Lecanemab ELISA Kit

Cat. No.: EJ1515725 | Pack size: 48T / 96T | Storage: 2-8 °C

Overview

Lecanemab is a monoclonal antibody drug indicated for the treatment of Alzheimer's disease. It is an anti-amyloid-β antibody administered intravenously to patients with mild cognitive impairment or mild dementia. In clinical trials, it demonstrated moderate efficacy in slowing the relative rate of cognitive decline compared with placebo. As a humanized monoclonal antibody derived from murine parent antibody mAb158, Lecanemab recognizes amyloid-β protofibrils and inhibits amyloid-β deposition in preclinical animal models of Alzheimer's disease.

Assay Principle

This kit adopts the indirect enzyme-linked immunosorbent assay (ELISA) method. Microwells pre-coated with human amyloid-beta antigen are sequentially loaded with samples, standards, and HRP-conjugated secondary antibody, with incubation and washing steps in between. Color development is performed using TMB substrate: TMB turns blue upon catalysis by horseradish peroxidase (HRP), and shifts to final yellow after acid termination. The color intensity is positively correlated with the concentration of Lecanemab in the sample. The absorbance (OD value) is measured at 450 nm using a microplate reader to calculate sample concentration.

Contents & Storage

Storage and Shipping

Item	Specification
Storage	Store at 2-8 °C
Shipped In	Wet ice
Stability and Storage	Store at 2-8 °C long term (6 months)

Check the lot-specific Certificate of Analysis (COA) for exact specifications.

Kit Components

Cat. No.	Component	Appearance	48T	96T	Storage
EJ1515725A	Pre-coated Assay Plate	—	48wells	96wells	2-8 °C
EJ1515725B	Standard	Solid	1vial	2 vials	2-8 °C
EJ1515725C	Universal Diluent	Liquid	1×20mL	2×20mL	2-8 °C
EJ1515725D	HRP-antibody (100×)	Liquid	60µL	120µL	2-8 °C
EJ1515725E	Wash Buffer (20×)	Liquid	1×10mL	2×10mL	2-8 °C
EJ1515725F	TMB Substrate	Liquid	5mL	10mL	2-8 °C
EJ1515725G	Stop Solution	Liquid	3mL	6mL	2-8 °C
EJ1515725H	Plate Sealer	—	4 pieces	4 pieces	2-8 °C

Note: EJ1515725B, EJ1515725D, EJ1515725E shall be diluted in accordance with the instructions.

Precautions

1. Strictly follow the specified incubation time and temperature to guarantee accurate results. All reagents must be equilibrated to room temperature (20–25°C) before use. Refrigerate reagents immediately after use.
2. Improper plate washing may lead to inaccurate readings. Ensure complete removal of residual liquid in wells prior to substrate addition. Avoid prolonged drying of microwells throughout the procedure.
3. Wipe residual liquid and fingerprints from the bottom of the microplate, as contaminants will interfere with OD values.
4. The TMB substrate solution shall remain colorless; discard substrate solution that has turned blue.
5. Prevent cross-contamination between reagents and samples to avoid erroneous test results.
6. Avoid direct intense light exposure during reagent storage and incubation.
7. All reaction reagents must not come into contact with bleach solvents or their volatile fumes; bleach components will destroy the biological activity of kit reagents.
8. Do not use expired products; components from different lot numbers or batch codes cannot be mixed.
9. Recombinant proteins from external sources may fail to be recognized due to mismatched antibody affinity with kit capture antibodies.
10. Handle all potentially infectious samples properly, and dispose of specimens and testing devices in accordance with standardized biosafety protocols.

