

Oral Fluid Operational Experience

DTAB

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Quest Diagnostics

Collection (1/2)

- Abstain from eating or drinking for 10 minutes
 - Intercept® DOA Specimen Collection Device (Orasure®)
- Place collection pad between lower cheek and gums - gently rub until moist
- Pad remains in mouth for 3 minutes - Collects ~0.4 mL
[Some employers utilize a 5 minute collection time]
- Donor places pad in specimen vial which contains 0.8 mL of buffer
- Collection Device Final Volume - ~1.2 mL
 - Dilution 1:2 (X3)

Collection (2/2)

- Donor snaps off applicator wand
- Donor places cap on specimen vial
- Donor places tamper evident seal on vial
- Complete CCF and package for shipping
- NOTE: Some employers collect two (“A” & “B”) samples

Pre-Analytic Sample Preparation

Receive / Accession

- Verify specimen identification
- Verify specimen integrity
- Assign laboratory accession number (LAN) to specimen storage tube
- Snap plastic tip and insert device into specimen storage tube
- Centrifuge (2-3 min.) to express specimen into specimen storage tube
- Original collection tube remains inserted in specimen storage tube to preserve original tamper-evident seal and to seal storage tube

Initial Testing

- 350 uL of Oral Fluid for initial aliquot
 - Parent tube is not loaded to the Hamilton
- Intercept® micro-plate EIA (96 well Elisa)
- Sample volume for each drug assay ranges between 15 uL – 50 uL
- Batch size
 - 16 calibrators and controls
 - 79 donors
 - 79 donors
- Controls are 50% and 200% of cutoff

Initial Test Cutoffs

- Amphetamine 100 ng/mL
- Methamphetamine 40 ng/mL
- Cocaine 5 ng/mL
- Marijuana 1 ng/mL
- Opiates 10 ng/mL
- Phencyclidine 1 ng/mL
- Immunoglobulin G (IgG) 0.5 ug/mL

Initial Test Equipment

- Hamilton Microlab AT / AT Plus
- Skatron Skan Washer / Stacker
- Titertek Multiskan MCC/340 Reader
- LabSystems Multidrop Dispenser
- Bio-Tek Ufill Reagent Dispenser

Confirmation Cutoffs

- Amp/MAmp/MDMA/MDA 40 ng/mL
- Benzylecgonine 2 ng/mL
- Marijuana (THC) 0.5 ng/mL
- Cod/Mor/HC/HM 10 ng/mL
- 6-AM 1 ng/mL
- Phencyclidine 0.5 ng/mL
- Immunoglobulin G (IgG) 0.5 ug/mL

Confirmation

- Quantitative aliquot
 - Aliquots are taken directly from the specimen storage tube to ensure no waste of specimen volume
 - Assays require between 150 – 300 uL of sample
 - Quality Controls are 50% or 80% and 125% of cutoff

Methods

- Amphetamines
 - Liquid/Liquid
 - HFBA
- THC
 - Liquid/Liquid
 - BSTFA
- PCP
 - Solid Phase
- Opiates
 - Solid Phase
 - Methoxyamine / BSTFA
- Cocaine metabolite
 - Solid Phase
 - HFIP

Instrumentation

- GC/MS
 - Amphetamines
 - Cocaine
 - D/L isomers
- GC/MS with Dean's Switch
 - PCP
 - THC
 - Opiates

Storage

- Any non-negative specimens are frozen for a minimum of 1 year
- Refrigerator and room temperature storage is not appropriate for long term storage

PT / Certification

- PT
 - NLCP
 - Pennsylvania
 - CAP
- Certification
 - CAP - FDT
 - New York

Challenges

- Specimen Volume
- THC or THCA
- Split Collections – 2 collections
- Retests
 - Inconsistency between labs LODs
- Automation