- Filters (clean, not scratched, not deteriorated)

CHM.22700 Filter Photometers **Phase II**

Filters (filter photometers) are checked at least annually to ensure they are in good condition (eg, clean, free of scratches).

Evidence of Compliance:

✓ Records of filter checks at defined frequency

CHM.22900 Burner/Chimney **Phase II**

The burner, chimney and appropriate optical surfaces are checked for dirt and film and cleaned at defined intervals.

Evidence of Compliance:

✓ Record of maintenance at defined frequency

GENERAL CHEMISTRY

CHEMISTRY

CHM.28850 Ethanol Specificity **Phase II**

If the laboratory tests for ethanol, the method has been evaluated for ethanol specificity.

NOTE: Elevated lactic acid concentration and lactate dehydrogenase (LD) activity may falsely elevate enzymatically determined ethanol levels.

Evidence of Compliance:

✓ Records of ethanol specificity evaluation studies **OR** evaluation of information provided by the manufacturer **OR** evaluation of published literature

REFERENCES

1) Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline.* 3rd ed. CLSI Document C52-Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.
2) 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.
3) Frederick DL, King DS. Lactate Dehydrogenase Can Cause False-Positive Ethanols. *Clinical and Forensic Toxicology News (Quarterly AACC/CAP)*. June 2012:4-7.

CHM.28875 Urine Opiates Immunoassay Cutoff **Phase I**

The urine opiates immunoassay cutoff is appropriate for the clinical setting.

NOTE: Opiate class immunoassays are primarily designed to detect naturally occurring opiates (eg, morphine and codeine), and have varying cross-reactivity to the semisynthetic opioids (eg, oxycodone, hydrocodone). Therefore, when utilized for clinical care, including support of emergency departments and pain management clinics, the 300 ng/mL cutoff for the urine opiates immunoassays should be utilized. The 2000 ng/mL cutoff is more appropriate for workplace drug testing. As a class assay, the 300 ng/mL cutoff has better detection for lower

concentrations of naturally occurring opiates (morphine and codeine) and for the semisynthetic opioids (oxycodone, hydrocodone) when compared to the 2000 ng/mL cutoff.

It is recommended that the laboratory review the package insert for its opiates immunoassay for cross-reactivity with the semisynthetic opioids (eg, oxycodone, hydrocodone). Specific immunoassays for the detection of semisynthetic and synthetic (eg, buprenorphine, fentanyl) opioids are available and should be used when reliable detection of those drugs is required; alternative targeted methods such as mass spectrometry may also be appropriate.

If cutoff values different than those defined by the manufacturer are used, the laboratory must perform appropriate validation studies to support the modification.

Evidence of Compliance:

✓ Patient reports with cutoffs appropriate for the clinical setting

REFERENCES

1) Magnani BJ, Kwong TC, McMillin G, Wu AHB., eds Clinical Toxicology Testing: A Guide for Laboratory Professionals. 2nd ed. Northfield, IL: CAP Press; 2020.

THERAPEUTIC DRUG MONITORING

Inspector Instructions:

	• Sampling of TDM policies and procedures • Sampling of TDM patient reports (dosage, time of drug administration)
	• How is the clinician able to link TDM laboratory results to the dosage and time the patient received the drug?

CHM.28900 Specimen Collection/Drug Dosing **Phase I**

As applicable, information is available to clinical personnel for the optimal specimen collection time in relation to drug dosing.

Evidence of Compliance:

✓ Test reference guide **OR** other mechanism for providing guidance for specimen collection for therapeutic drug testing

REFERENCES

1) Nicholson PW, *et al.* Ideal sampling time for drug assays. *Br J Clin Pharm.* 1980;9:467470
2) Howanitz PJ, Steindel SJ. Digoxin therapeutic drug monitoring practices. A College of American Pathologists Q-Probes study of 666 institutions and 18679 toxic levels. *Arch Pathol Lab Med.* 1993;117:684-690
3) Schoenenberge RA, *et al.* Appropriateness of antiepileptic drug level monitoring. *JAMA.* 1995;274:1622-1626
4) Williamson KM, *et al.* Digoxin toxicity: an evaluation in current clinical practice. *Arch Intern Med.* 1998;158:2444-2499

CHM.29000 TDM Results **Phase II**

Where applicable, TDM results are reported in relation to patient dosing and/or timing information.

NOTE: The intent is to have a mechanism whereby the clinician can easily and accurately link TDM results from the laboratory to the dosage and time of drug administration. Ideally, the test result, dose and administration time would be reported in juxtaposition on the patient chart. This may be the responsibility of the laboratory, or an integrating function of reported laboratory analytic data with clinical information from other sources.