- How does your laboratory verify calibration curves?

CHM.22300 Absorbance/Linearity **Phase II**

Absorbance and/or fluorescence linearity is checked and recorded at least annually or as often as specified by the manufacturer, with filters or standard solutions.

Evidence of Compliance:

✓ Records of absorbance and linearity checks at required frequency

CHM.22400 Spectrophotometer Checks **Phase II**

Spectrophotometer (including ELISA plate readers) wavelength calibration, absorbance, and linearity are checked at least annually (or as often as specified by the manufacturer), with appropriate solutions, filters or emission line source lamps, and the results recorded.

NOTE: Some spectrophotometer designs, eg, diode array, have no moving parts that can alter wavelength accuracy and do not require routine verification. The manufacturer's instructions should be followed.

Evidence of Compliance:

✓ Records of spectrophotometer checks at required frequency

CHM.22500 Stray Light **Phase II**

Stray light is checked at least annually with extinction filters or appropriate solutions, if required by the instrument manufacturer.

Evidence of Compliance:

✓ Records of stray light checks at required frequency

CHM.22600 Calibration Curves **Phase II**

For procedures using calibration curves, all the curves are rerun at defined intervals and/ or verified after servicing or recalibration of instruments.

NOTE: Calibration curves must be run following manufacturer's instructions, at minimum, and as defined in laboratory procedure.

Evidence of Compliance:

✓ Records of calibration curve rerun and/or verification at defined frequency

FLAME PHOTOMETERS

Inspector Instructions:

- Sampling of flame photometer policies and procedures
- Sampling of system cleaning

- 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