BOWEI-BIOTECH
for better bioassays

Immunoassays

Shanghai Bowei Biotechnology

Immunoassays

Intrduction

- Abundant small molecules in human and animal bodies exert critical regulatory functions throughout different physiological processes. Such small molecules can act as biomarkers to reflect diverse physiological and pathological conditions, as well as therapeutic outcomes of pharmaceutical interventions. Relatively, small-molecule drugs represent the most diversified class of clinical therapeutics available today. For a subset of these drugs, accurate quantification of their concentrations in bodily fluids is necessary to balance therapeutic efficacy and toxic side effects. Also, small-molecule contaminants are the primary pollutants found in food and environmental matrices. Sensitive and accurate detection of these compounds is essential to safeguard environmental and food safety. Although various techniques exist for determination of these small molecules, immunoassay delivers a promising, universally applicable alternative for sensitive, convenient testing of these targets.
- Bowei-Bio has focused on R&D of immune-analysis of small-molecules more than thirty years. Through long-term technical accumulation and iterative process upgrades, we have built a full-fledged technical workflow covering the design of haptens, generation of anti-small molecule antibodies, and the development of immunoassay for small-molecule analysis. Leveraging our self-developed library of anti-small-molecule antibodies and antigens, we have selected a range of small molecules as targets to develop immunoassay reagents which have definite application value but are rare in current market, in order to address some of the currently unmet clinical challenges, and provide tools for clinical researches, biomedicine discoveries, food and environmental monitoring, TDM, drug abuse screening, and other applications.
- The highly specific binding between antibodies and antigens is a natural molecular recognition system shaped by the long-term evolution of living organisms. This marvelous recognition system will be explored and utilized continually by humans to drive the advancement of related fields.

ELISA Series

Cat. No.	Analytes	Linear Range	Pack Size	Storage
BW-8-OHdG ELISA	8-Hydroxy-2'-Deoxyguanosine (8-OHdG)	0.2~5.0 ng/ml	96 T/Kit	2-8℃
BW-ADMA ELISA	Asymmetric Dimethylarginine	100~1600 ng/mL	96 T/Kit	2-8℃
BW-Busulfan ELISA	Busulfan	0.1~10 ng/mL	96 T/Kit	2-8℃
BW-E1S ELISA	Estrone-3-Sulfate	0.1~10 ng/mL	96 T/Kit	2-8℃
BW-LEV ELISA	Levetiracetam	2~100 μg/mL	96 T/Kit	2-8℃
BW-Olanzapine ELISA	Olanzapine	0.1~10 ng/mL	96 T/Kit	2-8℃
BW-SDMA ELISA	Symmetric Dimethylarginine	100~1600 ng/mL	96 T/Kit	2-8℃
BW-Venetoclax ELISA	Venetoclax	0.1~5 μg/mL	96 T/Kit	2-8℃

PETIA Series

Cat. No.	Analytes	Linear Range	Pack Size	Storage
BW-Polymyxin-B PETIA	Polymyxin-B	0~8.00μg/mL	100 T/Kit	2-8℃
BW-Busulfan PETIA	Busulfan	0~5000ng/mL	100 T/Kit	2-8℃
BW-Olanzapine PETIA	Olanzapine	0.1~10ng/mL	100 T/Kit	2-8℃

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8-OHdG ELISA

For Research Use Only
Cat. No.: BW-8-OHdG ELISA

1. Introduction

Reactive oxygen species play an important role in different kinds of DNA damages, which is known to contribute to age-related degenerative processes and diseases. Among the identified oxidative DNA damage products, 8-oxo-7,8-dihydro-2'-deoxyguanosine (8-OHdG) is one of the predominant forms of oxidative DNA lesion. 8-OHdG is produced by hydroxyl radical attack at the C-8 position of DNA guanine followed by a one-electron oxidation. Determination of 8-oxodG level has been cited as a preferential non-invasive biomarker of DNA damage induced by oxidative stress, and used to determine the overall effects of oxidative stress, to assess the risk, diagnose, and evaluate the treatment of autoimmune, inflammatory, neurodegenerative and cardiovascular diseases, diabetes, cancer and other age-related diseases [1, 2, 3].

This kit is used for sensitive and specific determination of 8-OHdG levels in biological samples.

2. Principle of the Assay

The principle of the 8-OHdG ELISA follows the typical competitive immunoassay principle.

Competition reaction occurs between the 8-OHdG coated on microwell surface and the 8-OHdG present in calibrators, controls and samples for binding a limited number of anti-8OHdG monoclonal antibody. The washing procedures remove unbound antibodies. After the washing, a sheep anti-mouse antibody-HRP conjugate is added for tracing the bound anti-8OHdG monoclonal antibody. After another washing, the bound enzyme conjugate is detected by the addition of a substrate that generates color by HRP. The intensity of the color formed is inversely proportional to the concentration of 8-OHdG in the sample. A set of calibrators is used to plot a calibrator curve from which the concentration of 8-OHdG in samples and controls can be directly read.

3. Package Components

Each 8-OHdG ELISA package contains reagents for 96 assays.
The expiry date of the complete package is stated on the outer label.

Components	Specification	Description
① Reaction Plate	8×12 wells, detachable	8-OHdG coated plate
② Primary Antibody	0.5ml, 25×	Monoclonal antibody
③ Assay Buffer	30ml	Phosphate Buffered Saline with BSA and Tween-20
④ Secondary Antibody	0.5ml, 25×	HRP-labeled sheep anti-mouse antibody
⑤ Chromogenic Substrate	15ml	TMB substrate used for color development
⑥ Wash Buffer	25ml, 10×	0.05% Tween-20/Phosphate Buffered Saline
⑦Reaction Stop Solution	15ml	1M Citric acid solution
⑧8-OHdG calibrators	6 vials (1ml each)	0, 0.2, 0.5, 1.25, 2.5, 5ng/ml

4. Storage and Shelf Life

- Store in a refrigerator (2~8℃). Desiccant bag must remain in foil pouch with unused strips. Keep pouch sealed when not in use to maintain a dry environment. Remove excess air before sealing.
- 12 months after production (use within 2 months after opening the reaction plate and reagent bottles/vials).

5. Equipment and Materials Required but not Provided

- 100µl micropipette and tips: For dispensing reagents and samples
- 12-channel micropipette and tips (50~200µl): For dispensing reagents
- 12-channel micropipette tray: For reagent dispensing
- Orbital shaker
- Microplate washer (optional)
- Microplate reader (measurement wavelength 450nm): For absorbance measurement
- Distilled water: For preparing wash buffer

5. Sample Collection and Storage

5.1 The test can be performed with serum as well as with urine as samples. The applicability for analyzing specimens other than serum or urine remains to be verified.

5.2 Urine Samples: If turbidity or precipitates are observed, centrifuge at 2000~5000g for 10 minutes to obtain the supernatant as sample.

5.3 Serum Samples: Separate the serum as soon as possible after blood collection. To remove the influence of high-molecular-weight components in the serum, perform filtration using an ultrafiltration membrane with a molecular weight cutoff of 10,000.

5.4 Hemolytic, lipemic and icteric specimens should not be used.

6. Experimental Procedure

6.1 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.)

6.2 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.

6.3 Pipette 50µL of the 8-OHdG calibrator (0.125, 0.25, 0.5, 1, 4, 10ng/mL) and samples into the bottom of each well.

6.4 Add 50µL of Primary Antibody solution to each well, incubate the frame for 90 minutes at room temperature on an orbital shaker at medium speed.

6.5 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. Alternatively, a washing device may be used.

6.6 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.

6.7 Dispense 100µL of Secondary Antibody solution into each well and incubate the frame for 60 minutes at room temperature on an orbital shaker at medium speed.

6.8 After incubation, wash the wells as in step 5.5. Ensure no residual wash buffer remains.

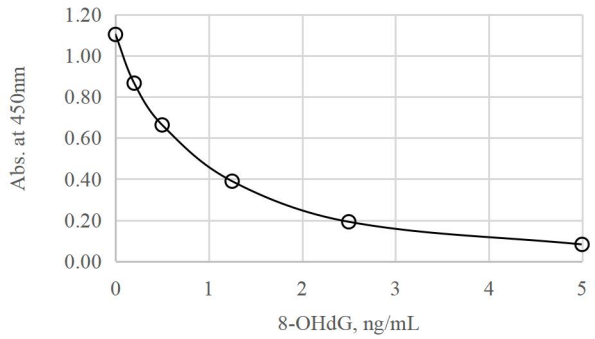
6.9 Dispense 100µL of Chromogenic Substrate solution into each well, and mix thoroughly. Incubate for 20 minutes at room temperature with slow shaking.

6.10 Add 100µL of Stop Solution into each well. Shake for at least 10 seconds on an orbital shaker.

6.11 Quantitation. Read the optical density at 450nm in a microplate photometer within 10 minutes. Plot absorbance vs. calibrator concentration to construct the 8-OHdG calibrator curve. When using analyzing software, it is recommended to use the Four Parameter Logistic (4PL) Regression (alternatively: cubic-spline or logit-log). The concentration of the controls and samples in ng/ml can be read directly from this calibration curve by using their average optical density.

7. Assay Characteristics

7.1 The typical calibration curve for the 8-OHdG ELISA is shown below.



7.2 Analytical sensitivity. The analytical sensitivity of the 8-OHdG ELISA is typically better than 0.079ng/mL (79pg/mL), if defined as the mean of the measurement values for the zero calibrator minus 2 standard deviations (mean value - 2SD).

