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# CEDIA® PHENCYCLIDINE (PCP) APPLICATION

CE

# Beckman Coulter AU400®, AU480®, AU640®, AU680®, AU2700®, AU5400®, AU5800®

Catalog No. 100172, 100173, 1815784

**Intended for the Qualitative and Semiquantitative Determination of Phencyclidine in Human Urine**

For In Vitro Diagnostic Use Only

## Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen preparation, specimen storage, quality control, and additional performance data.

Materials available from Microgenics, a part of Thermo Fisher Scientific

## Ordering Information

| Item | Size | Thermo Fisher Scientific Catalog No. |
|---|---|---|
| CEDIA Phencyclidine Assay Reagents | 3x17 mL<br>65 mL<br>495 mL | 100172<br>100173<br>1815784 |
| CEDIA Negative Calibrator | 5 mL<br>15 mL | 1557416<br>1661388 |
| CEDIA Primary Calibrator | 5 mL<br>15 mL | 1815326<br>1815334 |
| CEDIA Secondary Calibrator | 5 mL<br>15 mL | 1730428<br>1730517 |
| CEDIA Intermediate Calibrator | 5 mL<br>15 mL | 1730380<br>1732218 |
| CEDIA High Calibrator | 5 mL<br>15 mL | 1730398<br>1732226 |
| MGC Primary DAU Control Set | 3 x 5 mL | 100200 |

To place an order or for technical service contact:

| In USA | In Europe |
|---|---|
| **(800) 232-3342**<br>**Fax 510-979-5420** | **Tel: +49 (0)851-88 6890**<br>**Fax: +49 (0)851-88 68910** |


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*Continued on next page*

## Reagent Storage

Refer to the package insert for information on reagent storage.

## Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Reagent 1 (EA reagent) and Reagent 2 (ED Reagent) into appropriate containers. **Ensure that reagents have equilibrated to temperature of analyzer reagent compartment before starting analysis.**

## Results and Data Interpretation

Results for samples will be printed in ng/mL

Refer to package insert for information on results and data interpretation.

Additional, user-definable parameters present results that are interpretable in different ways. For further information, contact Microgenics Technical Support or your local Microgenics representative.



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# CEDIA Phencyclidine Assay - Qualitative
# Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

**Specific Test Parameters**

General | LIH | ISE | Range

Test Name: PCPQ ▽ < > Type: Urine ▽ Operation: Yes ▽

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 4.0 | µL | Dilution | 0 | µL | Pre-Dilution Rate: | 1 | | |
| Reagents: | R1 Volume | 87 | µL | Dilution | 0 | µL | Min OD | | Max OD | |
| | R2 Volume | 87 | µL | Dilution | 0 | µL | L | -2.00 | H | 2.50 |
| | | | | | | | Reagent OD limit: | | | |
| Wavelength: | Pri. | 570 ▽ | | Sec. | 660 ▽ | | First L | -2.00 | First H | 2.50 |
| Method: | | RATE* ▽ | | | | | Last L | -2.00 | Last H | 2.50 |
| Reaction slope: | | + ▽ | | | | | Dynamic Range: | | | |
| Measuring Point 1: | First | 24 | | Last | 27 | | L | # | H | # |
| Measuring Point 2: | First | | | Last | | | Correlation Factor: | | | |
| Linearity: | | | % | | | | A | 1 | B | 0 |
| No Lag Time: | | No ▽ | | | | | On-board stability period: | # | | |

**Specific Test Parameters**

General | LIH | ISE | Range

Test Name: PCPQ ▽ < > Type: Urine ▽

Value/Flag: # ▽ Level L: # Level H: #

Normal Ranges:

| | Sex | Age L Year | Age L Month | Age H Year | Age H Month | L | H |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ▽ | # | # | # | # | # | # |
| ☐ 2. | # ▽ | # | # | # | # | # | # |
| ☐ 3. | # ▽ | # | # | # | # | # | # |
| ☐ 4. | # ▽ | # | # | # | # | # | # |
| ☐ 5. | # ▽ | # | # | # | # | # | # |
| ☐ 6. | # ▽ | # | # | # | # | # | # |
| 7. None Selected | | | | | | # | # |
| 8. Out of Range | | L | | H | | # | # |

