

START

Antigen Excess Reagent

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
08059322190	Antigen Excess Reagent (1000 tests)	System-ID 2008 001 cobas c 303, cobas c 503

English

System information

START: ACN 20080

Intended use

In vitro reagent for the detection of antigen excess in human samples to be used in conjunction with the corresponding immunoturbidimetric assay reagent on Roche/Hitachi **cobas c** systems.

Test principle

After completion of the turbidimetric reaction, the antigen excess reagent is added as a third reagent and the resulting absorbance change evaluated.

Reagent – working solutions

Antigen Excess Reagent

Albumin in diluted serum (human); NaCl: 150 mmol/L; phosphate buffer: 50 mmol/L, pH 7.0; preservative

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.^{1,2}

Reagent handling

Ready for use

Storage and stability

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

On-board in use and refrigerated on the analyzer: 26 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

For details see Method Sheet of the corresponding assay.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

cobas c pack green of the corresponding assay

See appropriate Method Sheet for additional required materials.

Assay

For optimum performance of the assay follow the directions given in the Method Sheet of the corresponding assay. 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.

Performance data

See Method Sheet of the corresponding assay.

References

- 1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.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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Additions, deletions or changes are indicated by a change bar in the margin.

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