



## **SALIVABUSE<sup>®</sup> LIQUID CONTROL ORAL FLUID, ORAL-SKREEN PACKAGE INSERT**

### **INTENDED USE:**

The SALIVABUSE<sup>®</sup> ORAL-SKREEN Liquid control is an In Vitro Diagnostic (IVD) device, for prescription use only, that is intended for use as an oral fluid quality control to monitor the precision of laboratory oral fluid toxicology testing procedures for the analytes listed in the package insert.

### **SUMMARY AND EXPLANATION:**

The DEA exempt SALIVABUSE<sup>®</sup> product line of controls is manufactured using a synthetic 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.

### **DESCRIPTION:**

Each bottle contains stabilized synthetic oral fluid. Positive oral fluid controls are certified Positive by combination of screening and confirmation drug testing 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.**

#### **Unopened:**

- A. The POSITIVE controls are stable until the expiration date when stored at -20° to -10°C
- B. The NEGATIVE controls are stable until the expiration date when stored at -20° to 8°C (Do not freeze in plastic bottles)

#### **After Opening:**

- A. The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2° to 8°C.

Please store product only frozen or refrigerated as stated above; certain analytes are known to be heat labile; thus, no claims can be made if controls are not stored at the recommended storage conditions. **Maintain product in the original vials.**

### **PROCEDURE:**

Allow controls to come to room temperature followed by gentle swirling or inversion before use. **DO NOT SHAKE.** Transfer an appropriate aliquot of SALIVABUSE<sup>®</sup> control oral fluid as required by the drugs of abuse test device or screening method.

- A. Allow controls to come to room temperature followed by gentle swirling or inversion to avoid foaming before use. **DO NOT SHAKE.**
- B. Use an appropriate aliquot of SALIVABUSE<sup>®</sup> Oral Fluid control as required by the test device or screening method.
- C. To minimize adsorption loss from certain constituents, we recommend the following when handling any SALIVABUSE<sup>®</sup> control:
  - 1. Preferably, 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 vial.

*These same guidelines should also be followed when aliquoting a control (or sample) for future use.*

### **EXPECTED RESULTS:**

The positive SALIVABUSE<sup>®</sup> control must test positive on the drugs of abuse test device or screening method. The negative control must test negative.

### **PRECAUTIONS:**

**For In Vitro Diagnostic Use Only.** Please read the entire package insert before using the SALIVABUSE<sup>®</sup> control oral fluids. Please use the same safety precautions you would use for processing any "unknown" oral fluid sample. 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 drug screening testing methods. Consult test manufacturer's instructions when using this product; any changes in reagents, sample requirement, or methodology may affect test results. Although target values are provided with the SALIVABUSE<sup>®</sup> liquid controls, each laboratory should run these controls as unknowns to establish "in-house" assay values for them.

### **SALIVABUSE<sup>®</sup> CONTROLS, THC STABILITY:**

SALIVABUSE<sup>®</sup> controls are stable for the length of time under the storage conditions stated in the package insert. Despite this fact, under certain conditions, a gradual decline in THC levels may be observed 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 binds to surfaces, especially certain plastics<sup>1</sup> therefore we recommend following the procedure stated above.

### **REFERENCES**

- 1. 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.

# SALIVABUSE® Liquid Control Oral Fluid, ORAL-SKREEN

## Target Values (ng/mL)

| Test | Constituents             | NEGATIVE | 3X POSITIVE |
|------|--------------------------|----------|-------------|
| THC  | Delta-9-THC (Parent THC) | 0        | 120         |
| COC  | Cocaine (parent)         | 0        | 90          |
| COC  | Benzoyllecgonine         | 0        | 90          |
| PCP  | Phencyclidine (PCP)      | 0        | 30          |
| OPI  | Morphine                 | 0        | 120         |
| OXY  | Oxycodone                | 0        | 90          |
| AMP  | Amphetamine              | 0        | 150         |
| MDMA | MDMA                     | 0        | 150         |
| MET  | Methamphetamine          | 0        | 150         |
| BAR  | Secobarbital             | 0        | 150         |
| BZO  | Oxazepam                 | 0        | 150         |
| MTD  | Methadone                | 0        | 90          |
| COT  | Cotinine                 | 0        | 90          |
| ALC  | Ethanol (mg/dL)          | 0        | 75          |
| BUP  | Buprenorphine*           | 0        | 30          |

\* not listed on 510K

## ORDERING INFORMATION

| Catalog Number | DESCRIPTION                                 |
|----------------|---------------------------------------------|
| 702030         | ORAL-SKREEN, NEGATIVE & 3X POSITIVE, 2x20mL |
| 20200101-6pk   | ORAL-SKREEN, NEGATIVE, 6x20mL               |
| 20200109-6pk   | ORAL-SKREEN, 3X POSITIVE, 6x20mL            |
| 20200100       | ORAL-SKREEN, NEGATIVE, 500mL                |

*Custom formulations available upon request*



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## SYMBOL LEGEND

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