Panic Value: L # H # Unit: # Decimal places: #

**Calibration Specific**

General | ISE

Test Name: PCPQ ▽ < > Type Urine ▽

Calibration Type: AB ▽ Formula: Y=AX+B ▽ Counts: 2 Process: CONC ▽

| | Cal. No. | OD | CONC | Factor/OD-L | Factor/OD-H |
|---|---|---|---|---|---|
| Point 1: | # | | 100 | -99999 | 999999 |
| Point 2: | | | | | |
| Point 3: | | | | | |
| Point 4: | | | | | |
| Point 5: | | | | | |
| Point 6: | | | | | |
| Point 7: | | | | | |

1-Point Cal. Point: ☐ ☐ With CONC-0 Slope Check + ▽ Advanced Calibration ▽

MB Type Factor: Calibration Stability Period: #

# User Defined
*Can also be run as FIXED



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## CEDIA Phencyclidine Assay - Semiquantitative
## Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters

General | LIH | ISE | Range

Test Name: PCPSQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 4.0 | µL | Dilution | 0 | µL | Pre-Dilution Rate: | 1 | | |
| Reagents: | R1 Volume | 87 | µL | Dilution | 0 | µL | Min OD | | Max OD | |
| | R2 Volume | 87 | µL | Dilution | 0 | µL | L | -2.00 | H | 2.50 |
| | | | | | | | Reagent OD limit: | | | |
| Wavelength: | Pri. | 570 ∇ | | Sec. | 660 ∇ | | First L | -2.00 | First H | 2.50 |
| Method: | | RATE1* ∇ | | | | | Last L | -2.00 | Last H | 2.50 |
| Reaction slope: | | + ∇ | | | | | Dynamic Range: | | | |
| Measuring Point 1: | First | 24 | | Last | 27 | | L | 0 | H | 150 |
| Measuring Point 2: | First | | | Last | | | Correlation Factor: | | | |
| Linearity: | | | % | | | | A | 1 | B | 0 |
| No Lag Time: | | No ∇ | | | | | On-board stability period: | # | | |

Specific Test Parameters

General | LIH | ISE | Range

Test Name: PCPSQ ∇ < > Type: Urine ∇

Value/Flag: # ∇ Level L: # Level H: #

Normal Ranges:

| | Sex | Age L Year | Age L Month | Age H Year | Age H Month | L | H |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. None Selected | | | | | | # | # |
| 8. Out of Range | | L | | H | | # | # |

Panic Value: # # Unit: ng/mL Decimal places: #

Calibration Specific

General | ISE

Test Name: PCPSQ ∇ < > Type Urine ∇

Calibration Type: 4AB ∇ Formula: POLYGONAL ∇ Counts: 2 Process: CONC ∇

| | Cal. No. | OD | CONC | Factor/OD-L | Factor/OD-H |
|---|---|---|---|---|---|
| Point 1: | # | | 0 | -2.00 | 2.50 |
| Point 2: | # | | 25 | -2.00 | 2.50 |
| Point 3: | # | | 75 | -2.00 | 2.50 |
| Point 4: | # | | 150 | -2.00 | 2.50 |
| Point 5: | | | | | |
| Point 6: | | | | | |
| Point 7: | | | | | |

1-Point Cal. Point: ☐ With CONC-0 Slope Check + ∇ Advanced Calibration # ∇

MB Type Factor: Calibration Stability Period: #

*Can also be run as FIXED1
#User Defined



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# CEDIA Phencyclidine Assay - Qualitative
# Beckman Coulter System Parameters, AU480/AU680

| Parameters | Specific Test Parameters | | | | |
|---|---|---|---|---|---|
| General | LIH | ISE | HbA1c | Calculated Tests | Range |

