

MBP010

Hi-Thal Kit
(Turbidity based detection of Beta-Thalassemia)

Kit Contents

Product Code	Reagents / Materials provided	MBP010
		For 50 Samples
DS0198	Reagent Thal	10 ml
ML024	Molecular Biology Grade Water	170 ml

Other materials provided with the Kit

Materials	For 50 Tests
Empty Reaction Tubes	50 nos.
Test Tube Stand	1 no.
Dropper	1 no.
Mini Fixvo 0.025ml Micropipette	1 no.
Pipet Tips, (Vol. 0.2ml)	50 nos.

Intended Use:

The kit is designed to detect Beta-thalassemia individuals.

Introduction

Thalassemia is a group of genetic disorders characterized by quantitative defects in globin chain synthesis with subsequent absence or decrease of hemoglobin production leading to variable degrees of microcytic anemia; it is commonly found in people of Mediterranean, African, Middle Eastern, Indian, Chinese or Southeast Asian origin. Beta-thalassemia is an autosomal recessive single gene disorder characterized by reduced (β^+) or (β^0) beta globin chain synthesis leading to reduced hemoglobin A (HbA) synthesis.

Beta-Thalassemia is a disease of considerable public health importance. Apart from causing mortality and morbidity the disease also puts severe strain on family and medical resources. With the advent of DNA diagnostic techniques, it is now possible to offer antenatal diagnosis at 9-11 week of gestation by chorionic villus sampling.

Hi- Thal Kit

This kit is based on the limit of hypotonicity that the red cell can withstand. Red Blood cells in thalassemia patients have decreased osmotic fragility as compared to red blood cells in normal individuals. When red blood cells from thalassemia patients are introduced into higher concentration solution, the cells rupture leading to turbidity of the reaction mixture. These cells have low capacity to expand in low osmotic solutions.

Precautions while handling reagents

1. Reagent for laboratory use only.
2. Do not pipette by mouth.

- The reagent can be damaged due to microbial contamination or on exposure to extreme temperature.
- Use reagent of same lot numbers. Do not interchange reagent of different lot numbers.

Storage

The kit can be stored at room temperature (15-25°C) for up to 12 months without showing any reduction in performance (if stored at mentioned conditions). Store Reagent Thal (1X) [stock solution (1X)] at 4°C. Bring it to room temperature (15-25°C) before use. Always prepare fresh working stock solution.

General Preparation Instructions:

- Dilute Reagent Thal (10X) (DS0198) to Stock solution (1X) as follows:

Reagent Thal (10X) (DS0198)	Molecular Biology Grade Water	Total volume of stock solution (1X)
1 ml	10 ml	11 ml
5 ml	50 ml	55 ml
10 ml	100 ml	110 ml

- Dilute Stock solution (1X) to working solution as follows:

Stock solution (1X)	Molecular Biology Grade Water	Total volume of working stock solution	Number of reactions
1.3 ml	2 ml	3.3 ml	1 reaction
1.95 ml	3 ml	4.95 ml	2 reactions
2.6 ml	4 ml	6.6 ml	3 reactions
3.25 ml	5 ml	8.25 ml	4 reactions
4.55 ml	7 ml	11.55 ml	5 reactions
5.2 ml	8 ml	13.2 ml	6 reactions
5.85 ml	9 ml	14.85 ml	7 reactions
6.5 ml	10 ml	16.5 ml	8 reactions
7.15 ml	11 ml	18.15 ml	9 reactions
8.45 ml	13 ml	21.45 ml	10 reactions
9.1 ml	14 ml	23.1 ml	11 reactions
9.75 ml	15 ml	24.75 ml	12 reactions
10.4 ml	16 ml	26.4 ml	13 reactions
11.05 ml	17 ml	28.05 ml	14 reactions
12.35 ml	19 ml	31.35 ml	15 reactions
13 ml	20 ml	33 ml	16 reactions
13.65 ml	21 ml	34.65 ml	17 reactions
14.3 ml	22 ml	36.3 ml	18 reactions
15.6 ml	24 ml	39.6 ml	19 reactions
16.25 ml	25 ml	41.25 ml	20 reactions
16.9 ml	26 ml	42.9 ml	21 reactions
17.55 ml	27 ml	44.55 ml	22 reactions
18.2 ml	28 ml	46.2 ml	23 reactions
19.5 ml	30 ml	49.5 ml	24 reactions
20.15 ml	31 ml	51.15 ml	25 reactions
20.8 ml	32 ml	52.8 ml	26 reactions

21.45 ml	33 ml	54.45 ml	27 reactions
22.1 ml	34 ml	56.1 ml	28 reactions
23.4 ml	36 ml	59.4 ml	29 reactions
24.05 ml	37 ml	61.05 ml	30 reactions
24.7 ml	38 ml	62.7 ml	31 reactions
25.35 ml	39 ml	64.35 ml	32 reactions
26.65 ml	41 ml	67.65 ml	33 reactions
27.3 ml	42 ml	69.3 ml	34 reactions
27.95 ml	43 ml	70.95 ml	35 reactions
28.6 ml	44 ml	72.6 ml	36 reactions
29.25 ml	45 ml	74.25 ml	37 reactions
30.55 ml	47 ml	77.55 ml	38 reactions
31.2 ml	48 ml	79.2 ml	39 reactions
31.85 ml	49 ml	80.85 ml	40 reactions
32.5 ml	50 ml	82.5 ml	41 reactions
33.15 ml	51 ml	84.15 ml	42 reactions
34.45 ml	53 ml	87.45 ml	43 reactions
35.1 ml	54 ml	89.1 ml	44 reactions
35.75 ml	55 ml	90.75 ml	45 reactions
36.4 ml	56 ml	92.4 ml	46 reactions
37.05 ml	57 ml	94.05 ml	47 reactions
38.35 ml	59 ml	97.35 ml	48 reactions
39 ml	60 ml	99 ml	49 reactions
39.65 ml	61 ml	100.65 ml	50 reactions

Note: 2ml working stock solution is required for one reaction.