Sample Pretreatment and Requirements

1. The kit's detectable concentration range does not equal the analyte concentration range in raw samples. It is recommended to estimate sample concentrations via published literature and conduct pre-tests to confirm actual analyte levels. Dilute or concentrate samples appropriately if analyte concentrations fall outside the linear range.
2. If your sample matrix is not listed in this manual, perform a pre-test to verify assay compatibility.
3. Serum: Collect whole blood in serum separation tubes, incubate at room temperature for 2 hours or store overnight at 2–8°C, then centrifuge at 1000×g for 20 minutes. Collect the supernatant for immediate testing, or aliquot and store at -20°C / -80°C; avoid repeated freeze-thaw cycles.
4. Plasma: Collect blood using EDTA or heparin anticoagulant. Centrifuge specimens within 30 minutes post-collection at 1000×g, 2–8°C for 15 minutes. Harvest supernatant for immediate testing, or store at -20°C / -80°C; avoid repeated freeze-thaw cycles.
5. Tissue Homogenate: Rinse tissue with pre-cooled PBS (0.01 M, pH=7.4) to remove residual blood (lysed erythrocytes in homogenate interfere with detection). Weigh and mince tissue, then mix tissue with PBS at a standard weight-to-volume ratio of 1:9 (e.g., 1 g tissue in 9 mL PBS; adjust volume as needed and record details). Protease inhibitor cocktail is recommended for PBS. Transfer the mixture to a glass homogenizer and grind thoroughly on ice, or use a mechanical homogenizer. For complete cell lysis, sonicate the homogenate or perform repeated freeze-thaw cycles. Centrifuge the homogenate at 5000×g for 5–10 minutes and collect supernatant for testing.
6. Cell Culture Supernatant: Centrifuge culture media at 1000×g for 20 minutes, collect supernatant for immediate testing, or store at -20°C / -80°C; avoid repeated freeze-thaw cycles.
7. Cell Lysate: For adherent cells, wash gently with pre-cooled PBS, digest with trypsin, then harvest cells via centrifugation at 1000×g for 5 minutes. Suspension cells can be pelleted directly by centrifugation. Wash harvested cells 3 times with pre-cooled PBS, resuspend 1×10^6 cells in 150–200 µL PBS (protease inhibitors recommended; reduce PBS volume for low-abundance analytes). Lyse cells via repeated freeze-thaw or sonication. Centrifuge lysate at 1500×g, 2–8°C for 10 minutes and retain supernatant.
8. Other Biological Matrices: Centrifuge samples at 1000×g for 20 minutes and collect supernatant for testing.
9. Sample Appearance: Samples must be clear and transparent; all suspended particulates must be removed by centrifugation.
10. Sample Storage: Samples to be tested within 1 week can be stored at 4°C. For delayed testing, aliquot samples into single-use volumes and freeze at -20°C (stable for 1 month) or -80°C (stable for 6 months). Avoid repeated freeze-thaw cycles. Hemolyzed samples are unsuitable for this assay, as hemolysis distorts final readings.

Sample Dilution Protocol

Estimate analyte concentration in advance. Follow the dilution schemes below if sample dilution is required:

100-fold dilution (single step): Mix 5 µL sample with 495 µL Assay Diluent.

1000-fold dilution (two-step): Step 1: Dilute 5 µL sample into 95 µL diluent (20×). Step 2: Transfer 5 µL of the 20× diluted sample into 245 µL diluent (50×), achieving total 1000-fold dilution.

100000-fold dilution (three-step): Step 1: Mix 5 µL sample with 195 µL diluent (40×). Step 2: Transfer 5 µL 40× sample into 245 µL diluent (50×). Step 3: Transfer 5 µL 2000× sample into 245 µL diluent (50×), total dilution factor = 100000×.

Guidelines for dilution: Transfer volume per step ≥ 3 µL; single-step dilution factor ≤ 100×. Mix thoroughly after each dilution and avoid bubble formation.

Required Lab Equipment (User-Supplied)

1. Microplate reader (capable of 450 nm absorbance measurement).
2. High-precision pipettes and matching tips: 0.5–10 µL, 5–50 µL, 20–200 µL, 200–1000 µL.
3. 37°C incubator.
4. Distilled or deionized water.

Pre-Assay Reagent Preparation

1. Remove kit from refrigeration 10 minutes in advance and equilibrate to room temperature.
2. Serial Standard Working Solution Preparation: Reconstitute lyophilized standard with 1 mL Assay Diluent, incubate 15 minutes for full dissolution, then mix gently (stock concentration = 10 ng/mL). Prepare serial standards at concentrations: 10, 5, 2.5, 1.25, 0.625, 0.312, 0.156, 0 ng/mL. Serial dilution method: Prepare 7 EP tubes pre-filled with 500 µL Assay Diluent each. Transfer 500 µL 10 ng/mL standard into the first tube to make 5 ng/mL solution, then serially transfer 500 µL to each subsequent tube for gradient dilution. The final tube (0 ng/mL) serves as blank control with no standard added.

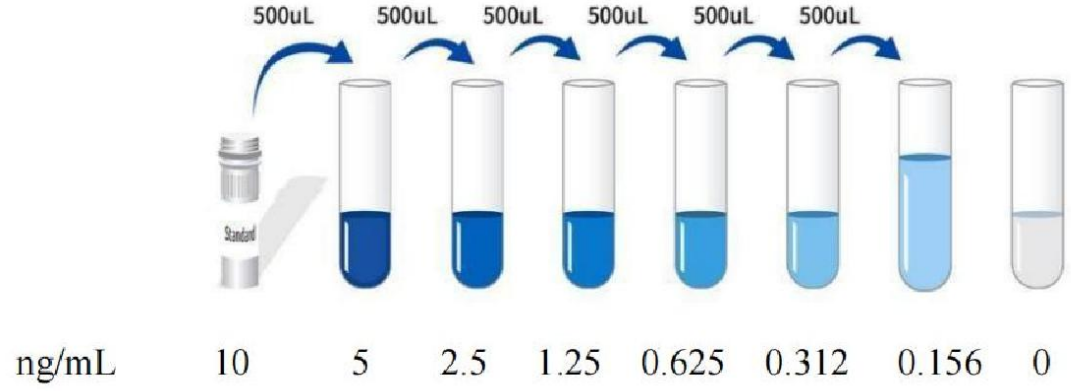

Figure 1. Serial dilution of the Lecanemab standard.

