MEBEP TECH(HK) Co., Limited
Email: sales@mebep.com Website: www.mebep.com
Tel: +86-755-86134126 WhatsApp/Facebook/Twitter: +86-189-22896756

Human β -amyloid protein 1-40 detection kit (magnetic particle chemiluminescence method)

Product Number: DTK579

Shipping and Storage

1. Unopened reagents, calibration samples, and quality control samples are stored at 2℃ to 8℃ with a validity period of 12 months;
2. After opening the reagent, be careful to store it away from light and avoid contamination. It can be stored for 28 days at 2℃ to 8℃. Calibration and quality control products can be stored in the dark at 2℃ to 8℃ after reconstitution, and can be stored for 28 days.
3. Please place the reagent kit vertically to ensure that the magnetic particles are fully effective during the automatic mixing process before use.
4. The production date and expiration date can be found on the product label.

Component

1. Specification 1:

Reagent	Component	Concentration
Reagent 1 (R1)	Biotin labeled human beta amyloid 1-40 antibody	0.5mg/L
	TRIS buffer solution	100mmol/L
	Preservative	0.1%
Reagent 2 (R2)	Acridine ester labeled human β - amyloid 1-40 antibody	0.5mg/L
	PBS buffer solution	100mmol/L
	Preservative	0.1%
M	Streptomycin coated magnetic particles	
	PBS buffer solution	100mmol/L
	Preservative	0.1%

Calibration standards: recombinant antigen of human β - amyloid protein 1-40, calf serum, preservatives;

Quality control products:recombinant antigen of human β - amyloid protein 1-40, calf serum, preservatives;

Note: The components of different batch numbers of reagent kits cannot be interchanged.

2. Specification 2:

Reagent	Component	Concentration
Magnetic particles (M)	Magnetic particle coated human beta amyloid 1-40 antibody	0.5mg/L
	TRIS buffer solution	100mmol/L
	Preservative	0.1%
Reagent (R)	Acridine ester labeled human β - amyloid 1-40 antibody	0.5mg/L
	PBS buffer solution	100mmol/L
	Preservative	0.1%

Calibration standards: recombinant antigen of human β - amyloid protein 1-40, calf serum, preservatives;

Quality control products: recombinant antigen of human β - amyloid protein 1-40, calf serum, preservatives;

Note: The components of different batch numbers of reagent kits cannot be interchanged.

Calibration and quality control products have batch specificity, and the specific concentration is obtained through the calibration curve card. Traceability of product calibration standards to internal working calibration standards within the enterprise

Required but not provided materials: pre excitation solution, excitation solution, cleaning solution, reaction cup, etc. for fully

automated chemiluminescence immunoassay system.

Testing principle

1. **Specification 1: This reagent kit adopts the sandwich immunoassay direct chemiluminescence test method, and the specific steps are as follows:**
   - 1.1. Incubation: The human beta amyloid 1-40 in the sample specifically binds to biotinylated human beta amyloid 1-40 antibodies and acridine ester labeled human beta amyloid 1-40 antibodies, forming antibody antigen antibody complexes.
   - 1.2. Streptomycin coated magnetic particles bind to immune complexes.
   - 1.3. Wash away unbound substances with instrument cleaning solution.
   - 1.4. Measure the relative luminescence intensity (RLU) by adding pre excitation solution and excitation solution to the reaction complex using an instrument.
   - 1.5. The final detection result is obtained through the calibration curve of the detector, which is generated from the calibration curve obtained through 2-point calibration.
2. **Specification 2: This reagent kit adopts a direct chemiluminescence and timely sandwich immunoassay method. The specific steps are as follows:**
   - 2.1. Incubation: The human beta amyloid protein 1-40 in the sample specifically binds to the magnetic particle coated human beta amyloid protein 1-40 antibody and the acridine ester labeled human beta amyloid protein 1-40 antibody, forming an antibody antigen antibody complex.
   - 2.2. Wash away unbound substances with instrument cleaning solution.
   - 2.3. Measure the relative luminescence intensity (RLU) by adding pre excitation solution and excitation solution to the reaction complex using an instrument.
   - 2.4. The final detection result is obtained through the calibration curve of the detector, which is generated by two-point calibration and the calibration curve obtained from the reagent QR code.

Application

Used to detect the content of human beta amyloid protein 1-40 (A β 1-40) in human serum and plasma, it is mainly used as an auxiliary diagnosis for Alzheimer's disease in clinical practice.

Applicable instruments

Confirmed fully automatic chemiluminescence immunoassay analyzer.

Specimen collection

1. Serum samples collected in standard test tubes or vacuum tubes with separation gel.
2. The human phosphorylated Tau-181 protein sample should be tested immediately after collection, and serum samples can be stable for 2 days at 2℃ to 8℃; If samples need to be stored for a long time, it is recommended to freeze them at -20℃ or below. They can be stored at -20℃ for 1 month to avoid repeated freezing and thawing, and the number of freezing and thawing should not exceed 3 times.
3. If there is sediment in the sample, please centrifuge before testing.
4. The following samples cannot be used: Heat inactivated specimens; Severe hemolysis, high blood lipid samples; Mixed samples; Samples clearly contaminated by microorganisms.
5. Before testing, please ensure that patient samples, calibrators and quality control products are balanced to room temperature (20℃~25℃) to avoid foam.
6. Considering the possible evaporation effect, the samples, calibration samples, and quality control samples on the machine should be measured within 2 hours.

