

ST-EUM08055(eng)

Rev: 0

Data: 28.09.2021

EUM08055 – 2-Levels Controls, lyophil.

LYOPHILIZED CONTROLS
FOR DRUGS OF ABUSE IN WHOLE BLOOD

Ref. EUM08055 Lot. M0855XXXX

IVD



Intended use:

Lyophilized controls (EUM08055), based on lyophilized human whole blood to which an aliquot of solutions containing drugs and metabolites is added before use, are used to verify the accuracy and precision of the analytical procedures for their quantitative determination. After following reconstitution instructions, calibrators should be handled in the same way as real samples.

Reconstitution and spinking:

Centrifuge 2 min at 10-12000 rpm screw-cap vials containing solutions of concentrated control solutions. Carefully remove the rubber cup from the vial and add exactly 0.6 mL of bi-distilled water. Close the vials and allow it to stand at room temperature for 10-15 min. Its content should be shaken and melted until completely blended. At each calibration level, 20 µL taken from the corresponding solutions contained in the screw cap tubes are added. After the spike allow the vials to equilibrate for 15 minutes. In order to ensure a proper homogenization, mix gently for reversal before use.

Storage and stability:

Storage: stock at -20 °C avoiding direct light and heat exposure. Stability:

- Before reconstitution: until the expiry date on the label has been reached.

- After reconstitution: 24 h if well closed and avoided direct light exposure at +2 - 8 °C

Values assignment:

Average values and acceptability ranges are determined from a representative sample of this batch' controls. These values are specific only for calibrators of this batch. Average values and acceptability ranges should be established by every laboratory according to instruments, reagents and intra-lab changes. They may vary slightly due to reagents and procedural modifications.

Packaging:

Controls:

Lyophilized human whole blood – Drugs of Abuse in Whole Blood; 2 Levels (Low - High), $3 \times 2 \times 0.6$ mL

Liquid concentrated controls – Drugs of Abuse in Whole Blood; 2 Levels (Low - High), 1 x 2 x 100 μ L Catalogue number: EUM08055



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Precautions for use:

After some analysis, original components have been found negative for HBsAG and for antibodies against HCV, HBc, HIV-1 and HIV-2. This product may contain unknown infectious agents and for this reason, it's recommended to handle the product using adequate safety measures.

Calibration levels and concentrations after spiking with concentrated solutions*:

ANALYTE	UNIT OF MEASUREMENT	LOW	RANGE	HIGH	RANGE
Amphetamines					
Amphetamine	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Methamphetamine	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
MDA	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
MDE	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
MDMA	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
MBDB	μg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Cocaine-Metabolites					
Cocaine	μg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
BEG	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
EME	μg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Coca ethylene	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Opiates					
Morphine	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Codeine	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Dihydrocodeine	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
6-MAM	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Cannabinoids					
THC	µg/L	2.50	2.00 - 3.00	12.5	10.0 - 15.0
THC-OH	µg/L	2.50	2.00 - 3.00	12.5	10.0 - 15.0
THC-COOH	µg/L	2.50	2.00 - 3.00	12.5	10.0 - 15.0
Substitution drugs					
Methadone	µg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
EDDP	μg/L	12.5	10.0 - 15.0	62.5	50.0 - 75.0
Buprenorphine	µg/L	2.50	2.00 - 3.00	12.5	10.0 - 15.0
Norbuprenorphine	µg/L	2.50	2.00 - 3.00	12.5	10.0 - 15.0
Other					
Ketamine	µg/L	12.5	10.0 - 15.0	12.5	10.0 - 15.0
LSD	μg/L	0.25	0.20 - 0.30	1.25	1.00 - 1.50

^{*} The above-mentioned concentrations are referred exclusively to EUM08055 lot M0855XXXX expiring on XX/XXXX.