7.3 Recovery. Spiked serum samples were prepared by adding varying levels of 8-OHdG to pooled serum specimens containing a known amount of 8-OHdG. Recoveries were in the range of 92 - 107% with a mean value of 102.2% (n=15).

7.4 Cross reactivity (at the 50% displacement level):

Substance	Cross Reactivity (%)
8-OHdG (8-oxodG)	100
8-OHG	0.12%
Guanosine	<0.01%
Uracil	<0.01%
Thymine	<0.01%
Guanine	<0.01%
Creatinine	<0.01%

7.5 Intra-assay Precision: ≤ 10%, Inter-assay Precision: ≤ 15%.

7.6 The range of measurement: 0.2 - 5.0ng/mL.

8. References

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Direct Asymmetric Dimethylarginine (ADMA) ELISA

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

1. Introduction

Asymmetric dimethylarginine (ADMA) is produced during the process of protein turnover and is actively degraded by the intracellular enzyme, dimethylarginine dimethylaminohydrolase (DDAH) [1, 2, 3, 4]. ADMA is an endogenous inhibitor of all forms of nitric oxide synthase (NOS), acting by displacement of the physiological substrate, L-arginine, from the enzyme. This inhibition leads to decreased NO production in the endothelium of vessel walls. Growing evidence indicates that circulating ADMA concentrations correlate with carotid intima-media thickness in the general healthy population [5], an elevated ADMA plasma level can be used as a strong predictor for cardiovascular disease, and also closely associates with other disorders characterized by impairment of the endothelial L-arginine–NO pathway and endothelial dysfunction, including atherosclerosis, hypercholesterolemia, diabetes mellitus, chronic kidney disease, and hypertension [6, 7, 8].

This kit is used for direct quantification of ADMA concentrations in biological samples without the need for ADMA derivatization required by other current immunoassays [9, 10, 11].

2. Principle of the Assay

The ADMA ELISA adopts a typical competitive immunoassay principle.

ADMA present in samples, calibrators, and controls competes with ADMA coated on the microplate wells for binding a limited number of anti-ADMA 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 ADMA concentration in the sample. A calibration curve is established using calibrators to calculate the ADMA concentrations 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 ADMA Coated Plate	8×12 wells, detachable	Microwells pre-coated with ADMA antigen
② Primary Antibody	1 bottle (0.3mL, 25×)	Monoclonal antibody against ADMA
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 ADMA Calibrators	6 vials (1mL each)	0, 100, 200, 400, 800, 1600ng/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

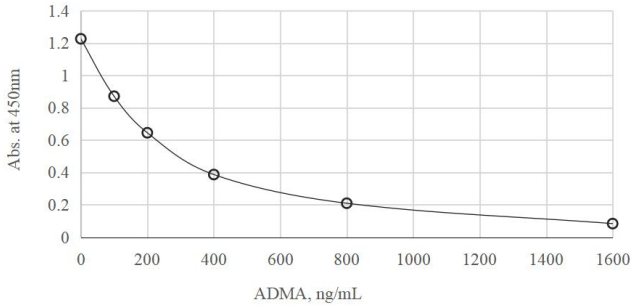
1) The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) The samples can be stored up to 12 hours at 2 - 8°C. For a longer storage (up to 18 months) the samples need to be frozen at -20°C. Repeated freezing and thawing should be avoided.
4) Hemolytic, lipemic and icteric specimens should not be used.

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 50µL of the ADMA calibrators (0, 0.1, 0.25, 0.5, 1.0, 2.0µg/mL) and samples into the bottom of each well.
4) Add 50µL 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 300 µl 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 ADMA 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.

7. Performance Characteristics

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



2) Analytical sensitivity. The analytical sensitivity of the ADMA ELISA is typically better than 15ng/mL, if 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 ADMA to pooled serum specimens containing a known amount of ADMA. Recoveries were in the range of 93 - 115% with a mean value of 103.9% (n=15).
4) Cross reactivity (at the 50% displacement level)

Substance	Cross Reactivity (%)
ADMA	100
SDMA	0.06%
N^G-Monomethyl-L-arginine (MMA)	0.52%
Homoarginine	<0.01%
Creatinine	<0.01%
Arginine	<0.01%

5) Intra-assay Precision: ≤ 10%, Inter-assay Precision: ≤ 15%.
6) The range of measurement: 100 - 1600ng/mL.

8. 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.

9. References

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Busulfan ELISA

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

1. Introduction

Busulfan is a commonly used alkylating agent in conditioning regimens before hematopoietic stem cell transplantation (HSCT) and for the treatment of myeloproliferative neoplasms [1].

Busulfan has a narrow therapeutic exposure window, which varies with disease type and graft sources. Elevated blood busulfan concentrations are proven to raise the risk of severe hepatic veno-occlusive disease, an intractable condition with no effective treatment. By contrast, suboptimal low busulfan levels are linked to the relapse of chronic myeloid leukemia, and further reduced exposure may lead to graft rejection. Therapeutic drug monitoring (TDM) of busulfan is therefore essential for balancing therapeutic efficacy and adverse toxicity, thereby enhances the success rates of HSCT and improves clinical patient outcomes. A therapeutic range for busulfan in HSCT is generally accepted as an AUC from 800 to 1500μmol·min/L [2, 3, 4, 5].

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

2. Principle of the Assay

The Busulfan ELISA adopts a typical competitive immunoassay principle.

Busulfan in samples, calibrators, and controls competes with a busulfan analogue pre-coated on microplate wells for binding a limited number of anti-busulfan 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 busulfan in the sample. A calibration curve is established using calibrators to calculate the busulfan 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 Busulfan Coated Plate	8×12 wells, detachable	Microwells pre-coated with busulfan analogue
② Primary Antibody	1 bottle (0.5mL, 25×)	Monoclonal antibody against busulfan
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 Busulfan 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

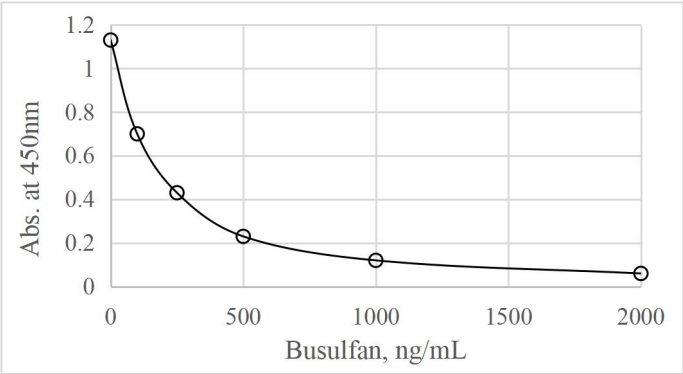
1) The blood should be centrifuged within 3h of collection. The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) The samples can be placed on an ice surface (0 ~ 3°C) up to 24h with < 5% reduction in concentration and AUC. 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 Busulfan 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 Busulfan 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 Busulfan-ELISA is shown below.



2) Analytical sensitivity. The analytical sensitivity of the Busulfan-ELISA is typically better than 26ng/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 Busulfan to pooled serum specimens containing a known amount of Busulfan. Recoveries were in the range of 96- 112% with a mean value of 97.5% (n=15).
4) The cross reactivities (at the 50% displacement level) with the major inactive metabolites of Busulfan were listed below.

Substance	Cross Reactivity (%)
Busulfan	100
Tetrahydrothiophene, , and	< 0.01%
tetramethyl sulfone	< 0.01%
tetrahydrothiophene-3-ol-1,1-dioxide	< 0.01%

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

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Specific Estrone-3-Sulfate (E1S) ELISA

For Research Use Only
Cat. No.: BW-E1S ELISA

1. Introduction

Determination of E1S in biological samples of female herbivores has long been used in livestock for pregnancy detection and litter size classification.

When being used as a marker for disease diagnosis in human populations, E1S is also useful for various of clinical settings [1], e.g., for assessing the risk stratification of breast cancer [2], monitoring of the proliferation promotion of endometrial cancer [3], providing prognostic information in advanced prostatic carcinoma [4], and monitoring of the response to certain hormonal therapy for malignancy [5]. A lot of immunoassays have been designed for E1S determination, however, the utility of these assays for human sample analysis are very limited, mainly due to their cross-reactivity with dehydroepiandrosterone sulphate (DHEAS) [6]. A very slight cross-reactivity with DHEAS in E1S immunoassay will lead to unacceptable bias in view of the 10- to 10000-fold excess of DHEAS over E1S in male serum [4]. Besides DHEAS, other steroids may also exert interferences on E1S immunoassay.

This assay is designed to specific determination of E1S concentration by using an anti-E1S McAb which show < 0.0001% cross-reactivity with DHEAS; also, it is direct assay without the need for sample pretreatment.