Test Name: PCPQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Sample Volume | | 4.0 µL | Dilution | 0 ∇µL | OD Limit | | | |
| Pre-Dilution Rate | | 1 ∇ | | | | Min.OD | -2.0000 | Max.OD 3.0000 |
| Reagent Volume | R1(R1-1) | 87 µL | Dilution | 0 µL | Reagent OD Limit | | | |
| | | | | | First | Low | -2.0000 | High 3.0000 |
| | R2(R2-1) | 87 µL | Dilution | 0 µL | Last | Low | -2.0000 | High 3.0000 |
| Common Reagent | Type | None | Name | | Dynamic Range | Low | # | High # |
| Wavelength | Pri. | 570 ∇ nm | Sec. | 660 ∇ nm | Correlation Factor | A | 1 | B 0 |
| Method | | FIXED* ∇ | | | Factor for Maker | A | 1 | B 0 |
| Reaction slope | | + ∇ | | | | | | |
| Measuring Point-1 | First | 24 | Last | 27 | Onboard Stability Period | | 30 Day | 0 Hour |
| Measuring Point-2 | First | | Last | | | | | |
| Linearity Limit | | % | | | | | | |
| Lag Time Check | | No ∇ | | | | | | |

| Parameters | Specific Test Parameters | | | | |
|---|---|---|---|---|---|
| General | LIH | ISE | HbA1c | Calculated Tests | Range |

Test Name: PCPQ ∇ < > Type: Urine ∇

Value/Flag: # ∇

Level — Low: # High: # Panic Value — Low: # High: #

Specific Ranges:

| | | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|---|
| ☐ | 1 | # ∇ | # | # | # | # | # | # |
| ☐ | 2 | # ∇ | # | # | # | # | # | # |
| ☐ | 3 | # ∇ | # | # | # | # | # | # |
| ☐ | 4 | # ∇ | # | # | # | # | # | # |
| ☐ | 5 | # ∇ | # | # | # | # | # | # |
| ☐ | 6 | # ∇ | # | # | # | # | # | # |
| | 7 | No demographics | | | | | # | # |
| | 8 | Not within expected values | | | | | # | # |

Unit: # Decimal Places: #



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## CEDIA Phencyclidine Assay - Qualitative
## Beckman Coulter System Parameters, AU480/AU680, *continued*

| Parameters | Calibration Parameters | | |
|---|---|---|---|
| Calibrators | Calibration Specific | STAT Table Calibration | |

Test Name: PCPQ ▽ | < | > | Type: Urine ▽ | □ Use Serum Cal.

Calibration Type: AB ▽ | Formula: Y=AX+B ▽ | Counts: 2 ▽

< Calibrator Parameters>

| | Calibrator | OD | Conc | Factor Range Low | Factor Range High |
|---|---|---|---|---|---|
| Point-1 | # ▽ | | 100 | -9999999 | 9999999 |
| Point-2 | ▽ | | | | |
| Point-3 | ▽ | | | | |
| Point-4 | ▽ | | | | |
| Point-5 | ▽ | | | | |
| Point-6 | ▽ | | | | |
| Point-7 | ▽ | | | | |
| Point-8 | ▽ | | | | |
| Point-9 | ▽ | | | | |
| Point-10 | ▽ | | | | |

Slope Check: None ▽

Allowable Range Check
□ Reagent Blank
□ Calibration

Advanced Calibration
Operation: No ▽
Interval (RB/ACAL): ▽

□ Lot Calibration

< Point Cal. For Master Curve > | No. of Correction Points: ▽ | Use Master Curve: ▽

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | ▽ | | | | |
| Point-2 | ▽ | | | | |

Stability

| | | | | |
|---|---|---|---|---|
| Reagent Blank | # | Day | # | Hour |
| Calibration | 30 | Day | 0 | Hour |

