

PARACETAMOL SERA CALIBRATOR KIT

- **Human sera based calibrators to improve accuracy and sensitivity**
- **Sensitivity: <3mg/L (0.02mmol/L)**
- **Measurement range: 3 - 378mg/L (0.02 - 2.50mmol/L)**
- **Calibration frequency: 168 hours**
- **Liquid ready to use**

APPLICATION

Human sera based 0mg/L and 302mg/L Paracetamol (Acetaminophen) Calibrators.

Calibrator shelf-life: 18 months, stable for one month after opening.

Traceability: Sera calibrators are manufactured using primary calibration material, Acetaminophen (98.0% - 101.0%) that meets USP specifications. They are manufactured gravimetrically and tested against independent controls.

SENSITIVITY

6 drug free patients were tested on a clinical chemistry analyser using the Paracetamol Kit and calibrated using the K8100 Paracetamol Sera Calibrators.

Mean = 1.53mg/L (0.010mmol/L)

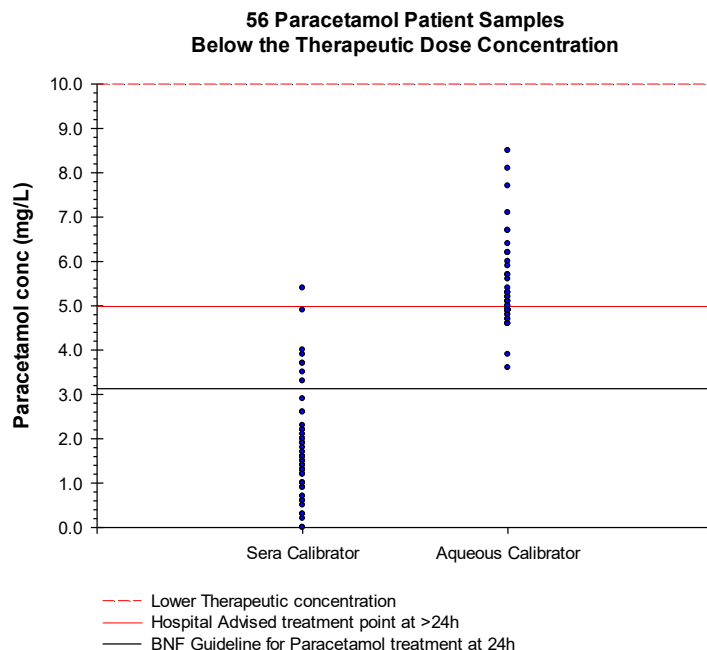
Std Dev = 0.39mg/L (0.003mmol/L)

Mean + 2SD = 2.31mg/L (0.016mmol/L)

56 patient samples that were <10mg/L (0.066mmol/L) Therapeutic Paracetamol on a clinical chemistry analyser were retested using the Paracetamol Kit and calibrated using the K8100 Paracetamol Sera Calibrators and normal calibrators.

Normal calibrators – 21/56 were <5mg/L (0.033mmol/L) remaining 35/56 gave a mean of 5.6mg/L (0.037mmol/L) and Std Dev 1.08mg/L (0.007mmol/L).

Sera calibrators – 48/56 samples would be <3mg/L (0.02mmol/L) the new cut-off. Mean of all samples is 1.7mg/L (0.011mmol/L) and Std Dev 1.16mg/L (0.008mmol/L).



98/79/EC
For in vitro diagnostic use
and Professional Use only.



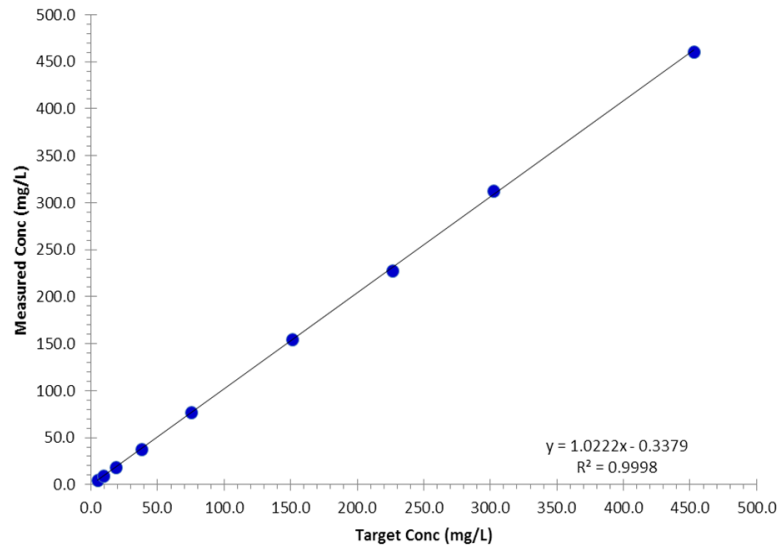
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Paracetamol Sera Calibrator Kit - Catalogue No. K8100

PRECISION

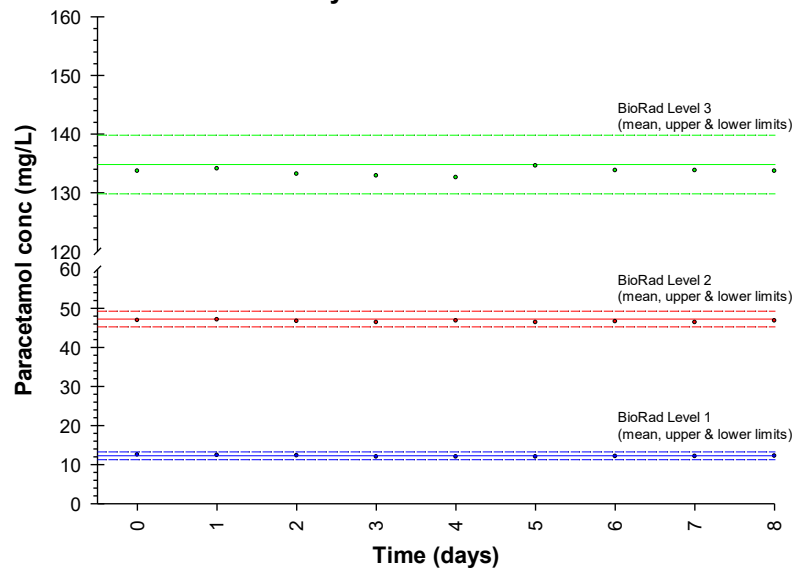
| Within Run Precision | | | Between Day Precision | | |
|----------------------|---------------|--------|-----------------------|---------------|--------|
| Mean (mg/L) | Mean (mmol/L) | CV (%) | Mean (mg/L) | Mean (mmol/L) | CV (%) |
| 12.8 | 0.085 | 1.85 | 12.2 | 0.081 | 2.21 |
| 49.6 | 0.328 | 0.76 | 46.8 | 0.310 | 1.28 |
| 141.3 | 0.936 | 0.51 | 133.8 | 0.886 | 1.05 |
| 2.69 | 0.018 | 3.88 | | | |
| 3.31 | 0.022 | 3.16 | | | |

LINEARITY



CALIBRATION STABILITY

Clinical Chemistry Analyser on-board stability calibrated with Sera Calibrators



- **Related Product:** Paracetamol
- **Safety Datasheet & Protocols available on-line at:**
<http://www.clsdiagnostics.com/downloads/>