2. Principle of the Assay

The E1S ELISA adopts a typical competitive immunoassay principle.
E1S present in samples, calibrators, and controls competes with E1S coated on the microplate wells for binding a limited number of anti-E1S monoclonal antibody. 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 produce a color reaction. The absorbance intensity is inversely proportional to the E1S concentration in the sample. A calibration curve is established using calibrators to calculate E1S concentrations 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 E1S Coated Plate	8×12 wells, detachable	Microwells precoated with E1S antigen
② Primary Antibody	1 bottle (0.5mL, 25×)	Monoclonal antibody against E1S
③ Assay Buffer	1 bottle (30mL)	PBS buffer containing BSA and Tween20
④ Secondary Antibody	1 bottle (0.5mL, 25×)	Sheep antimouse 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% Tween20 in PBS
⑦ Stop Solution	1 bottle (15mL)	1 M Citric acid solution
⑧ E1S Calibrators	6 vials (1mL each)	0, 0.2, 0.8, 2, 5, 10ng/mL

4. Kit Storage and Stability

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

5. Equipment and Materials Required but not Provided

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

6. Sample Collection and Storage

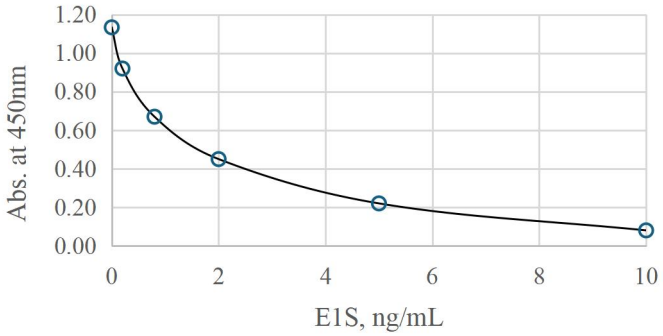
6.1 The test can be performed with serum as well as with EDTA plasma. The applicability for analyzing specimens other than plasma or serum remains to be verified.
6.2 Hemolytic and lipemic samples should not be used.
6.3 The samples can be stored up to 15 days at 2-8°C. For a longer storage (up to 18 months) the samples need to be frozen at -20°C. Repeated freezing and thawing should be avoided.
6.4 Hemolytic, lipemic and icteric specimens should not be used.

7. Experimental Procedure

7.1 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.
7.2 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.
7.3 Pipette 25µL of the E1S calibrator and samples into the bottom of each well.
7.4 Add 75µL of Primary Antibody solution to each well, incubate the frame for 90 minutes at room temperature on an orbital shaker at medium speed.
7.5 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. Alternatively, a Microplate washer may be used.
7.6 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.
7.7 Dispense 100µL of Secondary Antibody solution into each well and incubate the frame for 60 minutes at room temperature on an orbital shaker at medium speed.
7.8 After incubation, wash the wells as in step 7.5. Ensure no residual wash buffer remains.
7.9 Dispense 100µL of Chromogenic Substrate solution into each well, and mix thoroughly. Incubate for 20 minutes at room temperature with slow shaking.
7.10 Add 100µL of Stop Solution into each well. Shake for at least 10 seconds on an orbital shaker.
7.11 Quantitation. Read the optical density at 450nm in a microplate photometer within 10 minutes. Plot absorbance vs. calibrator concentration to construct the E1S calibrator curve. When using analyzing software, it is recommended to use the Four Parameter Logistic (4PL) Regression (alternatively: cubic-spline or logit-log). 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

8.1 The typical standard curve for the E1S-ELISA is shown below.



8.2 Analytical sensitivity. The analytical sensitivity of the E1S ELISA is typically better than 0.05 ng/mL, defined as the mean of the measurement values for the zero calibrator minus 2 standard deviations (mean value - 2SD).
8.3 Recovery. Spiked serum samples were prepared by adding varying levels of E1S to pooled serum specimens containing a known amount of E1S. Recoveries were in the range of 92- 101% with a mean value of 95.2% (n=15).
8.4 The cross reactivities (at the 50 % displacement level) with the steroids of similar structure were listed below.

Substance	Cross Reactivity (%)
ES	100
Estrone (E1)	0.02
DHEAS	0.00012%
Progesterone	<0.01
Testosterone	<0.01
Estrone glucuronide	<0.01
Estradiol (E2)	<0.01
17b-Estradiol 3-sulfate	<0.01

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

9. Notes

- This kit is for research use only, not for human diagnostic or therapeutic procedures.
- Avoid repeated freezing and thawing of reagents.
- Protect TMB substrate from light and avoid contact with metal ions.
- Strictly follow incubation time and temperature to ensure reproducibility.
- 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

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Levetiracetam ELISA

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

1. Introduction

Levetiracetam ([(S)-α-ethyl-2-oxo-1-pyrrolidine acetamide], LEV) is an anticonvulsant drug available as a monotherapy for epilepsy in the case of partial seizures, or as an adjunctive therapy for myoclonic and tonic-clonic seizures.

LEV exhibits linear pharmacokinetics, minimal plasma protein binding, and low potential for drug–drug interactions, making it well-tolerated in most patients. However, therapeutic drug monitoring of levetiracetam is helpful in patients with conditions [1, 2, 3, 4, 5] that may alter pharmacokinetic characteristics (elderly, children, pregnancy, or renal impairment), to tailor individual dosage regimens or to investigate patient compliance.

This Levetiracetam ELISA is used for quantitative determination of levetiracetam in biological samples of epilepsy patients.

2. Principle of the Assay

The Levetiracetam ELISA adopts a typical competitive immunoassay principle.

Levetiracetam (LEV) in samples, calibrators, and controls competes with a LEV pre-coated on microplate wells for binding a limited number of anti-LEV 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 LEV in the sample. A calibration curve is established using calibrators to calculate the LEV 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 LEV Coated Plate	8×12 wells, detachable	Microwells pre-coated with LEV
② Primary Antibody	1 bottle (0.5mL, 25×)	Monoclonal antibody against LEV
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 LEV Calibrators	6 vials (1mL each)	0, 2, 8, 20, 50, 100μg/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

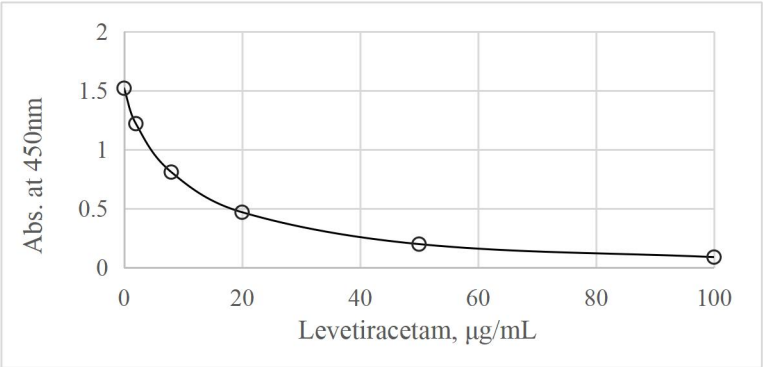
1) The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) The samples can be stored at 2 ~ 8°C up to one month with < 5% reduction in concentration. For a longer storage (> 1 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 LEV 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 LEV 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 LEV-ELISA is shown below.



2) Analytical sensitivity. The analytical sensitivity of the LEV-ELISA is typically better than 0.5 μg/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 LEV to pooled serum specimens containing a known amount of LEV. Recoveries were in the range of 93- 102% with a mean value of 96.6% (n=15).
4) The cross-reactivity (at the 50% displacement level) with the major inactive metabolites of LEV, UCB L057, was < 0.26%.
5) Intra- assay precision: ≤ 10%, Inter- assay precision: ≤ 15%.
6) The range of measurement: 2- 100μg/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) Yoshiaki Yamamotoa, Akiko Ohtaa, Naotaka Usui Bleyzac N, et al. Clinical value of therapeutic drug monitoring for levetiracetam in pediatric patients with epilepsy. Brain & Development 45 (2023) 285–292.
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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

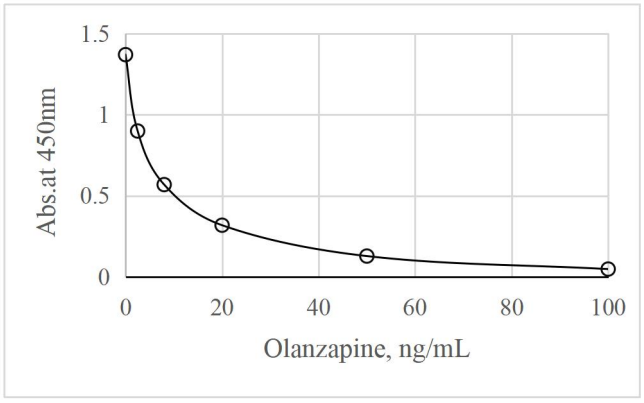
1) The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) The samples can be stored at 2 -8°C up to two weeks with < 5% reduction in concentration. For 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

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Direct Symmetric Dimethylarginine (SDMA) ELISA

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

1. Introduction

Symmetric dimethylarginine (SDMA) is a small-molecule compound produced via arginine methylation, which is released into the bloodstream during protein breakdown. SDMA is mainly cleared through renal excretion and serves as a valuable endogenous biomarker for evaluating glomerular filtration rate (GFR) [1].

In veterinary diagnostics, SDMA correlates well with glomerular filtration rate (GFR) in small animals, such as dogs and cats. SDMA increases earlier than creatinine (CREA), and so it is more sensitive for diagnosis of both active and chronic kidney disease. Unlike CREA, SDMA is not impacted by lean body mass. The SDMA Test now become a parameter for early detection of kidney diseases of small animals [2, 3, 4].

This kit is used for direct quantification of SDMA concentrations in biological samples.

2. Principle of the Assay

The SDMA ELISA adopts a typical competitive immunoassay principle.

