Bowei-biotech
for better bioassays

Olanzapine ELISA

For Research Use Only
Cat. No.: BW-Olanzapine ELISA

1. Introduction

Olanzapine (OLA; 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b] [1,5] benzodiazepine) is an atypical antipsychotic drug commonly prescribed treatment of schizophrenia, mania, and related agitation. OLZ has a lower risk of extrapyramidal symptoms and hyperprolactinemia compared with other antipsychotics. However, OLZ exhibits high pharmacokinetic variability because of the clinical and genetic factors; several non-genetic factors, such as age, gender, smoking, co-medication or disease states, also influence OLZ levels [1, 2, 3, 4, 5]. Under the recommended doses, the plasma OLZ concentration exhibits inter-individual variations of up to 25-folds. Toxicity can be induced when the OLZ level is higher than 100 ng/mL [6]. To ensure therapeutic effectiveness and minimize the side effects, TDM of OLZ is recommended for individualizing the dosage for patients with schizophrenia. The AGNP guidelines recommend the reference range for plasma OLZ levels as 20 to 80ng/mL and an alert level at 100ng/mL [6, 7].

This Olanzapine ELISA is designed for rapid and convenient monitoring of Olanzapine levels in serum or plasma samples.

2. Principle of the Assay

The Olanzapine ELISA adopts a typical competitive immunoassay principle.

Olanzapine in samples, calibrators, and controls competes with a Olanzapine analogue pre-coated on microplate wells for binding a limited number of anti-Olanzapine monoclonal antibodies. Unbound components are removed by washing. Horseradish peroxidase (HRP)-conjugated secondary antibody is added to trace the bound primary antibody. After a final wash, TMB substrate is added to initiate a color reaction. The absorbance intensity is inversely proportional to the concentration of Olanzapine in the sample. A calibration curve is established using calibrators to calculate the Olanzapine concentration in unknown samples.

3. Package Contents

Kit contents are sufficient for 96 tests (8×12 wells).
Expiry date is labeled on the outer box.

Components	Specification	Description
① Olanzapine Coated Plate	8×12 wells, detachable	Microwells pre-coated with Olanzapine analogue
② Primary Antibody	1 bottle (0.5mL, 25×)	Monoclonal antibody against Olanzapine
③ Assay Buffer	1 bottle (30mL)	PBS buffer containing BSA and Tween-20
④ Secondary Antibody	1 bottle (0.5mL, 25×)	Sheep anti-mouse IgG-HRP conjugate
⑤ TMB Chromogenic Substrate	1 bottle (15mL)	Single-component TMB for color development
⑥ Wash Buffer	2 bottles (25mL/bottle, 10×)	0.05% Tween-20 in PBS
⑦ Stop Solution	1 bottle (15mL)	1 M Citric acid solution
⑧ Olanzapine Calibrators	6 vials (1mL each)	0, 100, 250, 500, 1000, 2000ng/mL

4. Kit Storage and Stability

1) Store the entire kit at 2–8°C.
2) Unused plate strips must be kept in the aluminum foil bag with desiccant; keep sealed and dry.
3) Shelf life: 12 months from production.
4) Use opened reagents and plate strips within 3 months.

5. Equipment and Materials Required but not Provided

1) Single- channel micropipettes (10–100µL) and disposable tips
2) 8/12- channel micropipette (50–200µL)
3) Orbital microplate shaker
4) Microplate reader (detection wavelength: 450nm)
5) Distilled or deionized water
6) Microplate washer (optional)

6. Sample Collection and Storage

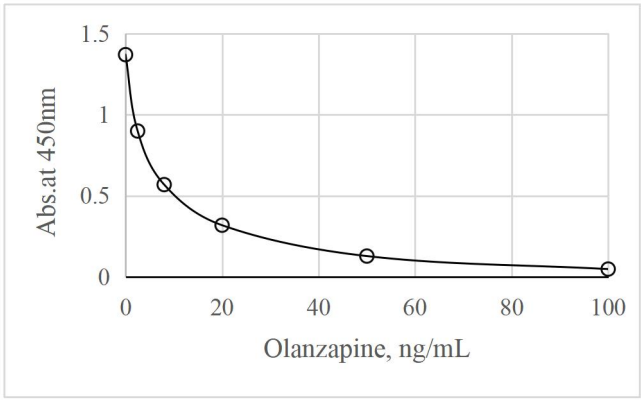
1) The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) The samples can be stored at 2 -8°C up to two weeks with < 5% reduction in concentration. For a longer storage (> 3 months) the samples need to be frozen at -20 ~ -80°C. Repeated freezing and thawing should be avoided.
4) Hemolytic, lipemic and icteric specimens should not be used.
5) Handle all patient samples as if they were potentially infectious.

