

## INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a forensic drug testing laboratory.



*Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.*

**Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

## EXTENT OF SERVICES PROVIDED

A specific menu of drugs tested is not required for accreditation. The test menu must be defined by the laboratory director, considering the needs of the laboratory's clients. The laboratory may offer different test menus to different clients based on client request.

The laboratory must comply with proficiency testing and other checklist requirements for all testing represented as accredited by the CAP FDT accreditation program. Proficiency testing requirements are found in the All Common Checklist.

### Inspector Instructions:

	<ul style="list-style-type: none"><li>Sampling of test referral policies and procedures</li><li>Sampling of screening and confirmatory test records (includes defined cut-off values)</li></ul>
	<ul style="list-style-type: none"><li>What is your course of action when ethanol testing yields a positive result?</li></ul>

### FDT.00300 Positive Result Confirmation

Phase II



**Positive screening results (excluding ethanol, see FDT.00350) are confirmed using a well-defined and scientifically acceptable mass spectrometric method (eg, GC/MS, LC/MS, GC/MS/MS, LC/MS/MS) that, when feasible, is analytically different from the screening method. Testing for screening and confirmatory phases are performed on two separate aliquots taken from the original specimen container.**

**NOTE: The CAP FDT program requires that all screen-positive drug tests be confirmed by a mass spectrometric method, but allows the confirmation to be performed at a CAP FDT-**

accredited or Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratory other than the original screening laboratory. If the laboratory is required by clients to report non-confirmed positive results for pre-employment samples, then the laboratory must have in place a system that differentiates this non-forensic drug testing service from its forensic drug testing service.

**Evidence of Compliance:**

- ✓ Records reflecting the confirmatory testing performed on positive results

**FDT.00310 Laboratory Qualifications - Confirmatory Tests Phase II**



All confirmatory tests are performed in-house or referred to a laboratory that is CAP FDT-accredited or SAMHSA-certified.

**FDT.00320 Referral Process Procedures Phase II**



If the laboratory refers any testing for re-screening and confirmation, the laboratory follows written procedures that fully describe the referral process from initial screening, specimen aliquoting, chain-of-custody, receipt of referral laboratory results, and reporting of results.

**FDT.00330 Screen-Positive Drugs - Confirmation Phase II**



The laboratory requires the confirming CAP FDT-accredited or SAMHSA-certified laboratory to both re-screen and confirm the presence of screen-positive drugs.

*NOTE: If the laboratory performing the initial screening test (for "screen-only" laboratories) refers any confirmation testing, it must be able to demonstrate that the confirming laboratory rescreens and confirms the screen-positive specimen. The requirement for re-screening as well as confirmation testing by the referral laboratory is mandated in order to maximize the defensibility of a reported positive drug test result.*

**FDT.00350 Ethanol Confirmation Phase II**



If positive, ethanol is tested and retested on separate aliquots of the original specimen by scientifically acceptable methods, one or both of which is/are gas chromatography.

**Evidence of Compliance:**

- ✓ Test reports and records with confirmatory results

**REFERENCES**

- 1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory*. 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.
- 2) Wu AHB, McKay C. National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Recommendations for the Use of Laboratory Tests to Support Poisoned Patients Who Present to the Emergency Department. *Clin Chem*. 2003;49(3):357-379.
- 3) Frederick DL, King DS. Lactate Dehydrogenase Can Cause False-Positive Ethanols. *Clinical and Forensic Toxicology News (Quarterly AACC/CAP)*. June 2012:4-7.

**FDT.00420 Cut-off Values Phase II**



The laboratory uses defined cut-off values for the screening and confirmation tests for all drugs.

*NOTE: The laboratory must use defined cut-off values for the screening and confirmation tests for all drugs and drug classes. Cut-off values may be defined by the laboratory or at the client's request. The laboratory, however, must be able to analyze challenges in the CAP/AACC UDC Forensic Urine Drug Testing (Confirmatory) Survey or a CAP approved alternative PT program at the reporting limits specified in the proficiency testing instructions.*