Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2155339	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Future Diagnostic Center	**Street Address, City, State** 4619 Allen, Allen Park, MI	
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
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to document the measurements taken and used in the accuracy study for quantitative toxicology testing on the Shimadzu LCMS-8050 for 1 of 1 analyzers used. Findings include: 1. A review of the laboratory's accuracy study revealed a lack of documentation of the measurements from the Shimadzu LCMS-8050 analyzer and the reference laboratory used to establish accuracy. 2. An interview on 9/29/21 at 10: 01 am with the Testing Personnel revealed the measurements from the Shimadzu LCMS-8050 analyzer and the reference laboratory used to establish accuracy were not present.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the General Supervisor (GS), the laboratory failed to establish control procedures that detect immediate errors in toxicology testing for 1 of 1 procedure reviewed. Findings include: 1. A review of the laboratory's "Control Policy" revealed the following acceptability ranges for their control procedures: a. "Low concentration +/- 45% because it is below the cutoff range." b. "Middle Controls range should be in +/- 35% range of accuracy." c. "High Controls should be in +/- 30% range." 2. The surveyor asked the GS how the wide ranges can detect immediate errors in the test system on 9/29/21 at 10:18 am and the GS indicated the laboratory had been passing the College of American Pathologists' (CAP) proficiency testing events three times annually. 3. A review of the laboratory's CAP proficiency testing records revealed the laboratory is enrolled in an event that assesses qualitative drug testing, not the quantification of each drug detected.

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 record review and interview with the General Supervisor (GS), the laboratory failed to document how it established the criteria of acceptability for the current lot of control materials used in quantitative toxicology testing. Findings include: 1. A review of the laboratory's "Control Policy" revealed the following acceptability ranges for their control procedures: a. "Low concentration +/- 45% because it is below the cutoff range." b. "Middle Controls range should be in +/- 35% range of accuracy." c. "High Controls should be in +/- 30% range." 2. The surveyor requested documentation of how the laboratory established the quality control ranges listed above on 9/29/21 at 10:08 am and it was not made available. 3. The surveyor asked the GS how the laboratory established the acceptability of the control materials used in the quantitative toxicology testing and the GS indicated the laboratory can accept quality control results within the ranges listed above based on the retention time, looking at the peak, and looking at the signal on 9/29/21 at 10:18 am.