Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2240667	04/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chromodx Llc	10809 Executive Center Dr Ste 319, Little Rock, AR	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Through review of the CMS 209 form, review of laboratory documentation of competency assessment, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to assess testing personnel competency on an annual basis on two of two testing personnel listed on the CMS 209 form. Findings follow: A) Review of the CMS 209 form revealed that two testing personnel were employed by the laboratory. B) Review of competency assessment records revealed that the employee (# 1 on the CMS 209 form) had a date of hire of 2021 and no record of competency evaluation was present; employee (# 2 on the CMS 209 form) had a hire date of May 2022 and no record of competency evaluation was present. C) Upon request, the laboratory was unable to provide competency assessments for either employee. D) In an interview on 4/7/23 at 10:35 am, the laboratory staff member (# 1 on the separate personnel list) confirmed that competency assessments for the dates and employees identified above were not performed and the employees had performed testing in the laboratory since their dates of hire.
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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in one of two rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 4/7/23 at 1:27 p.m. two rooms (main lab and storage room) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the storage room. C) During a tour of the laboratory on 4/7/23 at 1:27 p. m. Fisher Nitric Acid Trace- Metal Grade lot number 112109 and Fisher Hydrochloric Acid Trace-Metal Grade lot number 4121100 with a storage temperature requirement 15 degrees Centigrade to 25 C. Fisher Nitric Acid Trace-Metal lot number 21440074 with a storage temperature requirement 15 degrees C. to 20 degrees C. All three acid solutions found in the storage area inside a flammables cabinet. D) Upon request, the laboratory could not present the temperature records for the storage room area in which the supplies identified above were stored,. E) In an interview on 4/7/23 at 2:00 p.m. the laboratory staff member (# 1 on the separate personnel list) stated that the daily temperature of the storage room area in which the supplies identified above were stored had not been monitored and recorded.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 4/7/23 at 1:27 p.m. one iCAP Q/Qnova Calibration Solution (batch number 8325 use before date 12/2018) were observed on the left side next to the instrument. B) In an interview on 4/7/23 at 2:00 p.m. the laboratory staff member (number 1 on the separate personnel list) confirmed that the item, identified above, had exceeded their expiration date and was available for use.