

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2086497	<b>(X3) Date Survey Completed</b>  10/20/2021
<b>Name of Provider or Supplier</b>  Addiction Angels Of America, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Supervisor (TS) and Testing Personnel (TP#1), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. Findings Include: 1. Review of the laboratory's "Quality Assessment Review" policy and procedure electronically mailed 10/25/2021 at 10:22 AM, found the following statement: "The purpose of the Quality Assessment Review Policy is to assure that all pertinent aspects of the laboratory department are monitored and reviewed to assure that patient testing is completed in a safe and compliant manner to meet regulatory requirements. The review process must be sufficiently comprehensive to identify physical items and laboratory processes that are deficient/non-compliant or require improvement. 2. Review of temperature monitoring sheets provided on the date of inspection for the laboratory freezer found no temperatures had been recorded for April 2020 through September 13th 2021. 3. Review of temperature monitoring sheets provided on the date of inspection for the laboratory refrigerator found no temperatures had been recorded for June 2020 through September 13th 2021. 4. Review of the "Laboratory Director Quality Assessment Summary" sheets electronically mailed 10/22/2021 at 1:49 PM, from April 2020 through September 2021, found no mention of missed temperature monitoring for the laboratory's refrigerator or freezer. 5. The Surveyor requested the laboratory's analytic systems quality assessment documentation for April 2020 through September 2021 showing</p>

laboratory refrigerator and freezer temperature monitoring assessments from TP#1. TP#1 confirmed the laboratory did not monitor temperatures during the above mentioned timeframe and did not have analytical quality assessments which included refrigerator and freezer temperature monitoring assessments. TP#1 was unable to provide the requested documentation on 10/22/2021 at 1:46 PM.