

CEDIA® PROPOXYPHENE/METHADONE CALIBRATORS

HIGH/CUTOFF/INTERMEDIATE

thermo
scientific

IVD For In Vitro Diagnostic Use

Rx Only

| REF | Calibrator description name | Quantity |
|---------|-----------------------------|----------|
| 1662848 | Cutoff Calibrator | 1 x 5 mL |
| 1662856 | Intermediate Calibrator | 1 x 5 mL |
| 1662864 | High Calibrator | 1 x 5 mL |

Intended Use

The CEDIA® PPX/METD Cutoff, Intermediate, and High Calibrators are used to calibrate the CEDIA qualitative and semiquantitative assays for propoxyphene and methadone in urine

Each calibrator is sold separately and may be used with any reagent lot. The ready-for-use solutions contain human urine, stabilizer, and propoxyphene, and methadone.

| CEDIA PPX/METD Calibrator | | | |
|---------------------------|----------------|----------------------|--------------|
| Component | Cutoff (ng/mL) | Intermediate (ng/mL) | High (ng/mL) |
| Propoxyphene | 300 | 1200 | 5000 |
| Methadone | 300 | 600 | 1000 |

Precautions and warnings

The CEDIA PPX/METD Calibrators are prepared from nonsterile human urine. These calibrators should be handled at Biosafety Level 2, as recommended for any potentially infectious human serum, blood specimen, or urine in the Centers for Disease Control/National Institutes of Health manual *Biosafety in Microbiological and Biomedical Laboratories, 1993*. Avoid cross-contamination of calibrator levels. To do so, match colored calibrator caps to the appropriately colored dropper tips.

DANGER: CEDIA PPX/METD Calibrators contain ≤0.3% bovine serum albumin (BSA), sodium azide ≤0.09%.

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Storage and Stability

Store calibrators at 2 - 8°C. **DO NOT FREEZE.**

Stability **prior** to opening the bottle: up to the printed expiration date

Stability **after** opening the bottle: 60 days or until the printed expiration date, whichever comes first.

Do not use the calibrators beyond the expiration date.

Instructions for use

The calibrators are liquid and do not require reconstitution. Mix the contents of the vial before each use by gently inverting the vial 2 - 3 times. Remove the cap and dispense the required quantity of the calibrator into a sample cup as specified in the CEDIA Propoxyphene or Methadone application protocol or package insert. Record the date that the calibrator was opened on the vial label.

Test Procedure

Refer to the CEDIA Propoxyphene or Methadone Assay package insert or application protocol.

Materials Provided:

CEDIA Calibrators

Additional Materials Required:

CEDIA Propoxyphene Assay

CEDIA Methadone Assay

CEDIA Negative Calibrator

Results

Qualitative Results

The CEDIA PPX/METD Cutoff Calibrator is used as a reference in distinguishing between positive and negative samples. Samples producing a response value equal to or greater than the response value of the calibrator are considered positive. Samples producing a response value less than the response value of the calibrator are considered negative.

Semiquantitative Results

The CEDIA PPX/METD Cutoff Calibrator, when used in conjunction with the CEDIA Negative Calibrator and the CEDIA PPX/METD Intermediate and High Calibrators, can be used to estimate relative drug concentrations. Refer to the CEDIA Propoxyphene or Methadone Assay package insert and application protocol for specific information.

Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Limitations

The CEDIA PPX/METD Calibrators are intended for use solely as specified. Refer to the CEDIA Propoxyphene or Methadone Assay package insert and instrument application protocol for specific information.

Important

Manipulation of reagents and deviations from the storage conditions or working instructions may lead to erroneous results.

CEDIA® is a registered trademark of Roche Diagnostics.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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