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 re-screens 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.

Evidence of Compliance:

- ✓ Records of defined cut-off values for all screening and confirmatory tests

LABORATORY SAFETY

The inspector should review relevant requirements from the Safety section of the Laboratory General checklist, to assure that the forensic drug testing laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

QUALITY MANAGEMENT

Inspector Instructions:

	• Records of quality monitoring, including pre-analytic (correct collection, effects of excessive sample dilution or potential adulteration), analytic and post-analytic and corrective action when indicators do not meet threshold
	• What is your course of action when a false positive result is reported?
	• Further evaluate the responses and root-cause analysis for any false positive result reported

FDT.01200 Specimen Collection QM **Phase I**

There is evidence that the laboratory is involved in influencing the correct collection of client samples.

NOTE: This must include the monitoring of collection problems, chain-of-custody problems, transportation delays, etc. A system must be in place to inform and influence the improvement of these processes. The laboratory must discuss with each client the issues of potential adulteration or excessive dilution of samples and how these affect the analytical methods used by the laboratory. The laboratory must be able to perform ancillary tests that may aid in the detection of excessive dilute or potentially adulterated samples, eg, pH, specific gravity, or creatinine.

Evidence of Compliance:

- ✓ Records of collection monitoring with client communication or consultation

FDT.01400 Interpretive Consultations **Phase I**