

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2086497	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Addiction Angels Of America, Llc	Street Address, City, State 1525 Bethel Road, Columbus, OH	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Supervisor (TS), the laboratory failed to establish and follow written policies and procedures for the competency assessment of the Clinical Consultant (CC). This deficient practice had the potential to affect all patients tested at this laboratory in the subspecialty of Toxicology. Findings include: 1. Review of the laboratory's CMS-209 form, signed and approved by the Laboratory Director (LD) on 11/5/19, found one person serving as a CC. 2. Review of the laboratory's delegation documentation found the same person delegated to perform the regulatory roles and responsibilities of a CC by the LD, approved on 6/25/19. 3. Review of the laboratory's 'Performance/Competency Testing' policy failed to find mention of competency assessment of the CC, based on the regulatory responsibilities of that role, at a frequency determined by the lab. 4. Review of the laboratory's competency assessment documentation failed to find evidence that the CC was assessed for competency, based on the regulatory responsibilities of that role, at a frequency determined by the lab. 5. An interview with TS, on 1/5/19 at 12:21 pm, confirmed that the lab failed to assess the CC for competency, based on the regulatory responsibilities of that role, at a frequency determined by the lab.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification,</p>

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review, and an interview with the Technical Supervisor (TS), the laboratory failed to indicate the specimen source on the final report for 7 out of 7 final reports reviewed. This deficient practice has the potential to affect all patients tested at this lab in the subspecialty of Toxicology. Findings include: 1. Review of 7 patient final test reports, found that all 7 failed to indicate a specimen source: Date Source Patient #1: 9/3/19 none Patient #2: 10/8/19 none Patient #3: 10/21/19 none Patient #4: 10/25/19 none Patient #5: 10/30/19 none Patient #6: 11/1/19 none Patient #7: 11/4/19 none 2. An interview with the TS, on 11/5/19 at 12:02 pm, confirmed that the lab failed to indicate a specimen source on the patient final test report.