MB Type Factor: | 1-Point Calibration Point: ▽ | □ with Conc-0

\# User defined
* Can also be run as RATE



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# CEDIA Phencyclidine Assay - Semiquantitative
# Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: PCPSQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Sample Volume | | 4.0 µL | Dilution | 0 µL | OD Limit | | | |
| Pre-Dilution Rate | | 1 | | | | Min. OD | -2.00 | Max. OD 3.00 |
| Reagents Volume: | R1(R1-1) | 87 µL | Dilution | 0 µL | Reagent OD limit: | | | |
| | | | | | | First Low | -2.00 | High 3.00 |
| | | | | | | Last Low | -2.00 | High 3.00 |
| | R2 (R2-1) | 87 µL | Dilution | 0 µL | | | | |
| | | | | | | Dynamic Range Low | 0 | High 150 |
| | | | | | | Correlation Factor A | 1 | B 0 |
| Wavelength: | Pri. | 570 nm | Sec. | 660 nm | | Factor for Maker A | 1 | B 0 |
| Method: | | FIXED1* ∇ | | | | | | |
| Reaction slope: | | + ∇ | | | | Onboard Stability | 30 Days | 0 Hour |
| Measuring Point 1: | First | 24 | Last | 27 | | LIH Influence Check | # ∇ | |
| Measuring Point 2: | First | | Last | | | Lipemia | ∇ | |
| Linearity: | | % | | | | Icterus | ∇ | |
| No Lag Time: | | No ∇ | | | | Hemolysis | ∇ | |

Specific Test Parameters

General | | ISE | Range

Test Name: PCPSQ ∇ < > Type: Urine ∇

Value/Flag: VALUE ∇ Level L: # Level H: #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. No demographics | | | | | | # | # |
| 8. Not within expected values | | | | | | # | # |

Panic Value

| Low | High |
|---|---|
| # | # |

Unit ng/mL Decimal Places #

\# User defined
* Can also be run as RATE1



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## CEDIA Phencyclidine Assay - Semiquantitative
## Beckman Coulter System Parameters, AU480/AU680, *continued*

Calibration Specific

General | ISE

Test Name: PCPSQ ∇ | < | > | Type: Urine ∇ | ☐ Use Serum Cal.

Calibration Type: 4AB ∇ | Formula: Polygonal ∇ | Counts: 2

<Calibrator Parameters> | Slope Check: + ∇

| | Calibrator † | | OD | Conc | Factor Range Low | Factor Range High |
|---|---|---|---|---|---|---|
| Point 1: | # | ∇ | | 0 | -2.00 | 3.00 |
| Point 2: | # | ∇ | | 25 | -2.00 | 3.00 |
| Point 3: | # | ∇ | | 75 | -2.00 | 3.00 |
| Point 4: | # | ∇ | | 150 | -2.00 | 3.00 |
| Point 5: | | ∇ | | | | |
| Point 6: | | ∇ | | | | |
| Point 7: | | ∇ | | | | |
| Point 8: | | ∇ | | | | |
| Point 9: | | ∇ | | | | |
| Point10: | | ∇ | | | | |

Allowable Range Check: ☐ Reagent Blank ☐ Calibration

Advanced Calibration: Operation: No ∇ | Interval (RB/ACAL): ∇

<Point Cal. For Master Curve> | No. of Correction Points: ∇ | Use Master Curve: ∇ | ☐ Lot Calibration

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point 1: | | | | | |
| Point 2: | | | | | |

Stability: Reagent Blanks # Day # Hour | Calibration 30 Day 0 Hour

MB Type Factor: | 1-Point Calibration Point: None ∇ | ☐ With CONC-0

# User defined



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# CEDIA Phencyclidine Assay – Qualitative
# Beckman Coulter System Parameters, AU5800

| Parameters | Specific Test Parameters | | | | |
|---|---|---|---|---|---|
| General | LIH | ISE | HbA1c | Calculated Test | Range |

