

Laboratory Incident Investigation Reference

Investigation Item	Verified (Yes/No)
Training records reviewed	
Method/STP followed	
Instrument calibration current	
Maintenance records reviewed	
Raw data reviewed	
Chromatograms/spectra reviewed	
Reagents/standards verified	
Root cause identified	
CAPA assigned	
Effectiveness check completed	

GMP Requirements: Invalidated raw data, chromatograms, spectra, worksheets, and weight slips shall be retained and archived with the corresponding incident report. Significant incidents require documented investigation closure and CAPA effectiveness verification.