BECKMAN COULTER

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Instructions For Use

ITA 3
ITA Control Serum 3

REF ODC0016 6 x 2 mL (blue cap)

For *in vitro* diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The ITA Control Serum is a liquid human serum control intended to be used in-conjunction with ITA Control Sera ODC0014 and ODC0015 to monitor the analytical performance of the Beckman Coulter system reagents listed in the table below on Beckman Coulter analysers.

Reagent	Cat. No.	Reagent	Cat. No.
α-1 acidglycoprotein	OSR6162	Ferritin	OSR61203
α-1 antitrypsin	OSR6163	Haptoglobin	OSR6165
ASO	OSR6194	IgA	OSR61171
β-2 microglobulin	OSR6151	IgG	OSR61172
Ceruloplasmin	OSR6164	IgM	OSR61173
C3	OSR6159	Prealbumin	OSR6175
C4	OSR6160	RF Latex	OSR61105
CRP	OSR6147	Transferrin	OSR6152
CRP Latex	OSR6199		

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents, this product should be handled as a potentially infectious material.

REACTIVE INGREDIENTS

The ITA Control Serum is human serum based, containing the following constituents of human origin:

α-1 acidglycoprotein	Ferritin
α-1 antitrypsin	Haptoglobin
Anti-Streptolysin O	Immunoglobulin A
β-2 microglobulin	Immunoglobulin G
Ceruloplasmin	Immunoglobulin M
Complement 3	Prealbumin
Complement 4	Rheumatoid Factor
C-reactive protein	Transferrin

Also contains preservatives and stabilisers.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

STORAGE AND STABILITY

The control is stable, unopened, up to the stated expiry date when stored at 2…8°C. Once open, the control is stable for 30 days, provided it is free from contamination, tightly capped immediately after each use and stored at 2…8°C.

QUALITY CONTROL

CONTROL PREPARATION

The control is ready for use. Gently invert the vial several times prior to each use to ensure a homogeneous mixture. It is recommended to record the date the control was opened on the bottle label.

ASSAY VALUES

Refer to table of means and ranges.

Mean analyte values for ITA Control Serum have been assigned using appropriate variations in Beckman Coulter analyser, reagent and calibrator combinations that allow traceability to the relevant reference materials listed in the corresponding calibrator leaflets.

TESTING PROCEDURE(S)

Refer to relevant product instructions for use.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the enclosed table.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

ADDITIONAL INFORMATION

The lot number on the vial is the same as the one listed in the table on the value assign sheet.

The selected value is appropriate for the units on the analyzer parameter settings.

REVISION HISTORY

IFU updated to add Vietnamese language.

Updated INTENDED USE section

Updated Warning and Precautions section

Updated Additional Information section

Preceding version revision history

Added Revision History

Revised GHS section

Added new language requirement: Norwegian.

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