PCPSQ ∇ | < | > | Type: Urine ∇ | Operation Yes ∇

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample Volume | | 4 µL | Dilution | 0 µL | OD Limit | | | | | |
| Pre-Dilution Rate | | 1 ∇ | Diluent Bottle | Outside ∇ | | Min.OD | -2.00 | Max.OD | 3.00 | |
| Rgt. Volume | R1(R1-1) | 87 µL | Dilution | 0 µL | Reagent OD Limit | | | | | |
| | R1-2 | µL | Dilution | µL | 1st. | Low | -2.00 | High | 3.00 | |
| | | | | | Last | Low | -2.00 | High | 3.00 | |
| | R2(R2-1) | 87 µL | Dilution | 0 µL | | | | | | |
| | | | | | Dynamic Range | Low | # | High | # | |
| Common Rgt. Type | | None | Name | None | Correlation Factor | A | 1 | B | 0 | |
| Wavelength | Pri | 570 ∇nm | Sec. | 660 ∇nm | Factor for Maker | A | 1 | B | 0 | |
| Method | | FIXED* ∇ | | | | | | | | |
| Reaction Slope | | + ∇ | | | Onboard Stability Period | | 30 Day | 0 Hour | | |
| Measuring Point1 1st | | 24 | Last | 27 | LIH Influence Check | | # ∇ | | | |
| Measuring Point2 1st | | | Last | | Lipemia | | ∇ | | | |
| Linearity Limit | | % | | | Icterus | | ∇ | | | |
| Lag Time Check | | No ∇ | | | Hemolysis | | ∇ | | | |

| Parameters | Specific Test Parameters | | | | |
|---|---|---|---|---|---|
| General | LIH | ISE | HbA1c | Calculated Test | Range |

Test Name: PCPQ ∇ | < | > | Type: Urine ∇

Value/Flag: # ∇

Level Low # High #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. | Standard demographics | | | | | # | # |
| 8. | Not within expected values | | | | | # | # |

Panic Value Low # High # Unit # Decimal Places #

# User defined.

* Can also be run as RATE



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## CEDIA Phencyclidine Assay – Qualitative
## Beckman Coulter System Parameters, AU5800, *continued*

| Parameters | Calibration Parameters | | |
|---|---|---|---|
| Calibrators | Calibration Specific | STAT Table Calibration | |

Test Name: PCPQ ∇ | < | > | Type Urine ∇ | Cuvette ∇

□ Use Serum Cal

Calibration Type: AB ∇ Formula: Y=AX+B ∇ Counts: 2

< Calibrator Parameters>

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | # ∇ | | 100 | -99999 | 99999 |
| Point-2 | ∇ | | | | |
| Point-3 | ∇ | | | | |
| Point-4 | ∇ | | | | |
| Point-5 | ∇ | | | | |
| Point-6 | ∇ | | | | |
| Point-7 | ∇ | | | | |
| Point-8 | ∇ | | | | |
| Point-9 | ∇ | | | | |
| Point-10 | ∇ | | | | |

Slope Check: + ∇

Allowable Range Check
□ Reagent Blank
□ Calibration

Advanced Calibration
Operation: No ∇
Interval (RB/ACAL): ∇

□ Lot Calibration

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | ∇ | | | | |
| Point-2 | ∇ | | | | |

Stability
Reagent Blank # Day # Hour
Calibration 30 Day 0 Hour

MB Type Factor | 1-Point Calibration Point: None ∇ | □ with Conc-0

# User Defined Values



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## CEDIA Phencyclidine Assay – Semiquantitative
## Beckman Coulter System Parameters, AU5800

| Parameters | | | Specific Test Parameters | | |
|---|---|---|---|---|---|
| General | LIH | ISE | HbA1c | Calculated Test | Range |

