MultiTox, Fentanyl, & Cotinine

LIQUID CONTROL URINE

INTENDED USE:
The MultiTox Liquid control is an In Vitro Diagnostic (IVD) device, for prescription use only that is intended for use as quality control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in the package insert.

SUMMARY AND EXPLANATION:
The DEA exempt MultiTox product line of controls is manufactured using a human based matrix that has been stabilized to ensure that the product will be viable until the date of expiration. Positive controls are spiked with reference drug standards and/or appropriate metabolites that have been obtained from certified manufacturers. Standards are certified by the manufacturers to be at least 98% minimum purity. Specific gravity, pH, and creatinine fall within the limits of normal human urine.

DESCRIPTION:
Each bottle contains stabilized human based urine. Positive control urines have been spiked with authentic reference drug standards and/or appropriate metabolites. Negative control urines are certified negative by combination of Immunoassay, GC/MS and/or LC/MS for the constituents listed on our target sheets. *They should be treated as any "unknown" specimen while following the specific protocol of the assay being used. This product is intended to be used by health care professionals as an integral part of good laboratory practices.*

STORAGE & STABILITY - Please refer to Limitations for detailed instructions.

Unopened:
A. The controls are stable until the expiration date when stored at -10° to -20°C and protected from light.
B. The controls are stable until the expiration date when stored at 2° to 8°C, however Oxazepam is stable for only 6 months.

After Opening:
A. The controls are stable for six months or until the expiration date, whichever comes first, when stored at -10° to -20°C. (Controls can be thawed/frozen up to 5 times)
B. The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2° to 8°C.
C. Thaw controls as needed; allow to come to room temperature followed by gentle swirling before use.

PROCEDURE:
Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE. Transfer an appropriate aliquot of MultiTox control urine as required by the drugs of abuse test device or screening method

EXPECTED RESULTS:
The positive MultiTox control must test positive on the drugs of abuse test device or screening method. The negative control must test negative. Biochemical Diagnostics will (upon request), supply assay values derived from our contract assay laboratories and customer base on a particular lot of control material**.**

PRECAUTIONS:
For In Vitro Diagnostic Use Only. Please read the entire package insert before using the MultiTox control urines. Please use the same safety precautions you would use for processing any "unknown" urine sample containing potentially infectious biological material. Protect product from exposure to direct sunlight. Contains sodium azide: To prevent formation of explosive metal azides dispose of waste by flushing with copious amounts of water or according to local governing regulations.
Do not use beyond the expiration date.

LIMITATIONS OF PROCEDURE:
This control is meant to be used to validate the performance of immunoassay drug screening methods. Consult test manufacturer's instructions when using this product; changes in reagents, sample requirement, or methodology may affect test results. Although target values are provided with the MultiTox liquid controls, each laboratory should run these controls as unknowns in order to establish "in-house" assay values for them. *This product is not meant to be used as a standard or calibrator.*

MULTITOX CONTROLS, OXAZEPAM STABILITY:
Oxazepam has known stability problems in urine stored refrigerated, our studies indicates that Oxazepam will deteriorate when stored refrigerated for longer than 6 months.

MULTITOX CONTROLS, THC STABILITY:
MultiTox controls are stable for the length of time under the storage conditions stated in the package insert. In spite of this fact, under certain conditions, there may be observed a gradual decline in THC levels, over time, from continuous use of a single bottle of control material. This drop in THC values may occur from any THC sample (i.e. calibrators, controls, and samples). The apparent loss of THC most often occurs from handling and not from product instability.
It is well known that THC-COOH binds to surfaces, especially certain plastics[1,2] In order to minimize this adsorption loss we recommend the following when handling any sample (including MultiTox controls) which may contain THC: **1.** It is preferable to use glass pipettes or pour controls into sample cups. As an alternate, pipettors with disposable plastic tips may be used. Soft plastic transfer pipettes should be avoided. **2**. Do not rinse the pipette back and forth into the sample. **3**. Sample volume to surface area ratio should be as high as possible (i.e., when transferring, sample containers should be filled as much as possible with sample). Avoid rough surface plastic containers. **4**. When pipetting, immerse the pipette tip as little as possible into the sample solution. **5**. Do not return any unused material back into the original sample. These same guidelines should also be followed when aliquoting a control (or sample) for future use.

REFERENCES

1. Blanc JA, Manneh VA, et al.Adsorption losses from urine-based cannabinoid calibrators during routine use. Clin Chem 1993: 39:1705-1712
2. Roth KDW, Siegel NA, et al. Investigation of the effects of solution composition and container material type on the loss of 11-nor-delta 9-THC-9-carboxylic acid. J Anal Tox 1996; 20:291-300

MultiTox Liquid Control Urine

TEST	SAMHSA MANDATED	Cutoff	Negative	3X
THC	Delta-9-THC-COOH	50	0	150
COC	Benzoylecgonine	150	0	450
PCP	Phencyclidine	25	0	75
OPI/MOR	Morphine **(Low Opiate)**	300	0	3000
	Morphine **(High Opiate)**	2000	0	3000
AMP	d-Amphetamine	500	0	1500
MET	d-Methamphetamine	500	0	1500
	NON-MANDATED			
BARB	Secobarbital	300	0	900
BZO	Oxazepam	300	0	900
MTD	Methadone	300	0	900
MQL	Methaqualone	300	0	900
PPX	Propoxyphene	300	0	900
TCA	Nortriptyline	1000	0	3000
MDMA	MDMA	500	0	1500
OXY	Oxycodone	100	0	300
BUP	Buprenorphine Glucuronide	10	0	30
EDDP	EDDP	300	0	900
FEN	Norfentanyl	varies	0	60
TRA	Tramadol	200	0	600

ORDERING INFORMATION

Catalog #	Description	Size
MultiTox-PC-25E	MultiTox Urine Positive QC	25 mL
MultiTox-NC-25	MultiTox Urine Negative QC	25 mL
18007540	Detectabuse® FENTANYL POSITIVE (Norfentanyl 100ng/mL)	5mL
CLIA-COT-QC-SET	Detectabuse® COTININE, Negative and COT800ng/mL	6X5mL

Manufactured for:
CLIAwaived, Inc
2721 Loker Ave West
Carlsbad, CA 92010

Phone: (858)481-5031
Fax: (801-720-7568
Email: support@cliawaived.com
Website: www.cliawaived.com

For additional information on our other products please contact us or refer to our website.

EC REP EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands CE

PI-QP-36 Rev C. Aug 2021

SYMBOL LEGEND	
	Consult Instructions for Use
	Temperature Limits
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
REF	Product Catalog Number
	Manufacturers Identification
	Use by Date
	Caution, Consult Accompanying Documents
Rx only	For Prescription Use Only