7. Experimental Procedure

1) Separate the strips to be used by cutting through the protective tape with a sharp knife and transfer them to a strip frame. Pull off the protective tape from the strips intended for use. Return the remaining strips to the plastic tray pack and reseal.
2) According to the number of samples to be tested, add the Primary Antibody to the required volume of Assay Buffer at a ratio of 1:25, and mix thoroughly. This should be done within 60 minutes before use.
3) Pipette 25µL of the Olanzapine calibrators and samples into the bottom of each well.
4) Add 75µL of diluted Primary Antibody solution to each well, incubate the frame for 90 minutes at room temperature on an orbital shaker at medium speed.
5) Discard or aspirate the contents of the wells and wash thoroughly with 300µl wash buffer diluted 10 times with distilled water, remove residual liquid by tapping the inverted plate on a clean absorbent paper. Repeat this 3 times. Preferably, a Microplate Washer may be used.
6) Within 60 minutes before use, prepare the needed volume of Secondary Antibody solution by mixing 1.5mL Assay Buffer with 60µL Secondary Antibody stock solution (25×) per strip.
7) Dispense 100µL of diluted Secondary Antibody solution into each well and incubate the frame for 60 minutes at room temperature on an orbital shaker at medium speed.
8) After incubation, wash the wells as in step 7-5). Ensure no residual wash buffer remains.
9) Dispense 100µL of Chromogenic Substrate solution into each well, and mix thoroughly. Incubate for 20 minutes at room temperature with slow shaking.
10) Add 100µL of Stop Solution into each well. Shake for at least 10 seconds on an orbital shaker.
11) Quantitation. Read the optical density at 450nm in a microplate photometer within 10 minutes. Plot absorbance vs. calibrator concentration to construct the Olanzapine calibrator curve. When using analyzing software, it is recommended to use the Four Parameter Logistic (4PL) Regression. The concentration of the controls and samples in ng/ml can be read directly from this calibration curve by using their average optical density.

8. Performance Characteristics

1) The typical standard curve for the Olanzapine-ELISA is shown below.



2) Analytical sensitivity. The analytical sensitivity of the Olanzapine-ELISA is typically better than 2ng/mL, defined as the mean of the measurement values for the zero calibrator minus 2 standard deviations (mean value - 2SD).
3) Recovery. Spiked serum samples were prepared by adding varying levels of Olanzapine to pooled serum specimens containing a known amount of Olanzapine. Recoveries were in the range of 92- 102% with a mean value of 95.2% (n=15).
4) The cross reactivities (at the 50% displacement level) with the major metabolites of Olanzapine were listed below.

Substance	Cross Reactivity (%)
Olanzapine	100
Olanzapine-10-N-glucuronide	< 0.29%
Olanzapine 4′-N-glucuronide	< 0.01%
N-desmethyl olanzapine	< 0.55%

5) Intra- assay precision: ≤ 10%, Inter- assay precision: ≤ 15%.
6) The range of measurement: 0.1- 10ng/mL.

9. Notes

1) This kit is for research use only, not for human diagnostic or therapeutic procedures.
2) Avoid repeated freezing and thawing of reagents.
3) Protect TMB substrate from light and avoid contact with metal ions.
4) Strictly follow incubation time and temperature to ensure reproducibility.
5) If the OD value of the sample exceeds the range of the calibration curve, the sample needs to be diluted with the zero-concentration calibrator for detection to ensure that the result is within the linear range.

10. References

1) Nicolas Ansermot, Harish Vathanarasa, Setareh Ranjbar, et al. Therapeutic Drug Monitoring of Olanzapine: Effects of Clinical Factors on Plasma Concentrations in Psychiatric Patients. Ther Drug Monit. 2024, 46, 828–836.
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4) Skogh E, Reis M, Dahl ML, Lundmark J, Bengtsson F. Therapeutic drug monitoring data on olanzapine and its N-demethyl metabolite in the naturalistic clinical setting. Ther Drug Monit 2002;24:518-526.
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