Protocol

1. **Instrument and reagent preparation:**
   1.1. The preparation and maintenance procedures of the instrument should be carried out according to the instrument manual and reagent manual for testing.
   1.2. This reagent is ready to use and should not be used separately.
2. **Before packing the reagent into the machine for the first time, it is necessary to manually invert and mix the magnetic particles to resuspend the precipitated magnetic particles during transportation. Visually inspect the reagent bottle to confirm that the magnetic particles have been resuspended.**
3. **Testing method:**
   3.1. To achieve optimal detection performance, please refer to the guidance provided in this article for the corresponding analyzer. Refer to the corresponding operating manual for specific instrument testing instructions.
   3.2. The analyzer automatically remixes the magnetic particles before use.
   3.3. Place the refrigerated reagent directly in the reagent tray of the analyzer to avoid foam.
4. **Instructions for using calibration and quality control products:**
   4.1. Be careful to open the bottle cap and stopper, and dissolve in the labeled amount of deionized water at room temperature of 20℃ to 25℃.
   4.2. Mix thoroughly.
   4.3. After use, tighten the bottle cap to avoid contamination. Do not pour the used calibration product into the original packaging bottle.

Note: It is recommended to use our company's matching calibration quality control products. For detailed parameter settings, please contact our company.

Result calculation

The analyzer automatically calculates the concentration of the analyte for each sample, and the unit of the test result is pg/mL.

Reference value (reference range)

It is suggested that this project be jointly tested with the A β 1-42 index, and the content ratio of A β 1-42 to A β 1-40 should be interpreted with a cutoff value of 0.15.

This data is for reference only. The levels of A β 1-40 measured may vary depending on different regions, individuals, and methods used for testing. Therefore, we recommend that each laboratory establish its own reference value range.

Interpretation of Inspection Results

1. Each batch should be tested with both normal and abnormal quality control samples along with the tested sample. If the quality control results exceed the standard, confirmation testing must be conducted again.
2. When the measured result of the specimen is higher than 200 pg/mL, the analyzer will display ">200 pg/mL." The specimen should be diluted by a factor and retested. If it is manually diluted, the result of the specimen=measured value after dilution x dilution factor. If it is automatically diluted by the machine, the machine will automatically calculate the result. Below the blank limit, provide a detection result of<5.0 pg/mL.
3. Hook effect: No hook effect occurs when the sample concentration is within 2000 pg/mL.
4. Professional personnel are responsible for reviewing and analyzing the test results, which are usually considered normal within the reference range due to factors such as age, gender, diet, and region. If they exceed the range, they should be retested for confirmation. If the test results are inconsistent or even contradictory to clinical practice, the reasons should be analyzed and identified.
5. There may be deviations between the test results of reagents from different manufacturers, so they should not be compared with each other, which may lead to incorrect medical interpretations.

Limitations of testing methods

1. Anti interference ability: bilirubin ≤ 20mg/dL, hemoglobin ≤ 500mg/dL, triglycerides ≤ 1000mg/dL, biotin ≤ 10ng/mL in the sample have no significant effect on the determination of this reagent.
2. Hook effect: No hook effect occurs when the sample concentration is within 2000pg/mL.

The test results of the reagent kit are for clinical reference only and cannot be used as a basis for confirming or excluding cases. The clinical diagnosis and treatment of patients should be comprehensively considered based on their symptoms/signs, medical history, other laboratory tests, and treatment reactions. To achieve diagnostic purposes, this test result should be combined with clinical examination, medical history, and other examination results.

Product performance indicators

1. Blank limit of reagent: should be ≤ 5.0 pg/mL.
2. Measurement range: Within the linear range of (10.0, 5000.0) pg/mL, the linear correlation coefficient r should be ≥ 0.9900.
3. Precision: The coefficient of variation (CV) within the batch should be ≤ 5.0%; The inter batch variation (CV) should be ≤ 8.0%.
4. Accuracy: Relative deviation should be ≤ 10.0%
5. Calibration accuracy: | En | should be ≤ 1.
6. Uniformity of calibration samples: The uniformity inside the calibration sample bottle should be ≤ 10.0%.
7. The uniformity between calibration bottles should be ≤ 10.0%.
8. Validity of quality control product assignment: The measured value of the quality control product should be within the specified range.
9. Uniformity of quality control products: The coefficient of variation (CV) between bottles should be ≤ 10.0%.

Note

1. The reagent contains chemical reagents. Do not directly contact the mouth, skin, or eyes. If there is contact, please rinse with water; Seek medical attention at the hospital when necessary. During the experimental operation, the experimenters should take protective measures against potential infected samples.
2. This product is only used for in vitro diagnosis. The opened reagents should be stored in a sealed manner according to the specified method.
3. Different batch numbers of reagent components cannot be mixed. When changing the batch number of reagents, please recalibrate.
4. If any of the following situations occur with the reagent, please stop using it: The reagent kit has exceeded its expiration date; Magnetic particles agglomerate; R1 or R2 sends turbidity or precipitation; Do not mix reagents from the same or different reagent kits.
5. Reagents should avoid freezing.
6. This product uses bioactive ingredients and has the potential for infection.
7. This reagent is used together with supporting instruments and is discharged into the medical waste liquid treatment pipelines of each hospital through the instrument's sewage system. The container and accessories of this test kit must not be used for other purposes. Please dispose of any equipment that has come into contact with the reagents and test specimens in accordance with relevant medical waste disposal regulations.

Explanation of identification

Sign	Label annotation
	In vitro diagnostic medical devices
	Batch code

For Research Use Only

	date of manufacture
	period of validity
	Temperature limit