

CHROMATOGRAPHY AND MASS SPECTROMETRY

THIN LAYER CHROMATOGRAPHY (TLC)

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Sampling of TLC policies and procedures • Sampling of control, standards/calibrator records
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CBG.14600 Standard/Calibration Materials

Phase II



Appropriate standards, calibrators, or controls (as applicable) are included with each TLC plate.

NOTE: Appropriate standards must include compounds that test the chromatographic range of the TLC plate, and that test all phases of the staining/development system. This may consist of a standard solution, previously tested positive patient samples, or dot that contains appropriate compounds.

Evidence of Compliance:

- ✓ Records showing use of appropriate standards/calibrators with each plate

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.

CBG.14700 Daily QC - TLC

Phase II

Negative and appropriate positive controls are extracted and run through the entire procedure.

NOTE: Appropriate positive controls must include compounds that test the extraction, chromatographic range of the TLC plate, and the staining/development system. Negative and positive controls (when available) must be extracted and carried through the entire procedure with each plate or card.

Evidence of Compliance:

- ✓ QC records at defined frequency

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1256(d)]
- 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.

CBG.14800 Solvent Mixtures

Phase II



Solvent mixtures are prepared fresh as needed.

NOTE: If a mixture of solvents is used, certain components will evaporate with time faster than others. This leads to poor extraction or reproducibility of migration rates. If a commercial kit is used, the manufacturer's instructions must be followed.