

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

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-