

CSF CONTROL - LEVEL 2 (CSF CONTROL 2)

CAT NO. CF 1500 **LOT NO.** 083CF
SIZE: 10 x 3 ml **EXPIRY:** 2018-07

INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of diagnostic methods using CSF as a sample on clinical chemistry systems. The CSF controls are for the control of accuracy.

DEVICE DESCRIPTION

The CSF controls are supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the following analytes at both levels: Chloride, Glucose, IgG, Lactic Acid, Sodium and Total Protein (Pyrogallol Red). % Total Protein is quoted for Electrophoresis regions at both levels: Albumin, Alpha-1-Globulin, Alpha-2-Globulin, Beta Globulin and Gamma Globulin.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted CSF control material is stable for 14 days at +2°C to +8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

PREPARATION FOR USE

The CSF Control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised CSF control with exactly 3 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

CSF Control - Level 2 10 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Values are assigned internally at Randox Laboratories Ltd., in comparison to a master lot of control material.

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Range

| Analyte | unit | Target | low | high | methods |
|------------------------------------|--------|--------|-------|-------|-------------------------|
| Albumin (electrophoresis) | | 59.3 | 53.4 | 65.2 | % of total Protein |
| alpha-1-globulin (electrophoresis) | | 4.1 | 3.1 | 5.1 | % of total Protein |
| alpha-2-globulin (electrophoresis) | | 7.0 | 5.3 | 8.7 | % of total Protein |
| beta-globulin (electrophoresis) | | 12.0 | 9.1 | 14.9 | % of total Protein |
| gamma-globulin (electrophoresis) | | 17.7 | 13.5 | 21.9 | % of total Protein |
| Chloride | mmol/l | 88.4 | 81.3 | 95.5 | Ion selective electrode |
| Glucose | mmol/l | 3.26 | 2.77 | 3.75 | Glucose oxidase |
| | mg/dl | 58.7 | 49.9 | 67.5 | |
| | mmol/l | 3.13 | 2.66 | 3.60 | Hexokinase |
| | mg/dl | 56.4 | 47.9 | 64.9 | |
| Immunoglobulin G | mg/l | 52.7 | 43.2 | 62.2 | Immunoturbidimetric |
| Lactate | mmol/l | 0.45 | 0.37 | 0.53 | Enzymatic |
| | mg/dl | 4.01 | 3.29 | 4.73 | |
| Protein Total | g/l | 0.358 | 0.286 | 0.430 | Pyrogallol Red |
| | mg/dl | 35.8 | 28.6 | 43.0 | |
| | mg/l | 358 | 286 | 430 | |
| Sodium | mmol/l | 129 | 122 | 135 | Ion selective electrode |