

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2101443	(X3) Date Survey Completed 09/11/2019
Name of Provider or Supplier Aurora Life Sciences Llc	Street Address, City, State 6019 Fincham Dr, Rockford, IL	
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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of reagents; review of laboratory records and interview with Technical Supervisor #1, the laboratory failed to document all control procedures. Findings: 1. Quality Control reagents were in a kit that included positive and negative controls vials along with a Quality Control Certificate. 2. The manufacturer's lot number and "use by date" was included on the control vials. 3. Laboratory quality control records included a sticker titled, "Daily Control Kit." 4. The Daily Control Kit reads as follows: "Kit contains controls for use with AMiDot A/I testing. Kit will yield 4 runs. Remove kit from freezer and allow to thaw. Date and initial removal. Controls are prediluted. Run controls and return unused samples to freezer. Do not use past expiration date on vial." 5. A sticker for tracking and documenting the dates for the 4 runs of each kit is included with the documentation. 6. The lot number and use by date was not included in the documentation when the laboratory tracked the 4 runs of the quality control kits. 7 On 09/11/19 at 12:30 PM, the Technical Supervisor confirmed the surveyor's findings.</p>