iProtin Lp(a) assay cartridge kit

IVD

Revision date 2025-01, Version 1.5

This product is intended for professional use only

REF BMLPAP0110

[Notice]

- Prior to use, please read this instructions 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.

Intended use

This product is designed to quantify the concentration of lipoprotein(a) ("Lp(a)") in human finger capillary blood in combination with an iProtin reader. This is not a home-use in vitro diagnostic medical device for user self-testing. Doctors, nurse, healthcare professionals can help patient to screen their Lp(a) at clinics for companion diagnostics or public community screening. Lp(a) levels are genetically related lipoprotein, Lp(a) assessment values are considered to be one of feature of coronary artery disease development. The level of Lp(a) cannot be controlled by diet or lifestyle, but screening for diagnosis can help alert individuals at high risk to eliminate or control other high-risk factors as soon as possible.

Assay Methodology

This assay determines Lp(a) in whole blood using an antigen-antibody reaction. Following the collection of a blood sample from the patient's fingertip using a blood collection needle, the blood sample is dropped into the Lp(a) assay cartridge with a quantification dropper and captured by the anti-Lp(a) monoclonal antibody of the SAW detector pre-fixed in the cartridge. Based on the concentration of Lp(a) in whole blood, the elastic surface wave velocity of the SAW detector changes. The change is read by an iProtin reader and the Lp(a) concentration in whole blood can be determined.

Content

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

Required items not contained

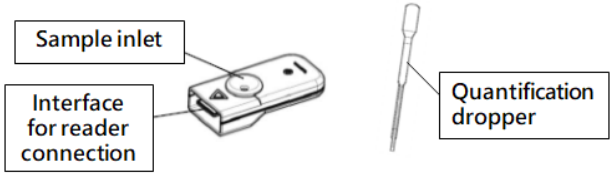
1. iProtin reader
2. Blood collection needle (of a capacity of more than 10 μL of blood)
3. Alcohol swabs

Testing Cartridge Description

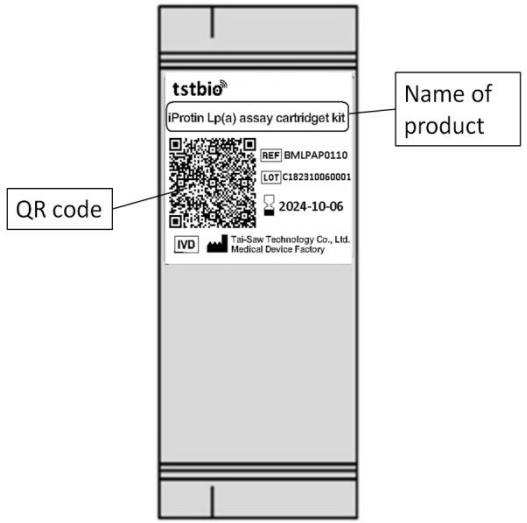
The test cartridge contains a sample inlet, a reagent drying area, and an interface to the iProtin reader. The foil package contains a label with specific information such as lot number and expiration date, as well as a QR-code for assay calibration that can be recognized by the iProtin reader.

Appearance

Testing Cartridge



Aluminum foil bag exterior



Testing Cartridge Reagents

Monoclonal mouse anti-Lp(a) antibody

Goat anti-rabbit IgG

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 temperature: 4-30℃
Transport conditions: 15-60℃; RH 30-85 %
Operating conditions: 20-24℃; 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 from veins containing the anticoagulant Heparin
※ This product is not suitable for blood samples containing EDTA which may lead to inaccurate measurement results.

Operational 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 swabs for disinfection.
- Please read and follow the instructions for blood collection and alcohol swab application.
- If the QR-code is damaged or smeared, scanning for information may fail.

Operation procedure

1. Separate equipment required: iProtin reader, blood collection needle, quantification dropper, alcohol swab
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 iProtin reader and refer to the iProtin reader instruction manual for the QR code on the aluminum foil package to confirm the accuracy of the assay.
   (2) Tear open the aluminum foil package and remove the test cartridge, insert the chip according to the instructions of the iProtin reader.
4. Collecting the sample
   (1) Disinfect the finger to be collected with alcohol swabs and make sure the finger is dry before collecting blood with the blood collection needle.
   (2) Collect 5 μL of whole blood with a quantification dropper.
5. Sample Assay
   (1) Drop the sample into the sample inlet according to the instructions of the iProtin reader.
   (2) After the sample is dropped, the measurement will start automatically and the value will be displayed on the screen of the iProtin reader.
   (3) After completing the measurement, remove the test cartridge and press and hold the power button to turn off the quantitative monitor.
6. When interpreting the test results, the patient's medical history should be carefully considered and no medical measures should be taken without consulting the physician.

