Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2155339	03/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Future Diagnostic Center	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
D0000	. A initial survey was completed on March 5, 2020. During the survey, it was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Toxicology- 42 CFR 493.1213
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on the number and severity of the deficiencies cited herein, the Condition: Toxicology was not met. Findings include: 1. The laboratory failed to verify the accuracy of toxicology testing at least twice annually. See D5217. 2. The laboratory failed to establish performance specifications of the laboratory-developed liquid chromatography mass spectrometry system used in toxicology testing before reporting patient results. See D5423. 3. The laboratory failed to use calibration criteria established by the laboratory to evaluate calibration acceptability. See D5481. 4. The laboratory failed to use laboratory-established quality control acceptability criteria to evaluate quantitative toxicology quality control results before reporting patient results. See D5481.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of toxicology testing at least twice annually for 2019. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of verification of accuracy testing for 47 toxicology analytes tested by the laboratory: a. Buprenorphine b. Codeine c. EDDP d. Fentanyl e. Hydrocodone f. Hydromorphone g. Hydroxybupropion h. Meperidine i. Methadone j. Morphine k. Norbuprenorphine l. Norfentanyl m. Norhydrocodone n, Normeperidine o. Oxycodone p. Oxymorphone q. Tramadol r. Amphetamine s. Amitriptyline t. Desipramine u. Imipramine v. Mortriptyline w. Gabapentin x. Pregabalin y. Alpha-hydroxyalprazolam z. Alpha-hydroxytriazolam aa. Alprazolam bb. Fluozetine cc. Lorazepam dd. Nordiazepam ee. Oxazepam ff. Temazepam gg. 6-Acetylmorphine hh. Benzoylecgonine ii. Ketamine jj. MDMA kk.Methamphetamine ll. Norketamine mm. PCP nn. THC-COOH oo. Cyclobenzaprine pp. Zolpidem qq. Cotinine rr. Tapentadol ss. N-dresmethylcitalopram tt. Paroxetine uu. Venlafaxine 2. An interview on 3/5 /2020 at 10:15 am with the GS confirmed the laboratory did not perform verification of accuracy testing for any toxicology analytes in 2019.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the General Supervisor (GS), the laboratory failed to label Ammonium Acetate solution used in toxicology testing with the identity, concentration, and expiration dates for the current bottle in use. Findings include: 1. An observation by the surveyor on 3/5/2020 at 10:55 am revealed a glass bottle labeled "ACN" that did not contain the following: a. Identity of the solution b. Concentration of the solution c. Expiration date 2. A review of the laboratory's established procedure manual revealed a section titled "Aqueous Solution Preparation" stating, "5 mM Ammonium Acetate in LCMS Grade Water: Weigh out 390 mg of LCMS grade Ammonium Acetate. Add 1 L of LCMS grade water. Mix well. Pour off into 20 mL disposable scintillation vials. Label properly. Store at room temperature. Dispose of after one week." 3. An interview on 3/5/2020 at 10:55 am with the GS confirmed the bottle had not been labeled with the information listed above and it contained an Ammonium Acetate solution.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv)

	Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the General Supervisor (GS), the laboratory failed to establish performance specifications of the laboratory-developed liquid chromatography mass spectrometry system used in toxicology testing before reporting patient results for 5 (October 2019 to March 2020) of 5 months. Findings include: 1. During a tour on 3/5/2020 at 10:50 am, the surveyor observed a Shimadzu LC/MS 8050 liquid chromatography mass spectrometry analyzer used in toxicology testing. 2. The surveyor requested verification of performance documentation for Future Diagnostic Center on 3/5/2020 at 11:50 am and it was not made available. 3. A review of the laboratory's "Future Test Menu" revealed it has 47 tests on it's menu: a. Buprenorphine b. Codeine c. EDDP d. Fentanyl e. Hydrocodone f. Hydromorphone g. Hydroxybupropion h. Meperidine i. Methadone j. Morphine k. Norbuprenorphine l. Norfentanyl m. Norhydrocodone n, Normeperidine o. Oxycodone p. Oxymorphone q. Tramadol r. Amphetamine s. Amitriptyline t. Desipramine u. Imipramine v. Mortriptyline w. Gabapentin x. Pregabalin y. Alpha-hydroxyalprazolam z. Alpha-hydroxytriazolam aa. Alprazolam bb. Fluozetine cc. Lorazepam dd. Nordiazepam ee. Oxazepam ff. Temazepam gg. 6-Acetylmorphine hh. Benzoylecgonine ii. Ketamine jj. MDMA kk.Methamphetamine ll. Norketamine mm. PCP nn. THC-COOH oo. Cyclobenzaprine pp. Zolpidem qq. Cotinine rr. Tapentadol ss. N-dresmethylcitalopram tt. Paroxetine uu. Venlafaxine 4. An interview on 3/5/2020 at 1:25 pm with the GS confirmed the laboratory did not establish performance specifications for the 47 analytes it tests using the toxicology system.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to use laboratory-established calibration criteria to evaluate calibration acceptability for 5 (October 2019 to March 2020) of 5 months. Findings include: 1. A review of the laboratory's established procedure manual revealed a section titled "Calibration Curve Preparation" stating, "Values must fall within acceptable criteria before patient samples are run. Samples for each level of a method, as shown in tables below, are made up in duplicate and run. The lowest linear points for each analyte must fall within 20% of the theoretical value. The highest linear

