BECKMAN COULTER

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Instructions For Use

Control Serum L2
CONTROL SERUM 2

REF ODC0004 20 x 5 mL (red cap)

For *in vitro* diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Control Serum 2 is a lyophilised human serum control intended to be used in-conjunction with the Control Serum 1 ODC0003 to monitor the analytical performance of the Beckman Coulter system reagents listed in the enclosed table on Beckman Coulter analysers.

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.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Lyophilised human serum with chemical additives and appropriate enzymes of human and animal origin. The serum also contains preservatives and stabilisers.

Note: These analyte concentrations are lot dependent and are listed in the enclosed table.

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 reconstituted the control is stable according to the reconstitution stability table below, provided it is free from contamination, tightly capped immediately after each use and stored at 2…8°C.

Note: Bacterial contamination produces a characteristic odour and a decrease in the glucose level, if observed discard the vial.

Reconstituted Stability	2…8°C	**-20°C****
Bilirubin-Total and Direct (Protect from light)	24 hours	5 days
Cholinesterase	24 hours	2 days
*ACP	24 hours	1 month
ALP, ALT, Amylase, AST, CK-NAC, GGT, GLDH, HBDH, LDH, Lipase, Inorganic Phosphorus, Triglyceride	2 days	1 month
Albumin, Calcium, Chloride, Cholesterol, Creatinine, Glucose, Iron, Lactate, Lithium, Magnesium, Potassium, Sodium, Total Protein, UIBC, Urea & Uric Acid, IgA, IgG, IgM, APO A1, APO B.	7 days	1 month

* ACP stabiliser provided in the reagent kit should not be added to this control.

**When frozen once.

QUALITY CONTROL

CONTROL PREPARATION

1. Allow the vial to equilibrate to room temperature before opening to prevent condensation in the vial.
2. Tap the top of the vial before opening to dislodge any lyophilisate caught in the stopper. Open the vial gently to prevent any loss of lyophilisate.
3. Add to the vial, fresh deionised water equilibrated to room temperature, (Approx. 20°C). Use a calibrated pipette that can accurately dispense 5.0 mL - weigh if unsure
4. Invert the vial 3 times and then leave to stand for 10 minutes. Dissolve the contents completely by gently mixing on a roller for 30 minutes. Do not shake the vial as this will cause foaming.
5. Continue mixing until the solution is homogenous and all the lyophilised material is reconstituted.
6. Record the date the vial was reconstituted on the bottle label. Store at 2…8°C.

Note: For determination of Alkaline Phosphatase, it is recommended that the reconstituted serum be allowed to stand for at least 2 hours at 2…8°C before use.

ASSAY VALUES

Refer to table of means and acceptable ranges.

Value assignment has been carried out using the Beckman Coulter System. These values represent the mean of either five-fold determinations from at least five independent series or three-fold determinations from at least eight independent series.

The ranges represent the maximum permissible deviation of a single determination according to Rilibäk.[1] For the analytes not listed in Rilibäk the ranges are given as +/-20% of the target mean value.

When using the analyser quality control software for surveillance of assay performance the analyte specific standard deviations have to be determined by each laboratory. These standard deviations cannot be deduced from the stated acceptable ranges.

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/blanking 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.

Please ensure that the lot number on the control vial is the same as the one listed in the enclosed table.

ADDITIONAL INFORMATION

REVISION HISTORY

IFU updated to add Vietnamese language.

Updated Warning and Precautions section

Updated Additional Information section

Preceding version revision history

Added Revision History

Updated Warning and Precautions section

Updated GHS hazard classification

REFERENCES

1. Richtlinien der Bundesärztekammer, DG Klinische Chemie Mitteilungen 2001;32(6).

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