SDMA present in samples, calibrators, and controls competes with SDMA coated on the microplate wells for binding a limited number of anti-SDMA 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 SDMA concentration in the sample. A calibration curve is established using calibrators to calculate the SDMA concentrations 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 SDMA Coated Plate	8×12 wells, detachable	Microwells pre-coated with SDMA antigen
② Primary Antibody	1 bottle (0.5mL, 25×)	Monoclonal antibody against SDMA
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 SDMA Calibrators	6 vials (1mL each)	0, 62.5, 125, 250, 500, 1000ng/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

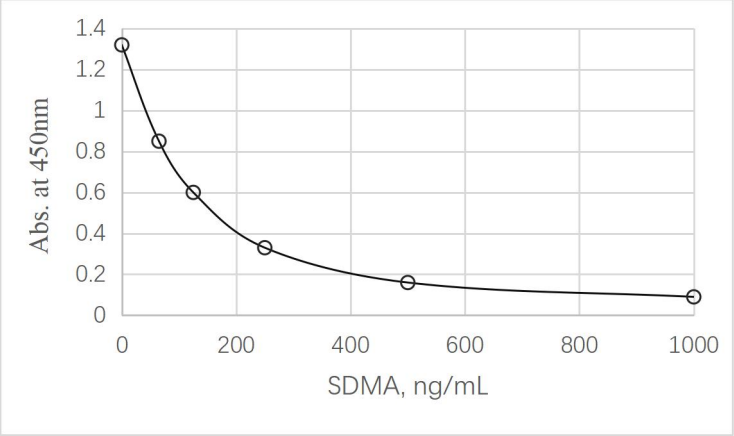
1) The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) The samples can be stored up to one month at 2 - 8°C. For a longer storage (up to 18 months) the samples need to be frozen at -20°C. Repeated freezing and thawing should be avoided.
4) Hemolytic, lipemic and icteric specimens should not be used.

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 SDMA calibrators (0, 62.5, 125, 250, 500, 1000ng/mL) 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 SDMA 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.

7. Performance Characteristics

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



2) Analytical sensitivity. The analytical sensitivity of the SDMA ELISA is typically better than 12ng/mL, if 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 SDMA to pooled serum specimens containing a known amount of SDMA. Recoveries were in the range of 96 - 117% with a mean value of 105.2% (n=15).
4) Cross reactivity (at the 50% displacement level)

Substance	Cross Reactivity (%)
SDMA	100
ADMA	0.22%
N^G-Monomethyl-L-arginine (MMA)	0.86%
Homoarginine	<0.01%
Creatinine	<0.01%
Arginine	<0.01%

5) Intra-assay Precision: ≤ 10%, Inter-assay Precision: ≤ 15%.
6) The range of measurement: 100 - 1600ng/mL.

8. 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.

9. References

1) Hendrik Meyer, Marcus Dörr, Anke Hannemann, et al. Symmetric dimethylarginine as a biomarker of renal impairment after a decade of follow-up. Scientific Reports, 2025, 15, 30520.

2) Rebecca Kohnken, Lauren Himmel, Michael Logan, et al. Symmetric Dimethylarginine is a Sensitive Biomarker of Glomerular Injury in Rats. Toxicologic Pathology. 2022, 50, 176-185.
3) Samantha CL, James MT , Timothy LW. Evaluation of symmetric dimethylarginine in cats with acute kidney injury and chronic kidney disease. Journal of Veterinary Internal Medicine, 2022, 36, 1669–1676.
4) Portia Tshidi Mashego, Emma H. Hooijberg. Analytical and Quality Control Validation of a Novel Symmetric Dimethylarginine Assay in Dogs and Cats. Veterinary Clinical Pathology, 2025, 54, 239–250.

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Venetoclax ELISA

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

1. Introduction

Venetoclax is a highly selective B-cell lymphoma-2 (BCL-2) inhibitor used in the treatment of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), acute myeloid leukemia (AML), and other hematologic malignancies. Due to its high selectivity for BCL-2 protein, venetoclax shows superior efficacy and better safety compared to other group of drugs [1, 2]. However, when venetoclax is administered at a fixed dose, the plasma concentration of venetoclax will vary widely between individuals, especially when venetoclax is co-administered with a strong CYP3A4 inhibitor. The continued use of venetoclax at high doses can result in life-threatening tumor lysis syndrome (TLS, 12%), and some frequent adverse events including neutropenia (45%), diarrhea (35%), nausea (33%), anemia (29%), and thrombocytopenia (22%) [3]. Close monitoring of the blood venetoclax concentration is highly recommended with an aim to reduce the risk of tumor-lysis syndrome and other complications including severe neutropenia and thrombocytopenia.

This Venetoclax ELISA is designed for the quantitative determination of venetoclax in serum or plasma.

2. Principle of the Assay

The Venetoclax ELISA adopts a typical competitive immunoassay principle.

Venetoclax in samples, calibrators, and controls competes with the venetoclax pre-coated on microplate wells for binding a limited number of rabbit anti-venetoclax polyclonal 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 venetoclax in the sample. A calibration curve is established using calibrators to calculate the venetoclax 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 Venetoclax Coated Plate	8×12 wells, detachable	Microwells pre-coated with venetoclax
② Primary Antibody	1 bottle (0.5mL, 25×)	Rabbit antibody against venetoclax
③ Assay Buffer	1 bottle (30mL)	PBS buffer containing BSA and Tween-20
④ Secondary Antibody	1 bottle (0.5mL, 25×)	Sheep anti-rabbit 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 Venetoclax Calibrators	6 vials (1mL each)	0, 0.2, 0.5, 1.0, 2.5, 5.0μg/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

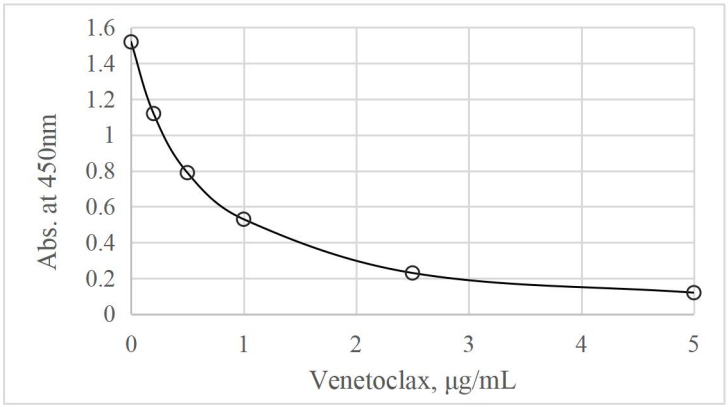
1) The test can be performed with serum and plasma as samples. The applicability for testing samples other than plasma or serum remains to be verified.
2) Hemolytic and lipemic samples should not be used.
3) Venetoclax in samples is stable up to 3 months at 2 -8°C with < 5% reduction in concentration. 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 Venetoclax 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 venetoclax 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 µg/ml can be read directly from this calibration curve by using their average optical density.

8. Performance Characteristics

1) The typical calibration curve for the Venetoclax-ELISA is shown below.



2) Analytical sensitivity. The analytical sensitivity of the Venetoclax-ELISA is typically better than 0.06μg/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 Venetoclax to pooled serum specimens containing a known amount of Venetoclax. Recoveries were in the range of 90.8- 103.2% with a mean value of 95.7% (n=15).
4) The cross reactivity (at the 50% displacement level) with M27, the major metabolites of venetoclax, was < 0.03%.
5) Intra- assay precision: ≤ 10%, Inter- assay precision: ≤ 15%.
6) The range of measurement: 0.1- 5μg/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) Konopleva M, Pollyea DA. Potluri J, et al. Efficacy and Biological Correlates of Response in a Phase II Study of Venetoclax Monotherapy in Patients with Acute Myelogenous Leukemia. Cancer Discov. 2016, 6, 1106–1117.
2) Eyre TA, Roeker LE, Fox CP, et al. The efficacy and safety of venetoclax therapy in elderly patients with relapsed, refractory chronic lymphocytic leukaemia. Br. J. Haematol. 2020, 188, 918–923.
3) Al-Sawaf O, Zhang C, Tandon M, et al. Venetoclax plus obinutuzumab versus chlorambucil plus obinutuzumab for previously untreated chronic lymphocytic leukaemia (CLL14): Follow-up results from a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol. 2020, 21, 1188–1200.

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PETIA *Polymyxin-B Assay*

(Particle-enhanced immunoturbidimetric inhibition assay for plasma polymyxin-B)

This package insert for the PETIA Polymyxin-B Assay must be read carefully prior to use, and the package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

1 NAME

PETIA Polymyxin-B Assay

2 PACKAGING SPECIFICATIONS

Reagents: R1: 33mL, R2: 11mL

Calibrator-A：3mL；Calibrator-B：1mL； Calibrator-C：1mL；Calibrator-D：1mL； Calibrator-E：1mL； Calibrator-F：1mL

3 INTENDED USE

The PETIA Polymyxin-B Assay is intended for the quantitative determination of Polymyxin-B in human plasma on automated clinical chemistry analyzers.

Polymyxin-B is a polypeptide antibiotic against multidrug-resistant Gram-negative bacteria, commonly used to treat severe infections caused by Pseudomonas aeruginosa, Acinetobacter baumannii, Klebsiella pneumoniae, etc. Polymyxin-B has a narrow therapeutic window. Low blood concentration cannot effectively kill bacteria, while excessively high concentration may easily cause severe adverse reactions such as nephrotoxicity, neurotoxicity, and respiratory depression. The toxic manifestations of Polymyxin-B often overlap with symptoms of severe infection. Therefore, blood concentration monitoring is helpful for optimizing dosage, improving efficacy and reducing toxicity. The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.

