause moderate to severe anemia and may cause serious health problems such as anemia and an enlarged spleen.



Both parents carry alpha thalassemia trait with two abnormal alpha globin genes on the same chromosome

normal hemoglobin

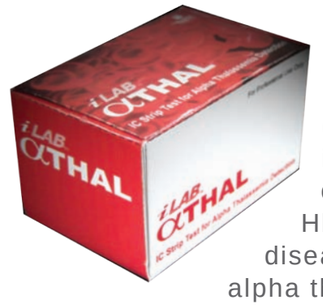
alpha thal trait (cis Type)

25% hydrops fetalis (alpha thal major)

then...

there is a 25% chance with each pregnancy that their child will inherit hydrops fetalis or alpha thalassemia major, in which all four alpha globin genes are abnormal.

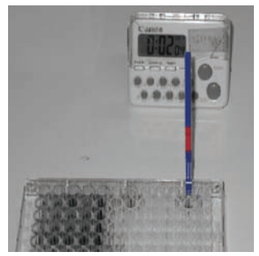
Most individuals with this condition die before or shortly after birth.



i+LAB αTHAL IC Strip Test is a rapid visually read, lateral flow chromatographic immunoassay for the qualitative determination of Hb Bart's in hemolysate. i+LAB αTHAL IC Strip Test will identify the presence of alpha thal 1 trait, Hb H (alpha thal1/ alpha thal2), Hb H-CS (alpha thal1/ HbConstantSpring), AEBart's disease (Hb H disease + Hb E trait), and homozygous alpha thal 2.

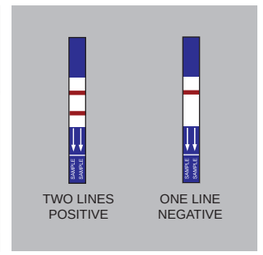
EASY PROCEDURE WITHIN 3 MINUTES

Step 1
HEMOLYSIS
BLOOD SAMPLE



Step 2
TEST
WITHIN 2 MINUTES

Step 3
WASH
THE STRIP



Read the result
EASY
TO INTERPRET

PERFORMANCE CHARACTERISTIC*

Sensitivity	**100 %**
Specificity	**98.50%**
Accuracy	**99.07%**

* Tested performed by Prof. Suthat Fucharoen MD., Thalassemia Research Center, Institute of Science and Technology for Research and Development, Mahidol University, Salaya Campus, THAILAND

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