

ACET2 calibrator

REF 07007515 190

1 x 2 mL Calibrator

English

System information

For use on Roche/Hitachi **cobas c** analyzers the calibrator code is 670.

For use on COBAS INTEGRA analyzers the system-ID is 0775649.

Intended use

ACET2 calibrator is for use in the calibration of the Acetaminophen Gen.2 Roche assay.

Summary

The ACET2 calibrator is prepared to contain a known quantity of acetaminophen in buffer. The calibrator is used to establish a standard curve from which the quantity of acetaminophen in unknown specimens can be determined.

Reagents – working solutions

Reactive components: 200 µg/mL Acetaminophen in phosphate buffer.

Non-reactive components: Preservatives.

The exact calibrator values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed calibrator barcode sheets for COBAS INTEGRA analyzers.

For the **cobas c** analyzers the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Traceability

The ACET2 calibrator is prepared by adding a quantity of acetaminophen in buffer and is traceable to USP.

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

For USA: For prescription use only.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling primarily follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Calibrator handling

The product is ready-for-use. Prior to use swirl bottle carefully to obtain a homogenous solution. Record the date that the bottle was opened on the relevant bottle label.

The enclosed barcoded labels are intended exclusively for **cobas c** systems to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

Storage and stability

Store at 2-8 °C. **Do not freeze.**

Store calibrator tightly capped (and protected from light) when not in use.

The calibrator may be used until the expiration date when stored at 2-8°C. Gross precipitation may result from exposure to extremes of temperature and may indicate component deterioration. Any calibrators with gross precipitation should not be used.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Use ACET2 calibrator as specified in the relevant Method Sheet for the system reagents.

Follow the applicable government regulations and local guidelines for quality control.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

	Contents of kit
	Calibrator
	Volume after reconstitution or mixing
	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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