

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657014	(X3) Date Survey Completed 03/25/2019
Name of Provider or Supplier Allegheny County Medical Examiners	Street Address, City, State 1520 Penn Avenue, Pittsburgh, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration records and interview with technical supervisor (TS) #1 the laboratory failed to establish a maintenance protocol to ensure 7 of 7 refrigerator/ freezer Temp-Chex Thermometers were calibrated from 09/2017 to the date of survey. Findings Include: The Temp-Chex Certificate of Accuracy, under Calibration statement, states, "Periodic re-calibration or verification should be scheduled by each laboratory in accordance with its accrediting agency and/or established procedure". The Quality Assurance procedure, under 11. Refrigerator /Freezer, 11.4 "Thermometers, in which temperatures are recorded, will be checked in accordance with the quality manual". 1. On the day of survey, 03/25/2019, the laboratory's, the ACOME Quality Manual: Forensic Laboratory procedure, did not include methods of calibration, nor did the laboratory have documentation for 7 of 7 refrigerator/ freezer Temp-Chex Thermometers in use, where toxicology standards and specimen were stored from 09/19/2017 to 03/25/2019. 2. TS #1 confirmed the findings above on 03/25/2019 around 3:00 pm.</p>