

DRUG CONTROL - LEVEL 3 (TDM CONTROL 3)

CAT NO. HD1669 **LOT NO.** 793DC
SIZE: 20 x 5ml **EXPIRY:** 2022-02-28
GTIN: 05055273203592

INTENDED USE

This product is intended for in-vitro diagnostic use in the quality control of drug residue analysis on clinical chemistry systems. The Drug Controls are for the control of accuracy and precision.

DEVICE DESCRIPTION

The Drug Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at 3 levels.

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 which has been added 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 serum is stable for 4 weeks 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 Drug Controls are supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 5ml 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.
- Refer to the control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Drug Control Level 3 20 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette

ASSIGNED VALUES

Each batch of serum is distributed to approximately 250 laboratories and values are assigned by a consensus of results obtained by these laboratories. A control range for individual parameters and for each parameter method is provided for each batch of serum. The control range is equivalent to the assigned mean ± 2 S.D.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com

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DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 793DC Size 20 x 5ml Expiry 2022-02-28

| Analyte | unit | Target | Range | | methods |
|---------------|--------|--------|-------|------|--------------------------------|
| | | | low | high | |
| Amikacin | µmol/l | 46.3 | 37.0 | 55.6 | Enzyme Immunoassay |
| | µg/ml | 27.1 | 21.7 | 32.5 | |
| | µmol/l | 45.1 | 36.1 | 54.1 | Polarisation Fluoroimmunoassay |
| | µg/ml | 26.4 | 21.1 | 31.7 | |
| | µmol/l | 45.4 | 36.3 | 54.5 | KIMS |
| | µg/ml | 26.6 | 21.3 | 31.9 | |
| Caffeine | µmol/l | 48.1 | 38.5 | 57.7 | Turbidimetric |
| | µg/ml | 28.2 | 22.5 | 33.9 | |
| Caffeine | µmol/l | 73.6 | 55.2 | 92.0 | Enzyme Immunoassay |
| | µg/ml | 14.3 | 10.7 | 17.9 | |
| Carbamazepine | µmol/l | 70.0 | 56.0 | 84.0 | Enzyme Immunoassay |
| | µg/ml | 16.5 | 13.2 | 19.8 | |
| | µmol/l | 69.8 | 55.8 | 83.8 | Polarisation Fluoroimmunoassay |
| | µg/ml | 16.5 | 13.2 | 19.8 | |
| | µmol/l | 59.7 | 47.8 | 71.6 | Chemiluminescence |
| | µg/ml | 14.1 | 11.3 | 16.9 | |
| Carbamazepine | µmol/l | 59.4 | 47.5 | 71.3 | Turbidimetric |
| | µg/ml | 14.0 | 11.2 | 16.8 | |
| Carbamazepine | µmol/l | 64.0 | 51.2 | 76.8 | KIMS |
| | µg/ml | 15.1 | 12.1 | 18.1 | |
| Cyclosporin | nmol/l | 550 | 440 | 660 | Chemiluminescence |
| | ng/ml | 661 | 529 | 793 | |
| Digoxin | nmol/l | 3.31 | 2.65 | 3.97 | Chemiluminescence |
| | ng/ml | 2.59 | 2.07 | 3.11 | |
| | nmol/l | 3.56 | 2.85 | 4.27 | Enzyme Immunoassay |
| | ng/ml | 2.78 | 2.23 | 3.33 | |
| | nmol/l | 3.49 | 2.79 | 4.19 | KIMS |
| | ng/ml | 2.73 | 2.18 | 3.28 | |
| Digoxin | nmol/l | 3.48 | 2.78 | 4.18 | Turbidimetric |
| | ng/ml | 2.72 | 2.17 | 3.27 | |
| Ethosuximide | µmol/l | 894 | 805 | 983 | HPLC (Reverse Phase) |
| | µg/ml | 127 | 114 | 140 | |
| Gentamicin | µmol/l | 15.6 | 12.5 | 18.7 | Enzyme Immunoassay |
| | µg/ml | 7.46 | 5.98 | 8.94 | |
| | µmol/l | 14.5 | 11.6 | 17.4 | Polarisation Fluoroimmunoassay |
| | µg/ml | 6.93 | 5.54 | 8.32 | |
| | µmol/l | 16.3 | 13.0 | 19.6 | Chemiluminescence |
| | µg/ml | 7.79 | 6.21 | 9.37 | |
| Gentamicin | µmol/l | 18.4 | 14.7 | 22.1 | Turbidimetric |
| | µg/ml | 8.80 | 7.03 | 10.6 | |
| Gentamicin | µmol/l | 11.9 | 9.52 | 14.3 | KIMS |
| | µg/ml | 5.69 | 4.55 | 6.83 | |

DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 793DC Size 20 x 5ml Expiry 2022-02-28

