

This product is intended for professional use only

REF Product Model No. : BMAPBP0110

[Notice]

- Prior to use, please read this leaflet and follow the instructions to ensure analysis results and to perform a comprehensive judgment based on other relevant test results and clinical symptoms.
- This is not a home-use in vitro diagnostic medical device for user self-testing.

Usage

This product is designed to quantify the concentration of apolipoprotein B ("ApoB") in human whole blood or fingerstick blood in combination with an iProtein reader.

Assay summary and description

This product is used for the quantitative detection of ApoB in human whole blood or fingerstick blood. It needs to be used with a iProtein reader. In clinical applications, the ApoB assessment value is considered to be one of the features that assists in diagnosing the risk of cardiovascular disease, and can be used as an indicator to assess the risk of coronary

heart disease. Current research results show that ApoA1 is negatively correlated with coronary heart disease, and ApoB is positively correlated with coronary heart disease. Patients with coronary heart disease generally have lower amounts of ApoA1 and higher amounts of ApoB. Diagnosis through screening can help remind high-risk individuals to eliminate or control other high-risk factors as soon as possible.

Assay methodology

This assay uses antigen-antibody reactions to measure ApoB in whole blood using a surface acoustic wave (SAW) chip. Use a blood collection needle to collect a 5 µL blood sample from the patient's fingertips (or use venous whole blood), then use a micropipette to absorb the blood sample, add it to the diluent and mix evenly, then drop the diluted sample into the ApoB test card cassette, the ApoB in the specimen will be captured by the anti-ApoB monoclonal antibody pre-fixed on the SAW chip of the detection cassette. Depending on the concentration of ApoB in the whole blood, the surface elastic wave velocity of the SAW chip will change to varying degrees. By reading this change with a quantitative

immunoassay analyzer, ApoB concentration in whole blood can be quantitatively determined.

Contents

1. Cartridge containing the test chip in an aluminum foil bag with desiccant
2. Dilution buffer
3. Product manual

Required item not included

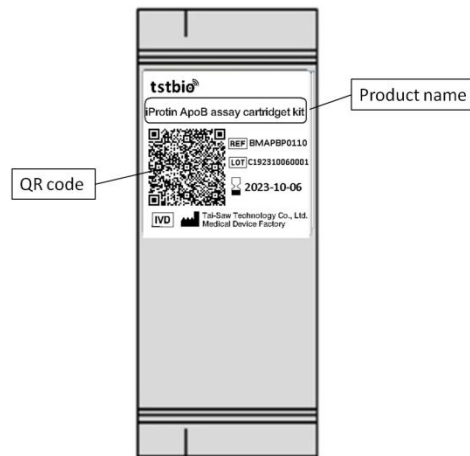
1. iProtein reader
2. Alcohol pad/ Blood collection needle (of a capacity of more than 10 µL of blood)
3. Micropipette

Description of test cartridge

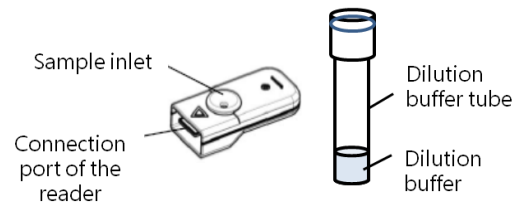
The upper part of the test cassette contains a sample inlet and an interface for connecting the iProtein reader. The label on the aluminum foil outer packaging contains specific information such as batch and expiry date, as well as a two-dimensional barcode (QR code) used for detection and calibration that can be recognized by the iProtein reader.

Appearance

Aluminum foil Exterior



Testing cartridge and dilution buffer tube



Testing cartridge reagent

1. Monoclonal ApoB antibody
2. Goat anti-rabbit IgG

Dilution buffer

1. PBS with sodium azide

Precautions and Notices

- For in vitro diagnostic use only.
- Please do not use test cartridges that have

exceeded their shelf life or have not been stored in the recommended manner.

- Please do not use products with visible damage on the foil package, desiccant, or cartridges
- Test cartridges are intended for single use only.
- Dispose of used test cartridges, sampling instruments, and patient samples immediately after use as they are potentially infectious and should be disposed of in accordance with local or national regulations.
- Replace gloves when testing for different patients.

Storage

Storage condition: 2~35°C

Transport condition: 5~60°C; RH 30~85%

Operating condition: 4-40°C; RH 45~85%

Expiration date

- One year under standard storage conditions, as indicated by the expiration date on the outside of the foil package. The cartridge can be stored in sealed foil packaging until the expiration date shown on the outside.
- Do not freeze

Opened cartridges

- Must be used within 15 minutes of opening the foil package.

- Keep out of direct sunlight.
- Avoid relative humidity above 85 %.
- Please avoid dropping or excessive impact, as it may cause breakage or abnormal measurements.

Collecting, preparing and preserving samples

Applicable samples for examination

1. Whole blood from fingertip
2. Whole blood in anticoagulant Heparin tube

※This product is not suitable for blood samples containing EDTA which may lead to inaccurate measurement result.

Operation Notes

- Please use whole blood. Please do not use samples other than whole blood (e.g., plasma).
- Please prepare a separate needle for blood collection (with a capacity of 10 µL or more) and alcohol pads for disinfection.
- Please read and follow the instructions for blood collection and alcohol pads application.
- If the QR-code is damaged or smeared, scanning for information may fail.

Operation procedure

1. Separate equipment required: iProtein reader, blood collection needle, micropipette, alcohol pad

2. Preliminary procedures

- (1) Please refer to the instruction manual of the iProtin reader for proper operation.
- (2) When taking out the test cartridge from the foil package, please lift it carefully from both sides and do not touch the sensing area of the chip or allow foreign objects to adhere to the surface of the reagent drying area.