4 PRINCIPLES OF THE PROCEDURE

The PETIA Polymyxin-B Assay is based on the principle of latex-enhanced competitive immunoturbidimetry. During the assay, Polymyxin-B in the sample competes with Polymyxin-B conjugated to BSA for binding to anti-Polymyxin-B monoclonal antibodies coated on the surface of latex particles. When the antibody-coated latex is added in the reaction vessels, Polymyxin-B-BSA conjugate reacts with the latex surface antibodies and forms aggregates. Since the turbidity of the reaction solution caused by latex aggregation is negatively correlated with the concentration of Polymyxin-B in the sample, the Polymyxin-B concentration can be determined by measuring the change of absorbance at 600nm.

5 REAGENTS

Reagent-1 (R1): Polymyxin-B-protein conjugate, stored in MES buffer; Preservative: Sodium azide.

Reagent-2 (R2): Latex particles sensitized with anti-Polymyxin-B monoclonal antibody, stored in buffer containing stabilizer; Preservative: Sodium azide.

Calibrators: Solutions with different concentrations of Polymyxin-B; Preservative: Sodium azide.

6 STORAGE AND SHELF LIFE

The PETIA Polymyxin-B Assay reagents are provided in liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Improper storage of reagents can affect the assay performance.

Reagents were stable up to 30 days when stored on-board the instrument based on supporting data.

The PETIA Polymyxin-B Assay reagents contain ⩽ 0.05% sodium azide. The affected plumbing and instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components

7 SAMPLE REQUIREMENTS

- EDTA-anticoagulated plasma is required. Please use blood collection tubes following the manufacturer's instructions. Fibrin, red blood cells, and other particulate matter may cause an erroneous result. Ensure adequate centrifugation.
- Do not induce foaming and avoid repeated freezing/thawing to preserve the integrity of the specimen before it is assayed.
- Clarified specimens may be stored up to one week at 2 to 8°C. If testing will be delayed more than 6 days, specimens should be stored frozen (≤ -20°C) up to four weeks prior to being tested.
- Handle all patient specimens as if they were potentially infectious.

8 INSTRUMENTS

This product is compatible with various types of automated analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer. The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer.

9 ASSAY PROCEDURE

- Confirm sufficient sample volume in the sample cup before detection.
- Calibration procedure must be performed for reagents used for the first time or requiring recalibration.
- Set detection parameters according to the following data.

Wavelength	600nm/None (Primary/Secondary)	Sample	4μL	Reaction Method	Two-point End-point Assay
Cuvette Light Path	1cm	R1	150μL	Calibration Type	Spline/Logit-log(4p)
Reaction Temperature	37℃	R2	50μL	Reaction Direction	Downward

An example of the assay procedure is indicated below.

	Calibrator	Sample
Calibrator	4μL	-
Sample	-	4μL
R1	150μL	150μL
Mix and incubate at 37°C for 3-5 minutes		
R2	50μL	50μL
Mix, incubate at 37°C for about 20 seconds, read absorbance A1, incubate for 5 minutes, read absorbance A2, calculate the concentration of Polymyxin-B based on the ΔA=A2-A1		

Sample Dilution Procedure

For samples with Polymyxin-B concentration > 8.00μg/mL, dilute the sample as follows:

- Mix 150μL sample with 150μL Calibrator A in a centrifuge tube.
- Test Result = Measured Value × 2.

Calibration

Perform a full calibration (6-point) procedure using the PETIA Polymyxin-B Calibrators A, B, C, D, E, and F; test calibrators in duplicate. The calibration curve is established by plotting the calibrator concentration against the absorbance change (ΔA) using non-linear fitting to evaluate the Polymyxin-B concentration in the sample.

- Calibration Range: 0.00-8.00μg/mL.
- After the system accepts and saves the calibration curve, subsequent samples can be tested without further calibration unless:
  1) A new batch number of the kit is used.
  2) The quality control value is out of the target range.

Quality Control

Certified quality control products can be used for quality control. The concentration of quality control products measured by each laboratory may be inconsistent, but it should be within the target range; if the measured value is out of the target range, please check:

- Whether the parameter settings are correct;
- Whether the sample needle and reagent needle are contaminated or blocked;
- Whether the light source is aging and the cuvette is clean;
- Whether the flow path of the instrument pipeline system is unobstructed;
- Whether the reaction temperature is correct;
- Whether the kit is expired.

10 RESULTS

The result units are reported as μg/mL. A therapeutic range for Polymyxin-B has not been well established. A steady-state concentration range across 24h ($C_{ss,\,avg}$) of 2 to 4μg/mL has been proposed, corresponding to an $AUC_{ss,\,24\,h}$ of 50–100 mg·h/L [1].

The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures. A comprehensive clinical evaluation of the patient is required before determining or changing the treatment regimen.

11 LIMITATIONS OF PROCEDURE

This assay is designed for use with EDTA-anticoagulated plasma. It is generally good practice to use the same method consistently for individual patient care due to the potential for method-to-method variabilities. Like other immunoassays, the PETIA Polymyxin-B Assay should be used in conjunction with information available from clinical evaluations and other diagnostic procedures. Clinicians should carefully monitor patients during therapy and dosage adjustments.

12 PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer.

- **Sensitivity**

1) The difference in absorbance between standard solution (0.5 μg/mL) and another standard solution (0μg/mL) is ⩾ 0.03.
2) The ratio of absorbance change of the 8μg/mL calibrator (ΔA_8) to that of the zero-value calibrator (ΔA_0) is < 15%.

- **Measurement Range**

The measurement range of the PETIA Polymyxin-B Assay is 0.5 – 8.0μg/mL. Specimens containing Polymyxin-B in higher concentrations (>8.0μg/mL) may be assayed by dilution of the specimen into the measurement range for a quantitative result or otherwise reported as detected above the measurement range.

- **Recovery**

Analytical recovery was assessed by adding concentrated Polymyxin-B drug into human plasma negative for Polymyxin-B, to obtain three samples with Polymyxin-B at (1.5 ± 0.5)μg/mL, (3.0 ± 0.5)μg/mL and (7.5 ± 0.5)μg/mL. Six replicates of each sample were assayed. The results were averaged and compared to the target concentration; the obtained Polymyxin-B concentration should be in the range of 85–115% of the expected values.

- **Precision**

Tri-level samples [*(1.5±0.5)μg/mL, (3.0±0.5)μg/mL and (7.5±0.5) μg/mL)*] were assayed in quadruplicate twice a day for 12 days. Each of the runs per day was separated by at least three hours. The within run, between day percent CVs were ≤15.0% for sample at (1.5±0.5)μg/mL, and ≤10.0% for samples at (3.0±0.5)μg/mL and (7.5±0.5)μg/mL.

- **Specificity**

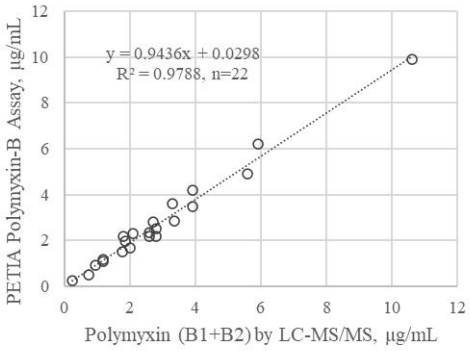
Polymyxin-B is a multi-component antibiotic with polymyxin B1 and B2 as its major components [2]. The PETIA Polymyxin-B Assay shows similar reactivity for polymyxin B1 and B2, and the cross-reactivity with polymyxin-E is less than 0.3%.

- **Interfering Substances**

Clinically high concentrations of the potentially interfering substances (bilirubin at 100mg/dL, Cholesterol at 600mg/dL, Hemoglobin at 1000mg/dL, and Triglycerides at 1000mg/dL) in serum with known levels of Polymyxin-B (3.0 and 6.0μg/mL) were evaluated. Each sample was assayed using the PETIA Polymyxin-B Assay. Measurement of Polymyxin-B resulted in ≤15% error in the presence of interfering substances.

- **Method Comparison**

Results from the PETIA Polymyxin-B Assay were compared with results from LC-MS/MS by measuring 22 specimens with Polymyxin-B concentrations ranged 0.2μg/mL to 10.6μg/mL. Passing-Bablok regression [3] statistics are shown below.



13 REFERENCES

1) Xiaofen LIU, Chenrong HUANG, Phillip J. BERGEN, et al. Chinese consensus guidelines for therapeutic drug monitoring of polymyxin B, endorsed by the Infection and Chemotherapy Committee of the Shanghai Medical Association and the Therapeutic Drug Monitoring Committee of the Chinese Pharmacological Society. Journal of Zhejiang University-SCIENCE B (Biomedicine & Biotechnology) 2023, 24(2):130-142.

2) Xiaofen Liu, Zhenwei Yu, Yu Wang, et al. Therapeutic drug monitoring of polymyxin B by LC–MS/MS in plasma and urine. Bioanalysis, 2020; 12: 845-55.

3) Bablok W, Passing H, Bender R. et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry. Part III. J Clin Chem Clin Biochem., 1988, 26:783-790.

