



SYNERGENT BIOCHEM INC.

SALIVA DRUGS OF ABUSE CONTROL, POSITIVE+25%

AMP25/COC12/METH25/OP110/PCP2.5/THC25

For *in vitro* diagnostic use

Cat. No. 560-11

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 8°C. 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 adsorb 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 (18-25°C) 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 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: 1106709 Expiry: 09 / 2012			
Drug	Value	Range	Unit
d-Amphetamine	27.6	22.1-33.1	ng/mL
Cocaine	17.4	13.9-20.9	ng/mL
d-Methamphetamine	30.5	24.4-36.6	ng/mL
Morphine	10.2	8.2-12.2	ng/mL
Phencyclidine	3.4	2.7-4.1	ng/mL
Δ^9 -Tetrahydrocannabinol	33.8	27.0-40.6	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

560-11 6 x 5 mL