

INTENDED USE

The Salivabuse® controls are designed to provide an estimation of the precision of a device test system, and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects, at levels established by SAMHSA, CAP/AACC, many state programs and device manufacturers QC requirements.

SUMMARY AND EXPLANATION

The DEA exempt Salivabuse® Oral Fluid product line of controls is manufactured using a synthetic matrix that has been stabilized to insure 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 ISO certified manufacturers. Standards are certified by the manufactures to be at least 98% minimum purity.

DESCRIPTION

Each bottle contains stabilized synthetic Oral Fluid, designed to simulate human oral fluid. Positive control Oral Fluids have been spiked with authentic reference drug standards and/or appropriate metabolites. Negative control Oral Fluids are certified negative for the constituents listed on our target sheets.

SALIVABUSE® Liquid Oral Fluid Control

Target Values (ng/mL)

Constituents (ng/mL)	Negative	-50%	Cutoff	+50%	2X w/High THC
Delta-9-THC (Parent)	0	2	4	6	120
Cocaine	0	10	20	30	40
Phencyclidine (PCP)	0	5	10	15	20
Opiates (Morphine)	0	20	40	60	80
Amphetamines (d-Amphetamine)	0	25	50	75	100
Methamphetamines (d-Methamphetamine)	0	25	50	75	100
Barbiturates (Secobarbital)	0	25	50	75	100
Benzodiazepines (Oxazepam)	0	10	20	30	40
Methadone	0	10	20	30	40
Nicotine Metabolite (Cotinine)	0	15	30	45	60
Ethanol (mg/dL)	0	12.5	25	37.5	50

PRECAUTIONS

For in vitro diagnostic use only

Please read the entire package insert before using the Salivabuse® Oral Fluid control. Please use the same safety precautions you would use for processing any "unknown" Protect product from exposure to direct sunlight. Contains a proprietary preservative compatible with all commonly used quantitative and qualitative oral fluid methods of detection. *Do not use beyond the expiration date.*

STORAGE & STABILITY - Please refer to Technical Note for detailed instructions.

Unopened:Negative, Cutoff -50%, Cutoff +50%, 2X Cutoff

The controls are stable until the expiration date when stored at -10 to -20°C and protected from light.

Unopened:Negative

The Negative controls are stable until the expiration date or 24 months, whichever comes first, when stored at 2-8°C

After Opening:

A. The controls are stable for 24 months or until the expiration date, whichever comes first, and 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 2-8°C

PROCEDURE

- 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® Oral Fluid control as required by the drugs of abuse test device or screening method.

DESCRIPTION

Oral Fluid, Negative
Oral Fluid, Cutoff -50%
Oral Fluid, Cutoff +50%
Oral Fluid, 2X Cutoff, High THC

CATALOG NUMBER

5ml 20ml
20200001 20200011
20200003
20200007
20200008

Negative, 500mL 18100003

* Custom formulations are available upon request. Please contact us for a quotation.

EXPECTED RESULTS

The positive Salivabuse 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.

TECHNICAL NOTE

SALIVABUSE® CONTROLS, THC STABILITY

Salivabuse 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 binds to surfaces, especially certain plastics^{1,2}. In order to minimize this adsorption loss we recommend the following when handling any sample (including Salivabuse controls) which may contain THC:

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 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

SALIVABUSE CONTROLS, BENZODIAZEPINE STABILITY

Salivabuse® CONTROLS, BENZODIAZEPINE STABILITY: Oxazepam and other Benzodiazepines has known stability problems when stored refrigerated, and to a lesser degree, frozen. Our experience indicates that Benzodiazepines will not deteriorate more than 10% of target level for at least one year when stored frozen at -20°C. Further deteriorations may occur beyond this period although Oxazepam ordinarily tests positive throughout the control's shelf life. Human IgG is denatured by freezing, whether in Salivabuse® control or human oral fluid. Samples should not be stored frozen if this compound is to be used as a marker to help validate that the sample is genuine and unadulterated.

LIMITATIONS OF PROCEDURE

This control is meant to be used to validate the performance of drug testing methods. Consult test manufacturers instructions when using this product; changes in reagents, sample requirement, or methodology may effect test results. Although target values are provided with the Salivabuse 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.*



**Biochemical
Diagnostics, Inc.**

SALIVABUSE®

LIQUID ORAL FLUID

CONTROL

Controls prepared from synthetic Oral Fluid available as a negative and at various constituent target levels to monitor the performance of drug detection devices.

Target Levels: Negative, Cutoff -50%,
Cutoff +50%, and 2X Cutoff with High THC

*Please read the entire package insert before using the
Salivabuse® Liquid Oral Fluid Control*



Temperature Limit



Consult Instructions for Use



For In Vitro Diagnostic Use.