SYNERGENT BIOCHEM INC.

SALIVA DRUGS OF ABUSE CONTROL, POSITIVE-25%

AMP25/BZO10/COC12/MTD15/METH25/OPI10/PCP2.5/THC25

For ***in vitro*** diagnostic use
Cat. No. 560-22

INTENDED USE
Synergent Biochem, Inc. Saliva Drugs of Abuse Control, Positive -25% is intended for use in monitoring the accuracy and precision of on-site and laboratory immunoassays, as well as GC/MS and LC/MS/MS tests for drugs of abuse.

SUMMARY AND PRINCIPLE
The use of assayed quality control materials in forensic and clinical chemistry procedures is necessary in maintaining good laboratory practices. This control is to be used exactly as directed for the patient samples, and the results evaluated to monitor the technical and performance errors.

REAGENT DESCRIPTION
This control is manufactured from artificial Saliva. Positive control is prepared by the gravimetric addition of high purity drugs and metabolites. Values are determined by GC/MS and/or LC/MS/MS. Each vial contains 5.0 mL of control.

STORAGE AND STABILITY
Saliva Drugs of Abuse Control, Positive -25% is stable until the expiration date on the package when stored tightly capped at 2 to 8ºC. Once opened, the control is stable for 30 days. If turbidity or gross microbial contamination appears, discard immediately.

PRECAUTIONS
This product contains sodium azide which may react with lead and copper plumbing to form highly explosive azides. If the control is discarded in to sink, flush with large volumes of water to prevent azide build-up. Certain drugs may absorb to glassware; therefore, to prevent loss, use silanized glassware with this control and/or patient samples.

PROCEDURE
Allow the refrigerated control to warm to room temperature (18-25ºC) before use. Gently swirl the content of vial to ensure a homogeneous preparation. This control should be treated in the same manner and assayed as the patient samples in accordance to the instrument manufacturer's instructions. This control may not to be used past the expiration date.

LIMITATIONS
An analytical laboratory result may not match the expected value listed. Likewise, screening device result may be affected by matrix differences between biological and artificial saliva. In this light, manufacturers should prequalify screening devices for use with this saliva control. Drug recovery is method dependent; varying technique, equipment, and experimental error may produce different values.

EXPECTED VALUES
The values in the table below have been determined by Gas Chromatography / Mass Spectrometry (GC/MS). Each laboratory should establish its own precision and accuracy parameters and use the values listed only as guidelines.

Lot: 1127002C Expiry: 03 / 2013

Drug	Value	Range	Unit
d-Amphetamine	20.8	16.6-25.0	ng/mL
Benzoylecgonine	8.0	6.4-9.6	ng/mL
Methadone	12.6	10.1-15.1	ng/mL
d-Methamphetamine	20.1	16.1-24.1	ng/mL
Morphine	8.9	7.1-10.7	ng/mL
Oxazepam	< 15	6.0-9.0	ng/mL
Phencyclidine	1.6	1.3-1.9	ng/mL
Δ^9-Tetrahydrocannabinol	22.1	17.7-26.5	ng/mL

REFERENCE
Substance Abuse and Mental Health Services Administration (SAMHSA), Rockville, MD 20857. Proposed Guidelines for Federal Workplace Alternative Specimen Drug Testing, Draft 3, June, 2001.

TECHNICAL ASSISTANCE
For technical assistance and ordering information contact Synergent Biochem, Inc. at 562-809-3389.

CATALOG NUMBER
560-22 6 x 5 mL

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