3. Operation

- (1) Activate the reader and scan the QR code on the aluminum foil package. And confirm the test item on the reader screen again. .
- (2) Open the aluminum foil package and take out the test cartridge, insert the chip according to the instructions of the reader.

4. Specimen collection and dilution

- (1) Open the outer packaging of the diluent and take out the diluent tube. Make sure there is liquid at the bottom of the diluent tube and place it upright on the table.
- (2) Use alcohol pads to disinfect the finger or venous blood collection site where blood is to be collected, and then use a blood collection needle to collect blood after confirming that the alcohol has evaporated.
- (3) After wiping off the first drop of blood, use a micropipette to absorb 5 μ L of whole blood from the collection site and add it to the dilution tube.

- (4) Shake the dilution tube up, down, left, and right at least ten times to fully mix the specimen and diluent, and confirm that there is no precipitation at the bottom of the dilution tube. Then tap the bottom of the dilution tube twice on the table to avoid liquid residue on the bottle or cap.

5. Testing

- (1) Use a micropipette to draw 5 μ L of the diluted specimen from the dilution tube. Avoid air bubbles when drawing.
- (2) Follow the instructions of the reader and drop the diluted sample into the cartridge port.
- (3) Drop the sample at once (avoid multiple drops), and 40 seconds after the reader automatically starts measuring, the value will be displayed on the screen.
- (4) After completing the measurement, remove the detection cartridge and long press the power button to turn off the reader.

6. Results

The patient's medical history should be carefully considered when interpreting test results, and no medical action should be taken without consulting a physician.

Determination of measurement results

Normal range of ApoB

Male: 46-174 mg/dL

Female: 46-142 mg/dL

✕Each laboratory should develop its own reference range in accordance with good laboratory practices.

Performance

(1) Linearity range

ApoB concentration: 8.0 ~ 202.2 mg/dL °
Conducted in accordance with CLSI EP6-A guidelines

(2) Accuracy

The limit of detection (LoB) for the blank is 5.47 mg/dL, while the limit of detection (LoD) is 8.01 mg/dL.

Conducted in accordance with CLSI EP17-A guidelines, 60 replicate tests were performed on low concentration samples.

(3) Precision

Intra-study : Conducted according to CLSI EP5-A2 guidelines, 3 whole blood samples were tested 20 times in the same assay.

Sample	#1	#2	#3
Concentration (mg/dL)	42.2	56.5	116.9
CV (%)	5.49	8.16	4.36

Inter-study: Three whole blood samples were tested for 5 consecutive days, with two replicates analyzed twice a day, for a total of 20 tests.

Sample	#1	#2	#3
Concentration (mg/dL)	44.3	58.2	121.3
CV (%)	7.73	6.72	8.75

(4) Interference

At the following concentrations, no significant interference occurs, and the deviation is within $\pm 10\%$.

- Hemolysate: 1000 mg/dL
- Bilirubin (conj.): 40 mg/dL
- Bilirubin (unconj.): 40 mg/dL
- Triglyceride-rich lipoproteins: 500 mg/dL

- Do not drop the sampled blood directly into the detection cassette. Be sure to mix it with the diluent before use. If it is not mixed, the measurement cannot be performed correctly.
- When inserting the cartridge into the immunoassay, insert it straight and firmly until you feel a click.
- Confirm the instructions of the reader before opening the cartridge.
- After the cartridge is inserted into the reader, place it on a flat surface until the result is displayed. Do not move the cartridge until the results are displayed.
- If the measurement value deviates significantly from the clinical symptoms and you have doubts regarding the measurement value, please re-examine or verify using other methods.

Waste disposal measures

After testing, please dispose of the test cartridge and the used parts in accordance with the local government or facility's standards (sterilization, disinfection, incineration, etc.) for infectious waste.

Comparison study

This product was compared with "Siemens" apolipoprotein B test reagent (non-sterile) (Taiwan Ministry of Health Medical Device No. 005869), and was conducted in accordance with CLSI EP9-A2 guidelines.

	y: iProtein x: ADVIA Chemistry XPT
No of Sample	47
Regression line	$y = 0.9741x + 5.1608$
Coefficient of correlation (R)	0.9287

Reference

1. Walldius, G., Jungner, I. Apolipoprotein B and apolipoprotein A-I: risk indicators of coronary heart disease and targets for lipid-modifying therapy. *Journal of internal medicine*, 255(2), 188–205 (2004).
2. H. Tineke W, et al. Apolipoprotein B and Coronary Artery Disease in Women. *Arteriosclerosis, Thrombosis, and Vascular Biology*, 18, 1101–1107 (1998).

Quality control

The quality control calibration reference material used to calibrate this product: can be traced to the World Health Organization (WHO) standard SP3-07.

Possible causes of false values

Limitations

- Applicable hematocrit (Hct) range: 40~50% °
- Avoid using cartridge sets that have exceeded their shelf life.
- The specimen is not fully mixed with the diluent in the dilution tube.

Precautions for use or handling

Precautions during operations

- Storage, transport and handling should be in accordance with the environmental conditions specified in this manual and used before the expiration date.
- Dropping or excessive impact may cause damage or abnormal measurements, please avoid if possible.
- Do not remove, deface or replace the QR code with another package as this may not result in accurate measurements.



tst biomedical electronics Co., Ltd.

Address: 2F, No. 3, Industrial 2nd Road, Ping-Chen Industrial District,

Taoyuan City 324, Taiwan

Telephone: +886-3-4690038

TAI-SAW TECHNOLOGY CO., LTD.



Address: No.3, 3-1, Industrial 2nd Road, Ping-Chen Industrial District, aoyuan City 324, Taiwan
Telephone: +886-3-4690038