

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 for 6 months when stored at 2° to 8°C and protected from light.

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.
- 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.

PROCEDURE:

Allow controls to come to room temperature followed by gentle swirling or inversion before use to ensure a homogeneous mixture. **DO NOT SHAKE.** Transfer an appropriate sample 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 monitor 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, 6-MAM & BUPRENORPHINE STABILITY:

These drugs have known stability problems in urine when stored refrigerated. Our studies indicates that Oxazepam, 6-MAM & Buprenorphine will deteriorate when stored refrigerated 2-8°C over time.

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

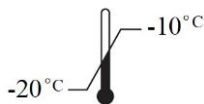
| TEST | SAMHSA MANDATED | Cutoff | Negative | 3X |
|---------------------|---------------------------|--------|---------------|------|
| THC | Delta-9-THC-COOH | 50 | None Detected | 150 |
| COC | Benzoylcegonine | 150 | None Detected | 450 |
| PCP | Phencyclidine | 25 | None Detected | 75 |
| OPI/MOR | Morphine | 1000 | None Detected | 3000 |
| AMP | d-Amphetamine | 500 | None Detected | 1500 |
| MET | d-Methamphetamine | 500 | None Detected | 1500 |
| NON-MANDATED | | | | |
| BARB | Secobarbital | 300 | None Detected | 900 |
| BZO | Oxazepam | 300 | None Detected | 900 |
| MTD | Methadone | 300 | None Detected | 900 |
| MQL | Methaqualone | 300 | None Detected | 900 |
| PPX | Propoxyphene | 300 | None Detected | 900 |
| TCA | Nortriptyline | 1000 | None Detected | 3000 |
| MDMA | MDMA | 500 | None Detected | 1500 |
| OXY | Oxycodone | 100 | None Detected | 300 |
| BUP | Buprenorphine Glucuronide | 10 | None Detected | 30 |
| EDDP | EDDP | 300 | None Detected | 900 |
| FEN | Norfentanyl | varies | None Detected | 60 |
| TRA | Tramadol | 200 | None Detected | 600 |
| FYT | Fentanyl | varies | None Detected | 5 |
| 6AM | 6-MAM | 10 | None Detected | 30 |

ORDERING INFORMATION

| CATALOG # | DESCRIPTION | SIZE |
|-----------------|----------------------------|-------|
| MultiTox-PC-25G | MultiTox Urine Positive QC | 25 mL |
| MultiTox-NC-25 | MultiTox Urine Negative QC | 25 mL |

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

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.

| SYMBOL LEGEND | |
|---------------|-----------------------------------------|
| | Consult Instructions for Use |
| | Temperature Limits |
| | In Vitro Diagnostic Medical Device |
| | Batch Code |
| | Product Catalog Number |
| | Manufacturers Identification |
| | Use by Date |
| | Caution, Consult Accompanying Documents |
| | For Prescription Use Only |