| Analyte | unit | Target | Range | | methods |
|------------------|--------|--------|-------|------|--------------------------------|
| | | | low | high | |
| Lithium | mmol/l | 1.79 | 1.58 | 2.00 | Ion selective electrode |
| | mg/dl | 1.24 | 1.10 | 1.38 | |
| | mmol/l | 1.74 | 1.53 | 1.95 | Spectrophotometric |
| | mg/dl | 1.21 | 1.06 | 1.36 | |
| Lithium (Vitros) | mmol/l | 2.20 | 1.76 | 2.64 | Vitros |
| | mg/dl | 1.53 | 1.22 | 1.84 | |
| Methotrexate | µmol/l | 8.60 | 6.88 | 10.3 | Enzyme Immunoassay |
| | µg/ml | 3.91 | 3.13 | 4.69 | |
| | µmol/l | 7.93 | 6.34 | 9.52 | Chemiluminescence |
| | µg/ml | 3.60 | 2.88 | 4.32 | |
| Paracetamol | mmol/l | 1.42 | 1.14 | 1.70 | Vitros |
| | mg/l | 215 | 172 | 258 | |
| | mmol/l | 1.27 | 1.02 | 1.52 | Colorimetric |
| | mg/l | 192 | 154 | 230 | |
| | mmol/l | 1.42 | 1.14 | 1.70 | Polarisation Fluoroimmunoassay |
| | mg/l | 215 | 172 | 258 | |
| | mmol/l | 1.31 | 1.05 | 1.57 | Enzymatic |
| | mg/l | 198 | 159 | 237 | |
| | mmol/l | 1.49 | 1.19 | 1.79 | Turbidimetric |
| | mg/l | 225 | 180 | 270 | |
| Phenobarbital | µmol/l | 221 | 177 | 265 | Enzyme Immunoassay |
| | µg/ml | 51.3 | 41.1 | 61.5 | |
| | µmol/l | 201 | 161 | 241 | Polarisation Fluoroimmunoassay |
| | µg/ml | 46.6 | 37.4 | 55.8 | |
| | µmol/l | 206 | 165 | 247 | Turbidimetric |
| | µg/ml | 47.8 | 38.3 | 57.3 | |
| | µmol/l | 210 | 168 | 252 | Chemiluminescence |
| | µg/ml | 48.7 | 39.0 | 58.4 | |
| | µmol/l | 201 | 161 | 241 | KIMS |
| | µg/ml | 46.6 | 37.4 | 55.8 | |
| Phenytoin | µmol/l | 96.2 | 77.0 | 115 | Enzyme Immunoassay |
| | µg/ml | 24.3 | 19.4 | 29.2 | |
| | µmol/l | 90.0 | 72.0 | 108 | Polarisation Fluoroimmunoassay |
| | µg/ml | 22.7 | 18.2 | 27.2 | |
| | µmol/l | 88.7 | 71.0 | 106 | Turbidimetric |
| | µg/ml | 22.4 | 17.9 | 26.9 | |
| | µmol/l | 88.0 | 70.4 | 106 | Chemiluminescence |
| | µg/ml | 22.2 | 17.8 | 26.6 | |
| µmol/l | 90.0 | 72.0 | 108 | KIMS | |
| µg/ml | 22.7 | 18.2 | 27.2 | | |
| Primidone | µmol/l | 57.0 | 45.6 | 68.4 | Polarisation Fluoroimmunoassay |
| | µg/ml | 12.4 | 9.95 | 14.9 | |
| Salicylic Acid | mmol/l | 2.86 | 2.29 | 3.43 | Vitros |
| | mg/dl | 39.5 | 31.6 | 47.4 | |
| | mmol/l | 2.69 | 2.15 | 3.23 | Colorimetric Trinder |
| | mg/dl | 37.2 | 29.7 | 44.7 | |

DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 793DC Size 20 x 5ml Expiry 2022-02-28

| Range | | | | | |
|----------------|--------|--------|------|-------------------|--------------------------------|
| Analyte | unit | Target | low | high | methods |
| Salicylic Acid | mmol/l | 2.70 | 2.16 | 3.24 | Enzymatic |
| | mg/dl | 37.3 | 29.8 | 44.8 | |
| Theophylline | µmol/l | 150 | 120 | 180 | Chemiluminescence |
| | µg/ml | 27.0 | 21.6 | 32.4 | |
| | µmol/l | 171 | 137 | 205 | Enzyme Immunoassay |
| | µg/ml | 30.8 | 24.7 | 36.9 | |
| | µmol/l | 170 | 136 | 204 | Polarisation Fluoroimmunoassay |
| | µg/ml | 30.6 | 24.5 | 36.7 | |
| | µmol/l | 169 | 135 | 203 | Turbidimetric |
| | µg/ml | 30.5 | 24.3 | 36.7 | |
| µmol/l | 161 | 129 | 193 | KIMS | |
| µg/ml | 29.0 | 23.2 | 34.8 | | |
| Tobramycin | µmol/l | 16.1 | 12.9 | 19.3 | Enzyme Immunoassay |
| | µg/ml | 7.53 | 6.04 | 9.02 | |
| | µmol/l | 15.9 | 12.7 | 19.1 | Turbidimetric |
| µg/ml | 7.44 | 5.94 | 8.94 | | |
| Valproic Acid | µmol/l | 987 | 790 | 1184 | Enzyme Immunoassay |
| | µg/ml | 142 | 114 | 170 | |
| | µmol/l | 930 | 744 | 1116 | Polarisation Fluoroimmunoassay |
| | µg/ml | 134 | 107 | 161 | |
| | µmol/l | 950 | 760 | 1140 | Chemiluminescence |
| | µg/ml | 137 | 110 | 164 | |
| Vancomycin | µmol/l | 899 | 719 | 1079 | Turbidimetric |
| | µg/ml | 130 | 104 | 156 | |
| | µmol/l | 17.0 | 13.6 | 20.4 | Enzyme Immunoassay |
| | µg/ml | 25.3 | 20.2 | 30.4 | |
| | µmol/l | 21.5 | 17.2 | 25.8 | Polarisation Fluoroimmunoassay |
| | µg/ml | 31.9 | 25.6 | 38.2 | |
| µmol/l | 18.8 | 15.0 | 22.6 | Chemiluminescence | |
| µg/ml | 27.9 | 22.3 | 33.5 | | |
| µmol/l | 17.9 | 14.3 | 21.5 | Turbidimetric | |
| µg/ml | 26.6 | 21.2 | 32.0 | | |