3. HRP-antibody Working Solution: Centrifuge 100× HRP-antibody at 1000×g for 1 minute 15 minutes before use. Dilute to 1× working concentration with Assay Diluent (example: 10 µL concentrate + 990 µL diluent). Prepare fresh right before use.

4. 1× Wash Buffer Dilution: Mix 10 mL 20× concentrated Wash Buffer with 190 mL distilled water. Crystallization of concentrated wash buffer upon refrigeration is normal; fully dissolve all crystals at room temperature before dilution.

Assay Procedure

1. Take required microplate strips from the aluminum foil pouch equilibrated at room temperature for 10 minutes. Seal unused strips in a zip bag and store at 4°C.
2. Sample Loading: Add 100 µL sample or serially diluted standard to respective wells; add 100 µL Assay Diluent to blank wells. Seal plate with sealing film and incubate at 37°C for 60 minutes. Recommendation: Dilute all test samples at minimum 1× with Assay Diluent before loading to reduce matrix interference. Multiply final calculated concentration by the dilution factor. Prepare technical replicates for all samples and standards.
3. Plate Washing: Discard liquid from wells, add 300 µL 1× Wash Buffer per well, incubate 1 minute, flick out buffer and tap plate dry on absorbent paper. Repeat wash cycle 3 times (automated plate washer is acceptable).
4. HRP-antibody Addition: Dispense 100 µL diluted HRP-antibody to each well, seal plate and incubate at 37°C for 30 minutes.
5. Plate Washing: Discard liquid, add 300 µL 1× Wash Buffer per well, incubate 1 minute, flick buffer and tap dry. Repeat wash cycle 5 times (automated plate washer is acceptable).
6. Substrate Development: Add 90 µL TMB substrate to each well, seal plate and incubate at 37°C protected from light for 15 minutes.
7. Reaction Termination & Reading: Remove microplate, add 50 µL Stop Solution to every well immediately, then measure absorbance (OD value) at 450 nm without delay.

Calculation of Assay Results

Data Analysis

1. Calculate the average OD value of replicate wells for standards and samples, subtract blank well OD to obtain corrected absorbance values. Plot a four-parameter logistic standard curve on a log-log graph with concentration as the X-axis and corrected OD as the Y-axis.
2. If sample OD exceeds the upper limit of the standard curve, dilute the sample appropriately and re-test; multiply the calculated concentration by the corresponding dilution factor for final reporting.

Reference Standard Curve Raw Data (For Reference Only)

Concentration (ng/mL)	10	5	2.5	1.25	0.625	0.312	0.156	0
Raw OD Value	2.42	1.55	0.88	0.49	0.29	0.19	0.14	0.07
Corrected OD Value	2.35	1.48	0.81	0.42	0.22	0.12	0.07	—

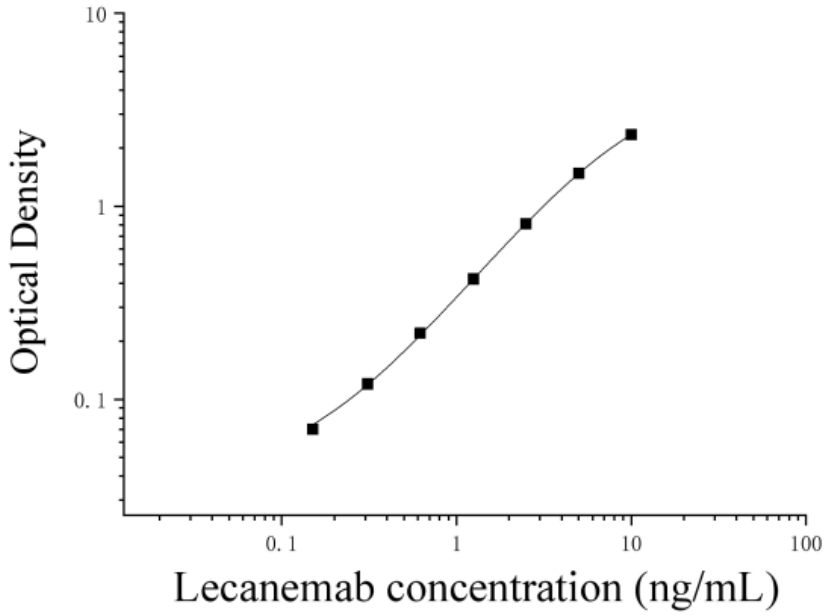

Figure 2. Reference standard curve for Lecanemab ELISA.

