

## Order information

REF	CONTENT	Analyzer(s) on which <b>cobas c</b> pack(s) can be used
04851013 190	Instrument Check (65 tests)	System-ID 07 6933 9 Roche/Hitachi <b>cobas c</b> 311, <b>cobas c</b> 501/502
20757144 322	Check Solution Sample	

## English

## System information

For **cobas c** 311/501 analyzers:

**CHKS:** ACN 473 (check of sample pipetting)

**CHKR1:** ACN 474 (check of R1 pipetting)

**CHKR2:** ACN 475 (check of R2 pipetting)

For **cobas c** 502 analyzer:

**CHKS:** ACN 8473 (check of sample pipetting)

**CHKR1:** ACN 8474 (check of R1 pipetting)

**CHKR2:** ACN 8475 (check of R2 pipetting)

## Intended use

Test for accuracy and precision of sample and reagent pipetting with dye solution and saline solution on Roche/Hitachi **cobas c** systems.

## Summary

Check Test Sample (CHKS):

Sample (diluted Check Solution Sample) and R3 (sodium chloride solution) are pipetted and absorbance is measured by the instrument. Mean and CV of 21 determinations are calculated and compared to the specifications given below (accuracy and precision).

Check Test R1 (CHKR1):

Dye solution (R1) and water are pipetted to sample (water) and absorbance is measured by the instrument. Mean and CV of 21 determinations are calculated and compared to the specifications given below (accuracy and precision).

Check Test R2 (CHKR2):

Dye solution (R2) and water are pipetted to sample (water) and absorbance is measured by the instrument. Mean and CV of 21 determinations are calculated and compared to the specifications given below (accuracy and precision).

## Test principle

Sample and reagent are pipetted and mixed, and the absorbance is measured photometrically.

## Reagents - working solutions

**R1** Orange G: 45 mg/L; TRIS: 3 g/L, pH 7.5; Tween 80: 0.25 g/L; preservatives

**R2** Orange G: 45 mg/L; TRIS: 3 g/L, pH 7.5; Tween 80: 0.25 g/L; preservatives

**R3** Sodium chloride: 1.54 mol/L

## 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: Caution: Federal law restricts this device to sale by or on the order of a physician.

## Reagent handling

Ready for use

## Storage and stability

## INSTC

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 7 days

## Specimen collection and preparation

Sample:

Check Solution Sample

Ingredients: Orange G: 5.2 g/L; TRIS: 3 g/L; Bovine serum albumin: 40 g/L; preservative

Before measurement of the Check Test Sample dilute the Check Solution Sample exactly 1 + 9 with distilled/deionized water.

Stability of dilution: 1 day at 15-25 °C. Store in a closed container.

## Materials provided

See "Reagents – working solutions" section for reagents.

## Materials required (but not provided)

See "Order information" section

General laboratory equipment

## Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

## Applications

**cobas c 311 test definition CHKS**

Assay type	1 Point		
Reaction time/Assay points	7 / 30		
Wavelength (sub/main)	660/480 nm		
Reaction direction	Increase		
Units	mABS		
Reagent pipetting		Diluent (H <sub>2</sub> O)	
R3	150 µL	–	
<i>Sample volume</i>	<i>Sample</i>	<i>Sample dilution</i>	
		Sample	Diluent (H <sub>2</sub> O)
Normal	2.0 µL	–	–

**cobas c 501/502 test definition CHKS**

Assay type	1 Point		
Reaction time/Assay points	7 / 45		
Wavelength (sub/main)	660/480 nm		
Reaction direction	Increase		
Units	mABS		
Reagent pipetting		Diluent (H <sub>2</sub> O)	
R3	150 µL	–	
<i>Sample volume</i>	<i>Sample</i>	<i>Sample dilution</i>	
		Sample	Diluent (H <sub>2</sub> O)
Normal	2.0 µL	–	–

**cobas c 311 test definition CHKR1**

Assay type	1 Point
Reaction time/Assay points	4 / 14
Wavelength (sub/main)	660/480 nm
Reaction direction	Increase
Units	mABS

Reagent pipetting		Diluent (H <sub>2</sub> O)	
R1	80 µL	100 µL	
<i>Sample volume</i>	<i>Sample</i>	<i>Sample dilution</i>	
		Sample	Diluent (H <sub>2</sub> O)
Normal	15.0 µL	–	–

**cobas c 501/502 test definition CHKR1**

Assay type	1 Point		
Reaction time/Assay points	3 / 20		
Wavelength (sub/main)	660/480 nm		
Reaction direction	Increase		
Units	mABS		
Reagent pipetting		Diluent (H <sub>2</sub> O)	
R1	80 µL	100 µL	
<i>Sample volume</i>	<i>Sample</i>	<i>Sample dilution</i>	
		Sample	Diluent (H <sub>2</sub> O)
Normal	15.0 µL	–	–

**cobas c 311 test definition CHKR2**

Assay type	1 Point		
Reaction time/Assay points	6 / 25		
Wavelength (sub/main)	660/480 nm		
Reaction direction	Increase		
Units	mABS		
Reagent pipetting		Diluent (H <sub>2</sub> O)	
R2	40 µL	140 µL	
<i>Sample volume</i>	<i>Sample</i>	<i>Sample dilution</i>	
		Sample	Diluent (H <sub>2</sub> O)
Normal	15.0 µL	–	–

**cobas c 501/502 test definition CHKR2**

Assay type	1 Point		
Reaction time/Assay points	6 / 36		
Wavelength (sub/main)	660/480 nm		
Reaction direction	Increase		
Units	mABS		
Reagent pipetting		Diluent (H <sub>2</sub> O)	
R2	40 µL	140 µL	
<i>Sample volume</i>	<i>Sample</i>	<i>Sample dilution</i>	
		Sample	Diluent (H <sub>2</sub> O)
Normal	15.0 µL	–	–

**Calibration**

Calibrator	S1: H <sub>2</sub> O (concentration 0.0)
Calibration mode	Linear Calibration is not performed. Calibration values 0 for S1 ABS and 10000 for K-Factor are entered manually.

**Specifications of performance**

Refer to target values for accuracy given on the **cobas c** pack (standardized for each new lot).

	Recovery of target value	CV
CHKS	+/- 8 %	≤ 1.5 %

	Recovery of target value	CV
CHKR1	+/- 5 %	≤ 0.5 %
CHKR2	+/- 5 %	≤ 1.0 %

Note: In case the target values are not reached the respective precision run (n = 21) has to be repeated.

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 (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

**CONTENT**

Contents of kit



Volume after reconstitution or mixing

**GTIN**

Global Trade Item Number

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