	points for each analyte must fall within 15% of the theoretical value. Aberrant points may be dropped as necessary, but both points for any one level may not both be dropped. The r value for calibration curve line shall be greater or equal to 0.99 and the r-squared value shall be greater or equal to 0.99." 2. An interview on 3/5/2020 at 2:30 pm with the GS revealed the laboratory accepts calibrations if the r value is at least 0.90. 3. A review of the laboratory's calibrations revealed on 12/4/19, hydromorphone was calibrated with an r-squared value of 0.6865470 and an r value of 0.8285813. 4. An interview on 3/5/2020 at 2:30 pm with the GS confirmed the laboratory did not ensure calibrations were within established acceptable limits.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 use laboratory-established quality control acceptability criteria to evaluate quantitative toxicology quality control results before reporting patient results for 5 (patients 1-5) of 5 patient testing days reviewed. Findings include: 1. A review of the laboratory's established procedure manual revealed a section titled "Daily Quality Controls to Verify Calibration Curve" stating, "A low, mid, and high QC relevant to each drug's linear curve must be evaluated daily. QC values must be in their established ranges for the QC level to pass for a drug. Low QC must each fall within plus or minus 20% of the theoretical value. Mid and high QCs must each fall within plus or minus 15% of the theoretical value. The results of the QC samples provide the basis of accepting or rejecting the run. All of the QC samples must be within the acceptable range of their respective theoretical value for the run to pass." 2. An interview on 3/5/2020 at 2:30 pm with the GS revealed the laboratory uses the retention time value, which is used to determine what analyte is present, but does not evaluate the numerical amount of drug (quantitative value) present in the sample, and compares it to the retention time value of the standard to see if it is close. 2. An interview on 3/5/2020 at 2:30 pm with the GS revealed the laboratory uses the retention time value, which is used to determine what analyte is present, but does not evaluate quantitative value (the numerical amount of drug) present in the quality control samples. The laboratory compares the retention time value of the analyte to the standard graph of known retention time values to see if it is close and verify the analyte is present. However, the laboratory is reporting a quantitative value (numerical value) for patients, but the quantitative value is not assessed for quality control. 3. On 3/5/2020 at 2:30 pm, the surveyor requested criteria for evaluating retention times and it was not made available. 4. A review of 5 patient testing days revealed retention times, not the established acceptance criteria of quantitative results, were used to evaluate the acceptance of quality control for the following days patients were reported: a. 9/23/19 b. 10/29/19 c. 12/4/19 d. 1/27/2020 e. 2/3/2020 5. An interview on 3/5/2020 at 2:30 pm with the GS confirmed the laboratory did not follow laboratory-established quality control acceptance criteria before reporting patient results.
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on observation, document review, and interview with the General Supervisor (GS), the laboratory failed to ensure personnel performing high complexity toxicology testing met educational requirements at 42 CFR 493.1489 for 2 (Testing Personnel #2 and one staff member not listed on the CMS-209 form) of 3 testing personnel. Findings include: 1. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures

	related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the General Supervisor (GS), the laboratory failed to ensure personnel performing high complexity toxicology testing met educational requirements at 42 CFR 493.1489 for 2 (Testing Personnel #2 and Testing Personnel X) of 3 testing personnel. Findings include: 1. An observation on 3/5/2020 at 10:38 am by the surveyor revealed a staff member not listed on the CMS-209 form (Testing Personnel X) was adding reagent to patient specimens. 2. A review of Testing Personnel X's education credentials and training revealed they did not have documentation of the following: a. Completion of a clinical laboratory training program or b. At least 3 months documented laboratory training in high complexity toxicology testing. 3. A review of educational credentials for Testing Personnel #2 provided by the laboratory included a Bachelor of Science diploma and a transcript stating, "Bachelor of Science 30-APR-2011 Primary degree Major: Health Case Management" and did not include at least 6 semester hours of chemistry as required in 42 CFR 493.1489. 4. An interview on 3/5/2020 at 10:38 am with the GS confirmed Testing Personnel #2 was not qualified to perform high complexity toxicology testing. 5. An interview on 3/5/2020 at 12:47 pm with the GS confirmed Testing Personnel X was not qualified to perform high complexity toxicology testing.