Test Name: PCPSQ ∇ < > Type: Urine ∇ Operation Yes ∇

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample Volume | | 4 | µL | Dilution | 0 | µL | OD Limit | | | |
| Pre-Dilution Rate | | 1 | ∇ | Diluent Bottle | # | ∇ | Min.OD | -2.00 | Max.OD | 3.00 |
| Rgt. Volume | R1(R1-1) | 87 | µL | Dilution | 0 | µL | Reagent OD Limit | | | |
| | R1-2 | | µL | Dilution | | µL | 1st. Low | -2.00 | High | 3.00 |
| | | | | | | | Last Low | -2.00 | High | 3.00 |
| | R2(R2-1) | 87 | µL | Dilution | 0 | µL | | | | |
| | | | | | | | Dynamic Range Low | 0 | High | 150 |
| Common Rgt. Type | | None | | Name | None | | Correlation Factor A | 1 | B | 0 |
| Wavelength | Pri | 570 | ∇nm | Sec. | 660 | ∇nm | Factor for Maker A | 1 | B | 0 |
| Method | | FIXED1* | ∇ | | | | | | | |
| Reaction Slope | | + | ∇ | | | | Onboard Stability Period | 30 | Day | 0 Hour |
| Measuring Point1 1st | | 24 | | Last | 27 | | LIH Influence Check | # | ∇ | |
| Measuring Point2 1st | | | | Last | | | Lipemia | | ∇ | |
| Linearity Limit | | | % | | | | Icterus | | ∇ | |
| Lag Time Check | | No | ∇ | | | | Hemolysis | | ∇ | |

| Parameters | | | Specific Test Parameters | | |
|---|---|---|---|---|---|
| General | LIH | ISE | HbA1c | Calculated Test | Range |

Test Name: PCPSQ ∇ < > Type: Urine ∇

Value/Flag: # ∇

Level Low # High #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. Standard demographics | | | | | | # | # |
| 8. Not within expected values | | | | | | # | # |

Panic Value Low # High # Unit ng/mL Decimal Places #

* Can be run as RATE1
# User Defined Values



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**CEDIA Phencyclidine Assay – Semiquantitative**
**Beckman Coulter System Parameters, AU5800, *continued***

| Parameters | Calibration Parameters | | |
|---|---|---|---|
| Calibrators | Calibration Specific | STAT Table Calibration | |

Test Name: PCPSQ ∇ | < | > Type: Urine ∇ Cuvette: ∇

□ Use Serum Cal

Calibration Type: 4AB ∇ Formula: POLYGONAL ∇ Counts: 2

< Calibrator Parameters>

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | # ∇ | | 0 | -2.0 | 3.0 |
| Point-2 | # ∇ | | 25 | -2.0 | 3.0 |
| Point-3 | # ∇ | | 75 | -2.0 | 3.0 |
| Point-4 | # ∇ | | 150 | -2.0 | 3.0 |
| Point-5 | ∇ | | | | |
| Point-6 | ∇ | | | | |
| Point-7 | ∇ | | | | |
| Point-8 | ∇ | | | | |
| Point-9 | ∇ | | | | |
| Point-10 | ∇ | | | | |

Slope Check: + ∇

Allowable Range Check
□ Reagent Blank
□ Calibration

Advanced Calibration Operation: No ∇
Interval (RB/ACAL): ∇

□ Lot Calibration

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇

| | Calibrator | OD | Conc. | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | ∇ | | | | |
| Point-2 | ∇ | | | | |

Stability

| | | | | |
|---|---|---|---|---|
| Reagent Blank | # | Day | # | Hour |
| Calibration | 30 | Day | 0 | Hour |