Note: Figure 2 is for reference only; sample concentration shall be calculated based on the standard curve generated from experimental data of each individual test run.

Kit Performance Specifications

1. Precision: Intra-assay coefficient of variation (CV) < 10%; inter-assay CV < 10%.
2. Spike Recovery: Three concentration levels of human Lecanemab were spiked into healthy human serum, plasma and cell culture supernatant to calculate recovery rates.

Sample Type	Recovery Range (%)	Mean Recovery (%)
Serum (n=8)	84–109	90
Plasma (n=8)	88–108	96
Cell Culture Supernatant (n=8)	95–111	99

3. Linearity upon Serial Dilution: High-concentration human Lecanemab was spiked into 4 individual batches of serum, plasma and cell culture supernatant, serially diluted within the standard curve dynamic range to assess linearity.

Dilution Ratio	Recovery (%)	Serum	Plasma	Cell Culture Supernatant
1:2	Range	84–98	88–99	90–112
1:2	Mean Recovery	91	92	95
1:4	Range	89–103	87–109	102–115
1:4	Mean Recovery	96	94	106

Troubleshooting Guide

If unsatisfactory assay results occur, take photos of color development, save experimental data, retain used microplate strips and unused reagents, then contact our technical support for troubleshooting. Refer to the troubleshooting items below:

1. Poor standard curve linearity

① Incorrect standard dilution: Reconstitute and dilute standard strictly following recommended protocol.
② Inaccurate pipetting: Calibrate pipettes regularly and verify tip tightness/sealing performance.
③ Evaporation of reaction solution: Seal microplate with plate sealer film.
④ Incomplete washing: Perform sufficient wash cycles with adequate volume of wash buffer.
⑤ Foreign residues at well bottom: Wipe microplate bottom prior to absorbance measurement.

2. Faint or absent color development

① Insufficient incubation duration: Adhere to specified incubation time.
② Incorrect incubation temperature: Incubate at recommended temperature.
③ Insufficient reagent addition volume: Verify pipette accuracy and follow operating procedure strictly.
④ Improper reagent dilution: Double-check dilution steps for all reagents.
⑤ Inactivated enzyme conjugate: Mix enzyme conjugate with substrate and verify activity via color reaction test.

3. Low OD readings

① Wrong microplate reader parameter: Confirm detection wavelength setting on instrument.
② Missing stop solution addition: Add appropriate volume of stop solution.
③ Overlong delay before plate reading: Measure absorbance immediately after termination.
④ Excessively high analyte concentration in sample: Determine optimal dilution factor via preliminary pre-test.
⑤ Too low analyte concentration in sample: Determine optimal dilution factor via preliminary pre-test.

6. High background signal

① Contaminated TMB substrate: Replace with fresh substrate solution.
② Excess substrate incubation time: Strictly control color development duration.
③ Wrong dilution for detection antibody or enzyme conjugate: Dilute reagents in accordance with official recommended protocol.
④ Incomplete plate washing: Carry out adequate wash cycles with sufficient wash buffer volume.

Recommended Applications

This kit is intended for quantitative measurement of Lecanemab in research samples, including serum, plasma, cell culture supernatant, tissue homogenate, cell lysate, and other biological matrices validated by the user.

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Whether you have a technical question, need help with a quotation, or want to inquire about an order, our regional teams are ready to assist. Please contact the office for your region; for general inquiries, the North American office is the corporate primary.

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Limitations & Disclaimer

- For Research Use Only (RUO). Not for use in human or animal diagnostics, therapeutics, or in vivo applications. Not for food, cosmetic, or household use.
- This product is not a CE-marked in vitro diagnostic device under IVDR (EU) 2017/746 and is not an FDA-cleared device under 21 CFR. Use is restricted to verified businesses, institutions, and qualified professionals for research and development purposes.
- Where any kit component is classified as hazardous under CLP (EC) 1272/2008 or OSHA HCS (29 CFR 1910.1200), the product Safety Data Sheet (SDS) takes precedence over this document for handling, storage, and disposal information.
- Performance depends on sample type, sample condition, handling, and operator technique. Users are responsible for validating the kit for their specific application.

- Aladdin product labels, SDS, COA, and approved specifications take precedence over this document. If product formulation, label, SDS, storage conditions, pack size, or quality specifications change, this document must be reviewed and reissued.