

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0920678	(X3) Date Survey Completed 02/25/2021
Name of Provider or Supplier Wv Office Of Laboratory Services	Street Address, City, State 4710 Chimney Drive Suite G, Charleston, WV	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) summary reports, corrective action (CA) reports and interview with the technical supervisor, the laboratory failed to ensure all non-regulated analytes it tests were taken appropriate corrective actions when results of CDC-LRN challenges for detection of Styrene and O-Xylene of Volatile Organic Compounds (VOC) panel in Serum failed to meet minimum passing scores (80%) in four of six events in 2019 and 2020. Findings include: 1. The laboratory receives three sets of challenges from the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) each calendar year. CDC-LRN challenges are used by the facility to twice annually assess the accuracy of analytes not included in Subpart I. The surveyor reviewed all CDC-LRN challenges the laboratory participated in during 2019 and 2020. 2. The laboratory received failing (less than 80%) scores in four challenges (2019-1 60%, 2019-2 70%, 2020-2 70%, and 2020-3 70%) during 2019 and 2020 for the analyte of Styrene. 3. The laboratory received failing (less than 80%) scores in one challenges (2019-2 70%) during 2019 for the analyte of O-Xylene. 4. Interview with the laboratory technical supervisor at approximately 12:00pm confirmed the findings.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p>

This STANDARD is not met as evidenced by:
Based on review of CDC-LRN challenge results, PT Reporting Form documentation and interview with staff, the laboratory director failed to ensure whenever reviews of CDC-LRN challenge results indicated less than acceptable performance (less than 80% scores), all appropriate staff were aware of the findings so that an evaluation of the laboratory's performance was conducted and to identify issues and/or problems with the lab's current method and/or process that required corrective action is taken: Findings include: Cross-reference D5217 and D6118.

D6118

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(5)

The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:
Based on review of completed PT Reporting Forms and interview with staff, the technical supervisor failed to ensure any technical problems were resolved satisfactorily and appropriate corrective actions were taken when results of CDC-LRN challenges for detection of Styrene and O-Xylene of Volatile Organic Compounds (VOC) panel in Serum failed to meet minimum passing scores (80%) in four of six events in 2019 and 2020. Findings include: 1. The laboratory received failing (less than 80%) scores in four challenges (2019-1 60%, 2019-2 70%, 2020-2 70%, and 2020-3 70%) during 2019 and 2020 for the analyte of Styrene. The laboratory received failing (less than 80%) scores in one challenges (2019-2 70%) during 2019 for the analyte of O-Xylene. The PT Reporting Form did not address/document: the cause of the failures, resolution of the problem(s) and a re-evaluation of samples tested to determine if the remedial action(s) taken by the lab actually corrected the problem. 2. During interview with the technical supervisor at approximately 12 pm confirmed the findings.