MB Type Factor: | 1-Point Calibration Point: None ∇ □ with Conc-0

# User Defined Values



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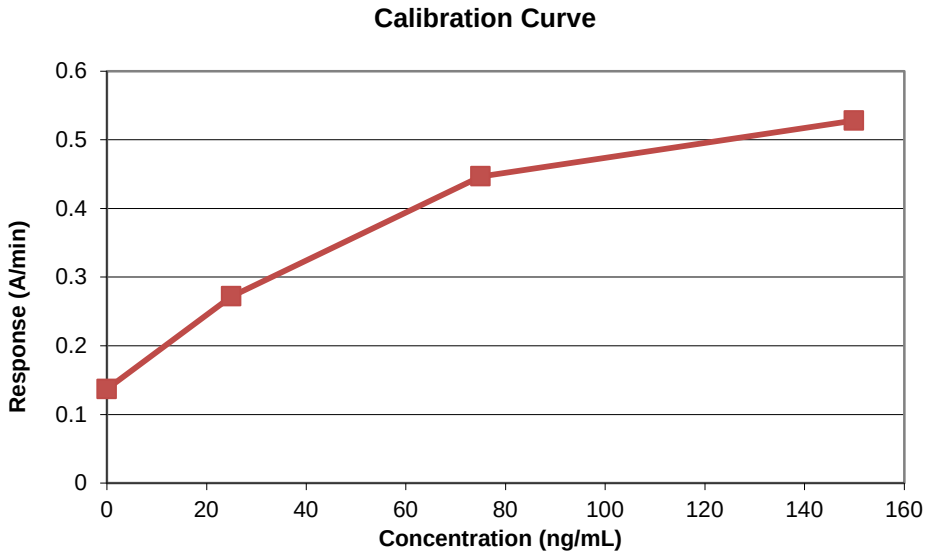
## Example Calibration Curve




## Limit Of Blank

The negative calibrator was run against the same calibration curve for 21 replicates. The LOB is calculated as 3*SD.

The observed LDD for Phencyclidine on:

AU480: 0.49 ng/mL
AU680: 0.64 ng/mL
AU5800: 0.92 ng/mL



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## Precision

Samples of the Low Control, Cutoff Calibrator, High Control were tested in replicates of 2, twice per day for 20 days, total N = 80/Level. The results are presented in the following tables:

| | Control Low | Cutoff | Control High |
|---|---|---|---|
| ***Qualitative AU400**** | | | |
| Mean (mA/min) | 275 | 321 | 361 |
| Within-Run SD (mA/min) | 3.2 | 3.4 | 5.3 |
| Within-Run CV (%) | 1.2 | 1.1 | 1.5 |
| Total SD (A/min) | 7.6 | 8.3 | 9.5 |
| Total CV (%) | 2.8 | 2.6 | 2.6 |
| ***Qualitative AU480*** | | | |
| Mean (mA/min) | 221 | 263 | 308 |
| Within-Run SD (mA/min) | 1.4 | 1.8 | 2.5 |
| Within-Run CV (%) | 0.6 | 0.7 | 0.8 |
| Total SD (A/min) | 7.3 | 8.7 | 10.4 |
| Total CV (%) | 3.3 | 3.3 | 3.4 |
| ***Qualitative AU640**** | | | |
| Mean (mA/min) | 259 | 306 | 345 |
| Within-Run SD (mA/min) | 2.8 | 3.4 | 3.5 |
| Within-Run CV (%) | 1.1 | 1.1 | 1.0 |
| Total SD (A/min) | 5.0 | 6.8 | 7.0 |
| Total CV (%) | 1.9 | 2.2 | 2.0 |
| ***Qualitative AU680*** | | | |
| Mean (mA/min) | 221 | 262 | 307 |
| Within-Run SD (mA/min) | 1.7 | 2.0 | 2.7 |
| Within-Run CV (%) | 0.8 | 0.7 | 0.9 |
| Total SD (A/min) | 4.2 | 4.5 | 5.1 |
| Total CV (%) | 1.9 | 1.7 | 1.7 |
| ***Qualitative AU5800*** | | | |
| Mean (mA/min) | 220 | 261 | 307 |
| Within-Run SD (mA/min) | 2.9 | 4.0 | 3.9 |
| Within-Run CV (%) | 1.3 | 1.5 | 1.3 |
| Total SD (A/min) | 5.7 | 7.3 | 7.8 |
| Total CV (%) | 2.6 | 2.8 | 2.5 |

