

# PARACETAMOL (Acetaminophen) Sera Calibrator Kit

**REF** K8100



Consult Instructions For Use



For *in vitro* diagnostic use only



Store at 2 - 8°C



## Intended Use

Paracetamol Sera Calibrators are used to calibrate K8001, K8002 and K8003 Paracetamol Kits on automated, semi-automated analysers and manual assays.

## Kit Contents

**Paracetamol Sera Calibrator Kit – REF: K8100**

**CAL 1**

4 vials: **0 mmol/L** (0 mg/L) Sera Calibrator  
0.5 mL each (ready-to-use)

**CAL 2**

4 vials: **2 mmol/L** (302 mg/L) Sera Calibrator  
0.5 mL each (ready-to-use)

1 instruction leaflet

## Storage

The Paracetamol Sera Calibrators should be stored at **2 - 8°C**. The reagents are stable until the expiry date given on the bottle. Do not freeze.

Do not expose the reagents to heat, sun, and strong light during storage and use.

## Warnings and Precautions

For *in vitro* diagnostic use only  
For Professional Use only.

Carefully read instructions for use. Deviations from the described procedure may alter the performance.

## Composition

Human based Paracetamol Sera Calibrators with preservatives.

## Assay Procedure

Before each use, mix by gently inverting the vial. Avoid bubbles before placing on the analysers.

### Refer to the relevant product instruction for use.

Replace the calibrator provided in the K8001, K8002 and K8003 Paracetamol Kits with these sera calibrators.

For automated analyser protocols, change the settings to 2 point calibration with **CAL 1** set to **0mmol/L** (0mg/L) and **CAL 2** set to **2mmol/L** (302mg/L).

Protocols are available for most clinical chemistry automates. Please contact Customer Services at Cambridge Life Sciences or your local distributor for further information. Current versions of the protocols can be obtained from our website; [www.cambridgelifesciences.co.uk](http://www.cambridgelifesciences.co.uk) and it is advised that the user confirms that the current version is being used.

## Safety Precautions

The product is not hazardous under EU specification. Safety data sheets are available on request from your local representative.

The calibrators contain human source material. Although found negative when tested for HIV-1 and HIV-2 antibodies, HCV and hepatitis B surface antigen, no test can guarantee their absence. Therefore, the calibrators should be handled using the same safety precautions employed when handling any potentially infectious material.

Used calibrators should be handled as clinical waste and incinerated or disposed of in accordance with local rules. It is recommended that gloves are worn when handling such items.

### Handling Precautions

Do not use the kit beyond the expiry date given on the label. Unused calibrators are stable at 2 - 8°C for 1 month after first opening the container. However, multiple re-use could increase the risk of reagent contamination.

Do not interchange the colour coded caps as contamination may occur and compromise results.

Always change pipette tips between different samples to prevent sample carryover and never allow the same pipette tip to be used with different reagents.

The test protocol must be strictly adhered to.

### Quality Control

Good laboratory practice requires that quality control specimens be included in every run to monitor assay performance. The quality control samples should be assayed repeatedly to establish mean values and working ranges. A minimum of two level controls spanning the medical decision range is recommended to be run daily. If quality control results do not meet acceptance criteria then recalibration may be necessary.



### Calibrator Standardisation

Paracetamol 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.

### Manufactured by

Cambridge Life Sciences Ltd.  
14 St. Thomas' Place  
Ely, Cambridgeshire CB7 4EX, UK

K5061.02  
Mar '17