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PETIA *Busulfan Assay*

(Particle-enhanced immunoturbidimetric inhibition assay for plasma/serum Busulfan)

This package insert for the PETIA Busulfan Assay must be read carefully prior to use, and the package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

1 NAME

PETIA Busulfan Assay

2 PACKAGING SPECIFICATIONS

Reagents: R1: 33mL, R2: 11mL

Calibrator-A：3mL；Calibrator-B：1mL； Calibrator-C：1mL；Calibrator-D：1mL； Calibrator-E：1mL； Calibrator-F：1mL

3 INTENDED USE

The PETIA Busulfan Assay is intended for the quantitative determination of Busulfan in human plasma on automated clinical chemistry analyzers.

Busulfan is an alkylating antineoplastic agent, mainly used for myeloablative conditioning prior to hematopoietic stem cell transplantation. It exerts antitumor effects by damaging the DNA structure of tumor cells and inhibiting cell proliferation. Busulfan has an extremely narrow therapeutic window: subtherapeutic concentrations may lead to transplantation failure and disease recurrence, while supratherapeutic concentrations frequently cause severe irreversible adverse reactions, including hepatic veno-occlusive disease (HVOD), myelosuppression, neurotoxicity, and pulmonary toxicity. These toxicities are often indistinguishable from other symptoms during the conditioning phase. Therefore, busulfan TDM is a core clinical practice to ensure transplantation safety and optimize dosing regimens.

The PETIA Busulfan Assay is designed for rapid and convenient monitoring of busulfan levels in patient's sample.

4 PRINCIPLES OF THE PROCEDURE

The PETIA Busulfan Assay is based on the principle of latex-enhanced competitive immunoturbidimetry. During the assay, Busulfan in the sample competes with Busulfan conjugated to BSA for binding to anti-Busulfan monoclonal antibodies coated on the surface of latex particles. When the antibody-coated latex is added in the reaction vessels, Busulfan-BSA conjugate reacts with the latex surface antibodies and forms aggregates. Since the turbidity of the reaction solution caused by latex aggregation is negatively correlated with the concentration of Busulfan in the sample, the Busulfan concentration can be determined by measuring the change of absorbance at 600nm.

5 REAGENTS

Reagent-1 (R1): Busulfan-protein conjugate, stored in MES buffer; Preservative: Sodium azide.

Reagent-2 (R2): Latex particles sensitized with anti-Busulfan monoclonal antibody, stored in buffer containing stabilizer; Preservative: Sodium azide.

Calibrators: Solutions with different concentrations of Busulfan; Preservative: Sodium azide.

6 STORAGE AND SHELF LIFE

The PETIA Busulfan Assay reagents are provided in liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Improper storage of reagents can affect the assay performance.

Reagents were stable up to 30 days when stored on-board the instrument based on supporting data.

The PETIA Busulfan Assay reagents contain ⩽0.05% sodium azide. The affected plumbing and instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components

7 SAMPLE REQUIREMENTS

- The blood should be centrifuged within 3h of collection. Serum and plasma can be used. Please use blood collection tubes following the manufacturer's instructions. Fibrin, red blood cells, and other particulate matter may cause an erroneous result. Ensure adequate centrifugation.
- Do not induce foaming and avoid repeated freezing/thawing to preserve the integrity of the specimen before it is assayed.
- Clarified specimens may be stored up to 24 hours on ice. If testing will be delayed more than 6 days, specimens can be stored frozen (≤ -20°C) up to four weeks prior to being tested.
- Handle all patient specimens as if they were potentially infectious.

8 INSTRUMENTS

This product is compatible with various types of automated analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer. The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer.

9 ASSAY PROCEDURE

- Confirm sufficient sample volume in the sample cup before detection.
- Calibration procedure must be performed for reagents used for the first time or requiring recalibration.
- Set detection parameters according to the following data.

Wavelength	600nm/None (Primary/Secondary)	Sample	4μL	Reaction Method	Two-point End-point Assay
Cuvette Light Path	1cm	R1	150μL	Calibration Type	Spline/Logit-log(4p)
Reaction Temperature	37℃	R2	50μL	Reaction Direction	Downward

An example of the assay procedure is indicated below.

	Calibrator	Sample
Calibrator	4μL	
Sample		4μL
R1	150μL	150μL
R2	50μL	50μL
Mix, incubate at 37℃ for about 20 seconds, read absorbance A1, incubate for 5 minutes, read absorbance A2, calculate the concentration of busulfan based on the ΔA=A2–A1		

Sample Dilution Procedure

For samples with Busulfan concentration > 5000ng/mL, dilute the sample as follows:

- Mix 150μL sample with 150μL Calibrator A in a centrifuge tube.
- Test Result = Measured Value × 2.

Calibration

Perform a full calibration (6-point) procedure using the PETIA Busulfan Calibrators A, B, C, D, E, and F; test calibrators in duplicate. The calibration curve is established by plotting the calibrator concentration against the absorbance change (ΔA) using non-linear fitting to evaluate the Busulfan concentration in the sample.

- Calibration Range: 0-5000ng/mL.
- After the system accepts and saves the calibration curve, subsequent samples can be tested without further calibration unless:
  1) A new batch number of the kit is used.
  2) The quality control value is out of the target range.

Quality Control

Certified quality control products can be used for quality control. The concentration of quality control products measured by each laboratory may be inconsistent, but it should be within the target range; if the measured value is out of the target range, please check:

- Whether the parameter settings are correct;
- Whether the sample needle and reagent needle are contaminated or blocked;
- Whether the light source is aging and the cuvette is clean;
- Whether the flow path of the instrument pipeline system is unobstructed;
- Whether the reaction temperature is correct;
- Whether the kit is expired.

10 RESULTS

The result units are reported as ng/mL. A therapeutic range for Busulfan has not been well established. A steady-state concentration range across 24h ($C_{ss,\ avg}$) of 600 to 900ng/mL has been proposed, corresponding to an $AUC_{ss,\ 24\ h}$ of 1200–1800 mg·h/L [1].

The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures. A comprehensive clinical evaluation of the patient is required before determining or changing the treatment regimen.

11 LIMITATIONS OF PROCEDURE

This assay is designed for use with EDTA-anticoagulated plasma. It is generally good practice to use the same method consistently for individual patient care due to the potential for method-to-method variabilities. Like other immunoassays, the PETIA Busulfan Assay should be used in conjunction with information available from clinical evaluations and other diagnostic procedures. Clinicians should carefully monitor patients during therapy and dosage adjustments.

12 PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer.

- **Sensitivity**

1) The difference in absorbance between standard solution (300ng/mL) and another standard solution (0 ng/mL) is ≥ 0.03.
2) The ratio of absorbance change of the 5000ng/mL calibrator (ΔA_8) to that of the zero-value calibrator (ΔA_0) is < 15%.

- **Measurement Range**

The measurement range of the PETIA Busulfan Assay is 300 – 5000ng/mL. Specimens containing Busulfan in higher concentrations (>5000ng/mL) may be assayed by dilution of the specimen into the measurement range for a quantitative result or otherwise reported as detected above the measurement range.

- **Recovery**

Analytical recovery was assessed by adding concentrated Busulfan drug into human plasma negative for Busulfan, to obtain three samples with Busulfan at (500±50)ng/mL, (800±50)ng/mL and (4000±50)ng/mL. Six replicates of each sample were assayed. The results were averaged and compared to the target concentration, the obtained Busulfan concentration should be in the range of 85–115% of the expected values.

- **Precision**

Tri-level samples [*(500±50)ng/mL, (800±50)ng/mL and (4000±50) ng/mL)*] were assayed in quadruplicate twice a day for 12 days. Each of the runs per day was separated by at least three hours. The within run, between day percent CVs were ≤15.0% for sample at (500±50ng/mL, and ≤10.0% for samples at (800±50)ng/mL and (4000±50) ng/mL.

- **Specificity**

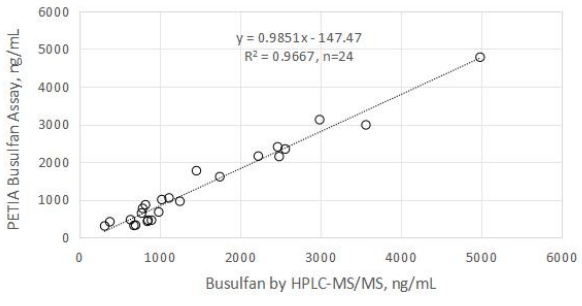
The assay shows good specificity to busulfan. No cross-reactivities were observed with 20 μ g/mL of Bu metabolites including tetramethyl sulfone, tetrahydrothiophene, and tetrahydrothiophene-3-ol-1,1-dioxide.

- **Interfering Substances**

Clinically high concentrations of the potentially interfering substances (bilirubin at 100mg/dL, Cholesterol at 600mg/dL, Hemoglobin at 1000mg/dL, and Triglycerides at 1000mg/dL) in serum with known levels of Busulfan (800 and 4000ng/mL) were evaluated. Each sample was assayed using the PETIA Busulfan Assay. Measurement of Busulfan resulted in ≤15% error in the presence of interfering substances.

- **Method Comparison**

Results from the PETIA Busulfan Assay were compared with results from LC-MS/MS by measuring 24 specimens with Busulfan concentrations ranged 314ng/mL to 4985ng/mL. Passing-Bablok regression [3] statistics are shown below.