*N=60/Level



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## Precision *(Continued)*

| | Control Low | Cutoff | Control High |
|---|---|---|---|
| ***Semiquantitative AU400**** | | | |
| Mean (ng/mL) | 17 | 23 | 30 |
| Within-Run SD (ng/mL) | 0.4 | 0.5 | 0.7 |
| Within-Run CV (%) | 2.5 | 2.0 | 2.3 |
| Total SD (ng/mL) | 0.8 | 1.1 | 1.5 |
| Total CV (%) | 4.7 | 4.5 | 5.1 |
| ***Semiquantitative AU480*** | | | |
| Mean (ng/mL) | 17 | 25 | 38 |
| Within-Run SD (ng/mL) | 0.3 | 0.5 | 0.7 |
| Within-Run CV (%) | 1.5 | 1.9 | 1.9 |
| Total SD (ng/mL) | 0.3 | 0.6 | 0.8 |
| Total CV (%) | 1.7 | 2.3 | 2.0 |
| ***Semiquantitative AU640**** | | | |
| Mean (ng/mL) | 19 | 26 | 33 |
| Within-Run SD (ng/mL) | 0.5 | 0.6 | 0.8 |
| Within-Run CV (%) | 2.4 | 2.4 | 2.4 |
| Total SD (ng/mL) | 0.7 | 0.9 | 1.3 |
| Total CV (%) | 3.7 | 3.5 | 3.9 |
| ***Semiquantitative AU680*** | | | |
| Mean (ng/mL) | 17 | 25 | 38 |
| Within-Run SD (ng/mL) | 0.3 | 0.4 | 0.8 |
| Within-Run CV (%) | 2.0 | 1.7 | 2.1 |
| Total SD (ng/mL) | 0.5 | 0.6 | 1.0 |
| Total CV (%) | 2.8 | 2.6 | 2.6 |
| ***Semiquantitative AU5800*** | | | |
| Mean (ng/mL) | 17 | 25 | 38 |
| Within-Run SD (ng/mL) | 0.5 | 0.8 | 0.9 |
| Within-Run CV (%) | 2.8 | 3.1 | 2.3 |
| Total SD (ng/mL) | 0.5 | 1.0 | 1.1 |
| Total CV (%) | 3.1 | 3.9 | 2.8 |

*N=60/Level

## Accuracy and Correlation

Patient samples were assayed using the CEDIA Phencyclidine Assay on the Beckman Coulter and tested against the reference analyzer, the Hitachi 717.

| Qualitative Method Comparison | | | |
|---|---|---|---|
| | **Positive Agreement (%)** | **Negative Agreement (%)** | **Total Agreement (%)** |
| AU400 | 100.0 | 98.7 | 99.4 |
| AU480 | 100.0 | 98.4 | 99.2 |
| AU640 | 100.0 | 100.0 | 100.0 |
| AU680 | 100.0 | 96.9 | 98.3 |
| AU5800 | 100.0 | 98.4 | 99.2 |



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## Accuracy and Correlation *(Continued)*

### CEDIA Phencyclidine Assay Qualitative Method Comparison

**AU400**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 54 | 1 |
| - | 0 | 77 |

**AU480**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 57 | 1 |
| - | 0 | 62 |

**AU640**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 54 | 0 |
| - | 0 | 78 |

**AU680**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 55 | 2 |
| - | 0 | 63 |

**AU5800**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 56 | 1 |
| - | 0 | 63 |

### Semiquantitative Method Comparison

| | Positive Agreement (%) | Negative Agreement (%) | Total Agreement (%) |
|---|---|---|---|
| AU400 | 100.0 | 98.7 | 99.4 |
| AU480 | 98.2 | 98.4 | 98.3 |
| AU640 | 100.0 | 100.0 | 100.0 |
| AU680 | 100.0 | 100.0 | 100.0 |
| AU5800 | 98.1 | 100.0 | 99.2 |

### CEDIA Phencyclidine Assay Semiquantitative Method Comparison

**AU400**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 54 | 1 |
| - | 0 | 77 |

**AU480**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 56 | 1 |
| - | 1 | 62 |

**AU640**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 54 | 0 |
| - | 0 | 78 |

**AU680**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 57 | 0 |
| - | 0 | 63 |

**AU5800**

| | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 53 | 0 |
| - | 1 | 66 |



*End*



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