Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2101443	01/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Life Sciences Llc	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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of patient test logs, maintenance records, manufacturer's inserts, and interview with technical supervisor (TS 1), the laboratory failed to monitor and document proper storage of AMiDot Autotimmune reagents stored in the Frigidaire Inventory Cold Storage Unit #3 refrigerator (Unit 3) for two of four days in February of 2022, impacting seven patients tests results. Findings Include: 1. Surveyor review of the "1-05-2022" maintenance sheet, documenting refrigerator temperatures for the Unit 3 refrigerator, found the laboratory failed to document temperatures for two of four days (02/03/2022 and 02/04/2022) in February of 2022. 2. Interview with TS 1 on 01/31/2023, at 1:03 p.m., confirmed that AMiDot Autoimmune reagents used for Autoimmune 30+ analytes testing are stored in the Unit 3 refrigerator. 3. Surveyor review of manufacturer's inserts for the following AMiDot reagents confirmed AMiDot Reagent Packs, Autoimmune Abdominal Panel Slide Packs, and Autoimmune Fatigue Panel Slide Packs must be stored at 2-8 degrees Celsius. 4. Review of patient test logs revealed seven patients (Patient Identification Numbers: ALS-1005FBP44480720, INT-44574-2, TWW-1016EBP4434115, 44589-1, INT-44585-1, ALS-1010EBP44502320, and TWW-1046EBT4397955) had Autoimmune 30+ analytes testing performed on 02/03/2022 when reagent storage temperatures failed to be monitored. 5. Interview with TS 1 on 1-31-2023, at 2:45 p.m. confirmed

	that the reagent storage temperatures were not monitored for the dates identified in February of 2022 due to a broken thermometer.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient reports, and interview with technical supervisor (TS 1), the laboratory failed to provide written documentation of the statistical parameters established over time for the upper and lower control limits for three of six AMiDot Autoimmune analytes control lot numbers used for testing on one of one days in January 2023, impacting 17 patients tests results. Findings include: 1. Surveyor review of laboratory quality control procedure marked, "Establish Upper and Lower Control Sample Limits (Form P-100-69) revealed the following purpose and procedure, "When a new control lot is received, the sample is to be tested to determine control limits" and "run the new control over 8 separate days to obtain 8 replicates of each sample for all analytes." 2. Review of laboratory records revealed the laboratory failed to provide a record of the established statistical parameters for upper and lower control lot values for three of six AMiDot Autoimmune analytes control lot numbers (Z7_POS Z7121422, Z7_POS1 Z7121422, and Z7_POS2 Z7121422) utilized for patient testing on 01/20/2023. 3. Review of patient reports revealed the laboratory reported AMiDot Autoimmune 30+ analytes test results on 01/20/2023, impacting 17 patients. 4. On 01/31/2023, at 1:48 p.m., technical supervisor 1 confirmed Findings 1 through 3.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with technical supervisor (TS 1); the laboratory failed to have available a corrective action policy to ensure accurate and reliable patient test results for Autoimmune 30+ testing performed in 2021 through the date of survey in 2023 (01/31/2023). Findings Include: 1. Review of laboratory records revealed the laboratory failed to have a corrective

	action policy to ensure accurate patient test results for Autoimmune 30+ testing. a. The laboratory failed to perform corrective actions for not following the laboratory quality control procedure marked, "Establish Upper and Lower Control Sample Limits (Form P-100-69)" for three of six AMiDot Autoimmune analytes control lot numbers (Z7_POS Z7121422, Z7_POS1 Z7121422, and Z7_POS2 Z7121422) utilized for patient testing on 01/20/2023. (Refer to D5469 and D5791) b. The laboratory failed to perform corrective actions for not documenting the temperature of the Unit 3 refrigerator utilized for storing AMiDot Autoimmune reagents for two of four days (02 /03/2022 and 02/04/2022) in February of 2022. (Refer to D5413 and D5791) 2. On 01 /31/2023 at 1:48 p.m., technical supervisor 1 confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with technical supervisor (TS 1), the laboratory failed to establish a written quality assessment policy to identify and correct problems with analytical performance of autoimmune testing performed in 2021 through the date of survey in 2023 (01/31/2023). Findings Include: 1. Review of the laboratory's procedures manual revealed the laboratory failed to establish an analytic quality assessment policy for autoimmune testing. The following issues were identified: a. The laboratory failed to follow laboratory quality control procedure marked, "Establish Upper and Lower Control Sample Limits (Form P-100-69)" for three of six AMiDot Autoimmune analytes control lot numbers (Z7_POS Z7121422, Z7_POS1 Z7121422, and Z7_POS2 Z7121422) utilized for patient testing on 01/20 /2023. (Refer to D5469 and D5779) b. The laboratory failed to document the temperature of the Unit 3 refrigerator utilized for storing AMiDot Autoimmune reagents for two of four days (02/03/2022 and 02/04/2022) in February of 2022. (Refer to D5413) 2. On 01/31/2023 at 2:45 p.m., technical supervisor 1 confirmed the above findings.