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for better bioassays

PETIA *Olanzapine Assay*

(Particle-enhanced immunoturbidimetric inhibition assay for plasma/serum olanzapine)

This package insert for the PETIA olanzapine Assay must be read carefully prior to use, and the package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

1 NAME

PETIA Olanzapine Assay

2 PACKAGING SPECIFICATIONS

Reagents: R1: 33mL, R2: 11mL

Calibrator-A：3mL；Calibrator-B：1mL； Calibrator-C：1mL；Calibrator-D：1mL； Calibrator-E：1mL； Calibrator-F：1mL

3 INTENDED USE

The PETIA Olanzapine Assay is intended for the quantitative determination of olanzapine in human plasma/serum on automated clinical chemistry analyzers.

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 100ng/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].

The PETIA Olanzapine Assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.

4 PRINCIPLES OF THE PROCEDURE

The PETIA Olanzapine Assay is based on the principle of latex-enhanced competitive immunoturbidimetry. During the assay, olanzapine in the sample competes with olanzapine conjugated to BSA for binding to anti-Olanzapine monoclonal antibodies coated on the surface of latex particles. When the antibody-coated latex is added in the reaction vessels, Olanzapine-BSA conjugate reacts with the latex surface antibodies and forms aggregates. Since the turbidity of the reaction solution caused by latex aggregation is negatively correlated with the concentration of olanzapine in the sample, the olanzapine concentration can be determined by measuring the change of absorbance at 600nm.

5 REAGENTS

Reagent-1 (R1): Olanzapine-protein conjugate, stored in MES buffer; Preservative: Sodium azide.

Reagent-2 (R2): Latex particles sensitized with anti-Olanzapine monoclonal antibody, stored in buffer containing stabilizer; Preservative: Sodium azide.

Calibrators: Solutions with different concentrations of olanzapine; Preservative: Sodium azide.

6 STORAGE AND SHELF LIFE

The PETIA Olanzapine Assay reagents are provided in liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Improper storage of reagents can affect the assay performance.

Reagents were stable up to 30 days when stored on-board the instrument based on supporting data.

The PETIA Olanzapine Assay reagents contain ≤0.05% sodium azide. The affected plumbing and instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components.

7 SAMPLE REQUIREMENTS

- Serum or EDTA-anticoagulated plasma can be used. Please use blood collection tubes following the manufacturer's instructions. Fibrin, red blood cells, and other particulate matter may cause an erroneous result. Ensure adequate centrifugation.
- Do not induce foaming and avoid repeated freezing/thawing to preserve the integrity of the specimen before it is assayed.
- Clarified specimens may be stored up to one week at 2 to 8°C. If testing will be delayed more than 6 days, specimens should be stored frozen (≤ -20°C) up to four weeks prior to being tested.
- Handle all patient specimens as if they were potentially infectious.

8 INSTRUMENTS

This product is compatible with various types of automated analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer. The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer.

9 ASSAY PROCEDURE

- Confirm sufficient sample volume in the sample cup before detection.
- Calibration procedure must be performed for reagents used for the first time or requiring recalibration.
- Set detection parameters according to the following data.

Wavelength	600nm/None (Primary/Secondary)	Sample	4μL	Reaction Method	Two-point End-point Assay
Cuvette Light Path	1cm	R1	150μL	Calibration Type	Spline/Logit-log(4p)
Reaction Temperature	37°C	R2	50μL	Reaction Direction	Downward

An example of the assay procedure is indicated below.

	Calibrator	Sample
Calibrator	4μL	
Sample		4μL
R1	150μL	150μL
R2	50μL	50μL
Mix, incubate at 37℃ for about 20 seconds, read absorbance A1, incubate for 5 minutes, read absorbance A2, calculate the concentration of olanzapine based on the ΔA=A2–A1		

Sample Dilution Procedure

For samples with Olanzapine concentration > 300ng/mL, dilute the sample as follows:

- Mix 150μL sample with 150μL Calibrator A in a centrifuge tube.
- Test Result = Measured Value × 2.

Calibration

Perform a full calibration (6-point) procedure using the PETIA Olanzapine Calibrators A, B, C, D, E, and F; test calibrators in duplicate. The calibration curve is established by plotting the calibrator concentration against the absorbance change (ΔA) using non-linear fitting to evaluate the olanzapine concentration in the sample.

- Calibration Range: 0.0-300.0ng/mL.
- After the system accepts and saves the calibration curve, subsequent samples can be tested without further calibration unless:
  1) A new batch number of the kit is used.
  2) The quality control value is out of the target range.

Quality Control

Certified quality control products can be used for quality control. The concentration of quality control products measured by each laboratory may be inconsistent, but it should be within the target range; if the measured value is out of the target range, please check:

- Whether the parameter settings are correct;
- Whether the sample needle and reagent needle are contaminated or blocked;
- Whether the light source is aging and the cuvette is clean;
- Whether the flow path of the instrument pipeline system is unobstructed;
- Whether the reaction temperature is correct;
- Whether the kit is expired.

10 RESULTS

The result units are reported as ng/mL. A therapeutic range for Olanzapine has not been well established. The therapeutic reference range concentration of Olanzapine between 20 to 80 ng/mL has been recommended, with a laboratory alert level at 100ng/mL [7].

The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures. A comprehensive clinical evaluation of the patient is required before determining or changing the treatment regimen.

11 LIMITATIONS OF PROCEDURE

This assay is designed for use with serum or EDTA-anticoagulated plasma. It is generally good practice to use the same method consistently for individual patient care due to the potential for method-to-method variabilities. Like other immunoassays, the PETIA Olanzapine Assay should be used in conjunction with information available from clinical evaluations and other diagnostic procedures. Clinicians should carefully monitor patients during therapy and dosage adjustments.

12 PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer.

- **Sensitivity**

1) The difference in absorbance between standard solution (15 ng/mL) and another standard solution (0 ng/mL) is ≥ 0.03.
2) The ratio of absorbance change of the 300ng/mL calibrator (ΔA_8) to that of the zero-value calibrator (ΔA_0) is < 15%.

- **Measurement Range**

The measurement range of the PETIA Olanzapine Assay is 15 – 300ng/mL. Specimens containing olanzapine in higher concentrations (>300ng/mL) may be assayed by dilution of the specimen into the measurement range for a quantitative result or otherwise reported as detected above the measurement range.

- **Recovery**

Analytical recovery was assessed by adding concentrated olanzapine drug into negative human plasma/serum for olanzapine, to obtain three samples with olanzapine at (15 ± 5)ng/mL, (30 ± 5)ng/mL and (100 ± 5)ng/mL. Six replicates of each sample were assayed. The results were averaged and compared to the target concentration. The obtained olanzapine concentration should be in the range of 85–115% of the expected values.

- **Precision**

Tri-level samples [*(15±5)ng/mL, (30±5)ng/mL and (100±5) ng/mL)*] were assayed in quadruplicate twice a day for 12 days. Each of the runs per day was separated by at least three hours. The within run, between day percent CVs were ≤15.0% for sample at (15±5)ng/mL, and ≤10.0% for samples at (30±5)ng/mL and (100±5)ng/mL.

- **Specificity**

The cross reactivities (at the 50% displacement level) with the major metabolites of Olanzapine were listed below.

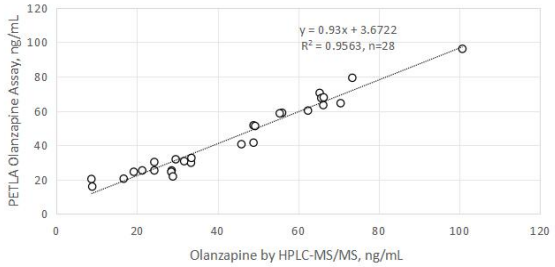
Substance	Cross Reactivity (%)
Olanzapine	100
Olanzapine-10-N-glucuronide	< 0.16%
Olanzapine 4′-N-glucuronide	< 0.01%
N-desmethyl olanzapine	< 0.235%

- **Interfering Substances**

Clinically high concentrations of the potentially interfering substances (bilirubin at 100mg/dL, Cholesterol at 600mg/dL, Hemoglobin at 1000mg/dL, and Triglycerides at 1000mg/dL) in plasma/serum with known levels of olanzapine (30 and 100ng/mL) were evaluated. Each sample was assayed using the PETIA Olanzapine Assay. Measurement of olanzapine resulted in ≤15% error in the presence of interfering substances.

- **Method Comparison**

Results from the PETIA Olanzapine Assay were compared with results from LC-MS/MS by measuring 28 specimens with olanzapine concentrations ranged 8.7ng/mL to 100.7ng/mL. Passing-Bablok regression [3] statistics are shown below.



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7) Christopher Noel. A review of a recently published guidelines' ''strong recommendation'' for therapeutic drug monitoring of olanzapine, haloperidol, perphenazine, and fluphenazine. Ment Health Clin [Internet]. 2019, 9, 287-93.

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PETIA *Acetaminophen Assay*

(Particle-enhanced immunoturbidimetric inhibition assay for plasma/serum acetaminophen)

This package insert for the PETIA Acetaminophen (N-acetyl-p-aminophenol, APAP) Assay must be read carefully prior to use, and the package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

1 NAME

PETIA Acetaminophen Assay

2 PACKAGING SPECIFICATIONS

Reagents: R1: 33mL, R2: 11mL

Calibrator-A：3mL；Calibrator-B：1mL； Calibrator-C：1mL；Calibrator-D：1mL； Calibrator-E：1mL； Calibrator-F：1mL

3 INTENDED USE

The PETIA Acetaminophen Assay is intended for the quantitative determination of acetaminophen in human plasma/serum on automated clinical chemistry analyzers.