Specimen Handling and collection

Collect whole blood in an anticoagulant tube (an EDTA tube is preferred) under sterile conditions (if to be used for future). Ensure that the blood is at room temperature before beginning the protocol.

Procedure

1. Place Empty Reaction Tubes in the Test Tube Stand (provided) and dispense 2ml of diluted working stock solution with the help of a dropper in the empty reaction tubes.

NOTE: Prepare diluted working stock solution as indicated in “General Preparation Instructions” section.

2. Gently add 25µl of freshly collected whole blood sample to each reaction tube with the help of a Mini Fixvo 25µl Micropipette.

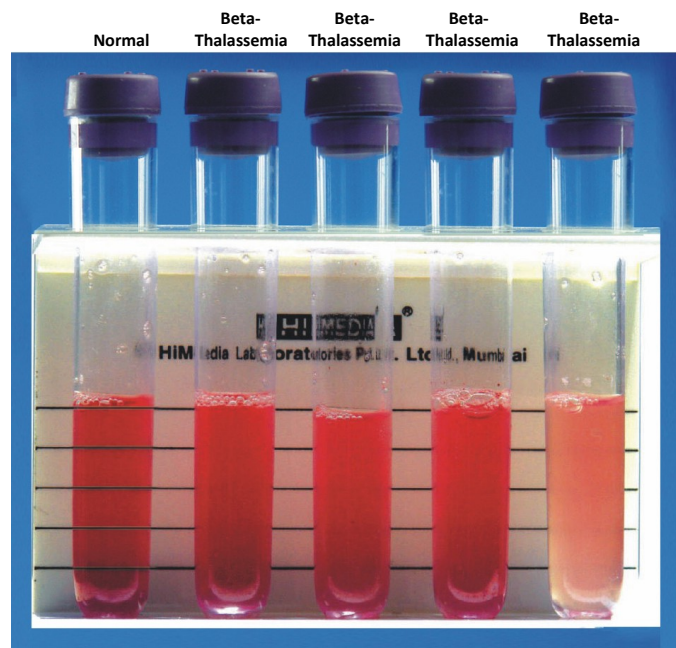
NOTE: Anticoagulated blood should be used if the test is not performed on freshly collected blood sample.

3. Gently mix the tubes for 10-15 seconds.
4. Allow the tubes to stand for 5 minutes at room temperature.
5. Place the tube in the Test Tube Stand provided with the kit and read for turbidity.

Interpretation of Results: Place the test tubes in the test tube stand and observe the results in a well-lit area.

- I. *Negative- If solution is clear and black lines visible.*
- II. *Positive- If Solution is turbid and black lines not visible.*

Sr. No	Turbidity	Clarity	Visibility of black lines through the tubes	Interpretation
I	No	Yes	Yes	Normal
II	Yes	No	No	Beta-thalassemia



NOTE: This Figure represents single set of experiment. Some slight color variation might be seen depending on hemoglobin content in blood sample.

Remarks

1. Negative control samples can be collected from normal, healthy individuals.
2. All positive results should be confirmed by Beta-Thalassemia Detection Kit (MBPCR014 or MBPCR014A)
3. The results of the test should be correlated with clinical findings to arrive at the final diagnosis.

Warning

Certified for *in vitro* Diagnostic Use (IVD). Not for Medicinal Use. Read the procedure carefully before beginning the protocol. Wear protective gloves/protective clothing/eye protection/face protection. Follow good clinical laboratory practices while handling clinical samples. Standard precautions should be followed as per established guidelines. Safety guidelines may be referred in safety data sheets of the product.

Precautions

Read the procedure carefully before starting the experiment.

Performance and Evaluation

Each lot of HiMedia's Hi- Thal Kit is tested against predetermined specifications to ensure consistent product quality.

Quality Control

Type of Sample	Turbidity observed	Clarity
Normal Blood Sample	No	Yes
Thal Blood Sample	Yes	No

- I. **Negative- If solution is clear and black lines visible.**
- II. **Positive- If Solution is turbid and black lines not visible.**

Limitations of the test

1. Conditions like severe anemia (hemoglobin level less than 7 gm/dL) can result in false negatives.

References

1. 'NESTROFT'-AN EFFECTIVE SCREENING TEST FOR BETA THALASSEMIA TRAIT Mamta Manglani, M.R. Lokeshwar, Vani V.G., Nishi Bhatia and Vijay Mhaskar
2. Comparative evaluation of NESTROFT and RDW as screening tests for beta thalassemia trait in pregnancy Pritibala Patel, Nivedita Sarda, Renu Arora, Harsha Shailesh Gaikwad
3. Evaluation of NESTROFT as a marker of differentiation between β - Thalassemia Trait & Iron Deficiency Anemia Afshan Sumera, Sulaiman Ahmed, SM Adnan Ali, Rafiq Khanani

Safety Information

Take appropriate laboratory safety measures and wear gloves while handling. Not compatible with disinfecting agents containing bleach. Please refer Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed off in accordance with current laboratory techniques.

Please refer disclaimer Overleaf.

Technical Assistance

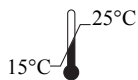
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In vitro diagnostic medical device



CE Marking



Storage temperature



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