Determination of measurement results

Reference normal value (reference range): less than 50 mg/dL (less than 125 nmol/L)

※ Each laboratory should establish its own reference range in accordance with its own good laboratory standards.
※ Unit conversion: 1 mg/dL = 2.5 nmol/L

Product Performance Properties

(1) Linearity range
Lp(a) concentration: 10~140 mg/dL。In accordance with CLSI EP6-A guidelines.

(2) Limit of detection (LoD)
The limit of blank detection (LoB) was 1.45 mg/dL and the limit of minimum detection (LoD) was 5.83 mg/dL. In accordance with CLSI EP17-A guidelines.

(3) Precision
Intra-group reproducibility: 3 whole blood samples were tested 20 times in the same assay in accordance with CLSI EP5-A2 guidelines.

Sample	1	2	3
Avg. concentration (mg/dL)	66.69	42.85	18.68
CV (%)	7.19	4.02	7.66

Inter-group reproducibility: 3 whole blood samples were tested for 20 consecutive days in accordance with CLSI EP5-A2 guidelines.

Sample	1	2	3
Avg. concentration (mg/dL)	71.36	47.43	19.78
CV (%)	7.97	9.51	9.47

(4) Interference

In the following concentrations, no significant interference occurred, within ±10% of the deviation value.

- Hemolysate: 1000 mg/dL
- Bilirubin (conj.): 40 mg/dL
- Bilirubin (unconj.): 40 mg/dL
- Rheumatoid factor:183 IU/mL
- Triglyceride–rich lipoproteins: 800 mg/dL

Quality Management

The calibration reference material used to calibrate this product can be traced back to IFCC SRM-2B standard.

Possible causes of false values

Limitations

- Applicable hematocrit (Hct) range: 25~55%.
- Do not use diluted whole blood samples.
- Avoid using cartridge sets that have exceeded their shelf life.

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.
- When inserting the cartridge into the iProtin reader, insert it straight and firmly until you feel a click.
- Confirm the instructions of the immunoassay 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 t used parts in accordance with the local government or facility's standards (sterilization, disinfection, incineration, etc.) for infectious waste.

Comparison of methodology

This product was compared with "DiaSys Lp(a) 21 FS " Lipoprotein(a) test in accordance with CLSI EP9-A2 guidelines

Whole blood measurement:

	y: iProtin x: DiaSys Lp(a) 21 FS
Sample Size (N)	55
Regression Line	y = 0.9771x + 0.5972
Corr. Coefficient (R)	0.987

Reference

1. Clinical and Laboratory Standards Institute (CLSI). "Evaluation of the linearity of quantitative measurement procedures: a statistical approach; approved guideline." CLSI/NCCLS Document EP6-A 23.16 (2003).
2. Tholen, Daniel W., et al. "Protocols for determination of limits of detection and limits of quantitation; approved guideline." CLSI EP17-A 24 (2004): 34.
3. Tholen, D. W., et al. "Evaluation of precision performance of quantitative measurement methods; approved guideline—second edition. CLSI document EP5-A2." (2004).
4. McEnroe, R. J., et al. "CLSI: EP7-A2. Interference testing in clinical chemistry." (2005).
5. Krouwer, J. S., et al. "Method comparison and bias estimation using patient samples; Approved guideline, NCCLS document EP9-A2, 2002." (2002).

tst biomedical electronics Co., Ltd.
2F, No. 3, Industrial 2nd road, Ping-Chen Industrial District, Taoyuan City 324, Taiwan
+886-3-4690038

TAI-SAW TECHNOLOGY CO., LTD.
No.3, 3-1, Industrial 2nd road, Ping-Chen Industrial District, Taoyuan City 324, Taiwan
+886-3-4690038

EC REP
Emergo Europe B.V.
Address: Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands