Biochemical Diagnostics, Inc.
A Kova International Company

SALIVABUSE® LIQUID CONTROL ORAL FLUID, ORAL-SKREEN

INTENDED USE:
The SALIVABUSE® 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® 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 - Please refer to Limitations for detailed instructions.

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.

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® control oral fluid as required by the drugs of abuse test device or screening method.

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.

PRECAUTIONS:
For In Vitro Diagnostic Use Only. Please read the entire package insert before using the SALIVABUSE® 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; changes in reagents, sample requirement, or methodology may affect test results. Although target values are provided with the SALIVABUSE® liquid controls, each laboratory should run these controls as unknowns to establish "in-house" assay values for them.

SALIVABUSE® CONTROLS, THC STABILITY:
SALIVABUSE® 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[1] therefore we recommend maintaining storage in the original vials.
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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	Benzoylecgonine	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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For additional information on our other products please contact us or refer to our website.

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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