Acetaminophen is a widely used antipyretic and analgesic agent for mild to moderate pain and fever control, commonly applied to relieve headache, arthralgia, postoperative pain and pyrexia of various origins. Overdose can cause severe, potentially fatal hepatic necrosis. Timely measurement of plasma/serum acetaminophen concentration is critical for assessing risk and guiding N-acetylcysteine treatment [1, 2, 3, 4].

The measurement of an APAP levels after overdose should be as soon as possible in order to timely confirm the patient's risk of toxicity and thus the need to initiate NAC (N-acetylcysteine). The PETIA Acetaminophen Assay is designed for rapid, automated determination of APAP levels in human serum or plasma. It aids in the diagnosis and management of acetaminophen overdose and guides antidotal therapy.

The PETIA Acetaminophen Assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.

4 PRINCIPLES OF THE PROCEDURE

The PETIA Acetaminophen Assay is based on the principle of latex-enhanced competitive immunoturbidimetry. During the assay, acetaminophen in the sample competes with acetaminophen conjugated to BSA for binding to anti-Acetaminophen monoclonal antibodies coated on the surface of latex particles. When the antibody-coated latex is added in the reaction vessels, Acetaminophen-BSA conjugate reacts with the latex-surface antibodies and forms aggregates. Since the turbidity of the reaction solution caused by latex aggregation is negatively correlated with the concentration of acetaminophen in the sample, the acetaminophen concentration can be determined by measuring the change of absorbance at 600 nm.

5 REAGENTS

Reagent-1 (R1): Acetaminophen-BSA conjugate, stored in MES buffer; Preservative: Sodium azide.

Reagent-2 (R2): Latex particles sensitized with anti-Acetaminophen monoclonal antibody, stored in buffer containing stabilizer; Preservative: Sodium azide.

Calibrators: Solutions with different concentrations of acetaminophen; Preservative: Sodium azide.

6 STORAGE AND SHELF LIFE

The PETIA Acetaminophen Assay reagents are provided in liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed.

If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Improper storage of reagents can affect the assay performance.

Reagents were stable up to 30 days when stored on-board the instrument based on supporting data.

The PETIA Acetaminophen Assay reagents contain ⩽ 0.05% sodium azide. The affected plumbing and instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components

7 SAMPLE REQUIREMENTS

- EDTA-anticoagulated plasma or serum is required. Please use blood collection tubes following the manufacturer's instructions. Fibrin, red blood cells, and other particulate matter may cause an erroneous result. Ensure adequate centrifugation.
- Do not induce foaming and avoid repeated freezing/thawing to preserve the integrity of the specimen before it is assayed.
- Clarified specimens may be stored up to one week at 2 to 8°C. If testing will be delayed more than 6 days, specimens should be stored frozen (≤ -20°C) up to four weeks prior to being tested.
- Handle all patient specimens as if they were potentially infectious.

8 INSTRUMENTS

This product is compatible with various types of automated analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer. The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer.

9 ASSAY PROCEDURE

- Confirm sufficient sample volume in the sample cup before detection.
- Calibration procedure must be performed for reagents used for the first time or requiring recalibration.
- Set detection parameters according to following data.

Wavelength	600nm/None (Primary/Secondary)	Sample	3μL	Reaction Method	Two-point End-point Assay
Cuvette Light Path	1cm	R1	150μL	Calibration Type	Spline/Logit-log (4p)
Reaction Temperature	37℃	R2	50μL	Reaction Direction	Downward

An example of the assay procedure is indicated below.

Assay procedure	Calibrator	Sample
Calibrator	3μL	-
Sample	-	3μL
R1	150μL	150μL
Mix and incubate at 37℃ for 3-5 minutes		
R2	50μL	50μL
Mix, incubate at 37℃ for about 20 seconds, read absorbance A1, incubate for 5 minutes, read absorbance A2, calculate the concentration of acetaminophen based on the ΔA=A2-A1		

Sample Dilution Procedure

For samples with acetaminophen concentration > 200μg/mL, dilute the sample as follows:

- Mix 150μL sample with 150μL Calibrator A in a centrifuge tube.
- Test Result = Measured Value × 2.

Calibration

Perform a full calibration (6-point) procedure using the PETIA Acetaminophen Calibrators A, B, C, D, E, and F; test calibrators in duplicate. The calibration curve is established by plotting the calibrator concentration against the absorbance change (ΔA) using non-linear fitting to evaluate the Acetaminophen concentration in the sample.

- Calibration Range: 0-200μg/mL.
- After the system accepts and saves the calibration curve, subsequent samples can be tested without further calibration unless:
  1) A new batch number of the kit is used.
  2) The quality control value is out of the target range.

Quality Control

Certified quality control products can be used for quality control. The concentration of quality control products measured by each laboratory may be inconsistent, but it should be within the target range; if the measured value is out of the target range, please check:

- Whether the parameter settings are correct;
- Whether the sample needle and reagent needle are contaminated or blocked;
- Whether the light source is aging and the cuvette is clean;
- Whether the flow path of the instrument pipeline system is unobstructed;
- Whether the reaction temperature is correct;
- Whether the kit is expired.

10 RESULTS

- Results are calculated automatically by the analyzer. No additional manipulation of data is required unless samples have been manually diluted.
- The concentration of acetaminophen in serum or plasma depends on the time of drug ingestion, concomitant drug therapy, sample condition, time of sample collection, and individual variations in absorption, distribution, biotransformation, and excretion. These parameters must be considered when interpreting results.
- In acute acetaminophen overdose, a single serum or plasma level determination, plotted on the Rumack-Matthew nomogram, provides a good indication of whether overdose therapy is required [5, 6].
- The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures. A comprehensive clinical evaluation of the patient is required before determining or changing the treatment regimen.

11 LIMITATIONS OF PROCEDURE

This assay is designed for use with EDTA-anticoagulated plasma or serum. It is generally good practice to use the same method consistently for individual patient care due to the potential for method-to-method variabilities. Like other immunoassays, the PETIA Acetaminophen Assay should be used in conjunction with information available from clinical evaluations and other diagnostic procedures. Clinicians should monitor patients carefully during therapy and dosage adjustments.

12 PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained on the Hitachi 7180 Biochemical analyzer. Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer.

- **Sensitivity**

1) The difference in absorbance between standard solution (6 μg/mL) and another standard solution (0 μg/mL) is ⩾ 0.03.
2) The ratio of absorbance change of the 100μg/mL calibrator (ΔA_8) to that of the zero-value calibrator (ΔA_0) is < 15%.

- **Measurement Range**

The measurement range of the PETIA Acetaminophen Assay is 2-200μg/mL. Specimens with APAP higher than 200 μg/mL may be assayed by dilution of the specimen into the measurement range for a quantitative result or otherwise reported as detected above the measurement range.

- **Recovery**

Analytical recovery was assessed by adding concentrated acetaminophen drug into human plasma negative for acetaminophen, to obtain three samples with acetaminophen at (5.0 ± 0.5) μg/mL, (20 ± 2) μg/mL and (80 ± 8) μg/mL. Six replicates of each sample were assayed. The results were averaged and compared to the target concentration; the obtained acetaminophen concentration should be in the range of 85–115 % of the expected values.

- **Precision**

Tri-level samples [*(5.0±0.5)μg/mL, (20±2)μg/mL and (80±8) μg/mL)*] were assayed in quadruplicate twice a day for 12 days. Each of the runs per day was separated by at least three hours. The within run, between day percent CVs were ≤15.0% for sample at (5.0±0.5)μg/mL, and ≤10.0% for samples at (20±2)μg/mL and (80±8)μg/mL.

- **Specificity**

The cross reactivities (at the 50 % displacement level) with the major metabolites of APAP were listed below.

Substance	Cross Reactivity (%)
APAP	100
APAP sulfate	< 0.09%
APAP glucuronide	< 0.01%
Acetylcysteine	< 0.01%
N-acetyl-p-benzoquinoneimine	< 0.05%

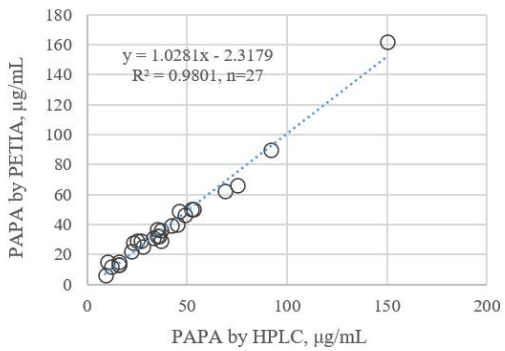
- **Interfering Substances**

Clinically high concentrations of the potentially interfering substances (bilirubin at 100mg/dL, Cholesterol at 600mg/dL, Hemoglobin at 1000mg/dL, and Triglycerides at 1000mg/dL) in serum with known levels of acetaminophen (3.0 and 20μg/mL) were evaluated. Each sample was assayed using the PETIA Acetaminophen Assay. Measurement of acetaminophen resulted in ≤15% error in the presence of interfering substances.

- **Method Comparison**

Results from the PETIA Acetaminophen Assay were compared with results from HPLC by measuring 27 specimens with Acetaminophen concentrations ranged 6.2μg/mL to151 μg/mL.

Passing-Bablok regression statistics are shown below.



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