Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1010918	09/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
City Medical	30581 Stephenson Hwy, Madison Heights, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to follow laboratory's rejection policy and manufacturer's instructions for storage and preservation of specimens tested for Cocaine and Norhydrocodone for 8 of 10 (8567, 6786, 3541, 3822, 3249, 3421, 3188, 8065) patient test records reviewed. Findings include: 1. Based on record review of patient reports (8 of 10), the surveyor observed prolonged testing times after specimen collection of patient samples: 1.) Patient 1(8567): Collected 11/27/2023 and tested on 12/05/2023 2.) Patient 2 (6786): Collected 06/26/20240 and tested on 7/04/2024 3.) Patient 3 (3541): Collected 09/18/2024 and tested on 09/27/2023 4.) Patient 4(3822): Collected 07/24/2023 and tested on 08/03/2023 5.) Patient 5 (3249): Collected 06/20/2023 and tested on 06/28/2023 6.) Patient 6 (3421): Collected 1/20/2023 and tested on 1/31 /2023 7.) Patient 7(3188) : Collected 12/21/2022 and tested on 01/04/2023 8.) Patient 8 (8065): Collected 03/10/224 and tested on 03/20/2024 2. Review of manufacturer's instructions revealed sample must be frozen if tested beyond 5 days for Cocaine and Norhydrocodone to ensure specimen stability. 3. Interview with TC1 confirmed the that specimens were not rejected per laboratory's policy and not frozen according to manufacturer's instructions.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: . . Based on record review and interview with Technical Consultant #1 (TC1) the laboratory failed to ensure the time the laboratory received specimens was documented for 10 of 10 (8567, 6786, 3541, 3822, 3249, 3421, 3188, 8065, 7507, 4813) patient test records reviewed. Findings include: 1. A review of the laboratory's test records revealed a lack of time the laboratory received specimens for the following patients: 1) Patient 1 (8567): Collected 11/27/2023 2) Patient 2 (6786): Collected 06/26/2024 3) Patient 3 (3541): Collected 09/18/2024 4) Patient 4(3822): Collected 07/24/2023 5) Patient 5 (3249): Collected 06/20/2023 6) Patient 6 (3421): Collected 1/20/2023 7) Patient 7 (3188): Collected 12/21/2022 8) Patient 8 (8065): Collected 03/10/2024 9) Patient 9 (7507): Collected 03/03/2023 10) Patient 10 (4813): Collected 09/28/2022 2. An interview with TC1 on 09/16/2024 at 12:20 pm confirmed the laboratory did not document the time the laboratory received specimens.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1) the laboratory failed to ensure the current Laboratory Director (LD) approved, signed and dated laboratory procedures before use. Findings include: 1. Record review of laboratory policies and procedures revealed they were not signed, dated, and approved by the current lab director. 2. Interview with TC1, on 09/16/2024 at 10:50 am confirmed that laboratory policies and procedures were not signed, dated and approved by the current LD.
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 observation, record review, and interview with Technical Consultant #1, the laboratory failed to ensure proper storage of urine toxicology specimens for two (September 2022 to September 2024) of two years reviewed. Findings include: 1. The surveyor observed the laboratory's freezer on 9/16/24 at 9:13 am with urine specimens inside. 2. A review of the laboratory's "Temperature Log" documentation from

	September 2022 to September 2024 revealed the freezer acceptable temperature range was "less than or equal to -20 degrees C" and all readings were documented as "-12." 3. A review of the laboratory's "Policy and Procedures for Urine Drug Testing at City Medical" revealed a section stating, "A urine aliquot will remain frozen on site for 5 days." 4. A review of the laboratory's "Siemens Cocaine Metabolite Assay" instructions for use revealed a section titled "Specimen Collection and Preparation" stating, "After 7 days unrefrigerated or 30 days refrigerated, samples should be stored frozen (-20 degrees C) for up to 3 years." 5. A review of the laboratory's "Siemens Buprenorphine Assay" instructions for use revealed a section titled "Specimen Collection and Preparation" stating, "If not analyzed immediately, specimens may be stored refrigerated or unrefrigerated up to 5 days. After 5 days specimens should be stored frozen at -20 degrees C." 6. A review of the laboratory's "Siemens Oxycodone Assay" instructions for use revealed a section titled "Specimen Collection and Preparation" stating, "After 7 days specimens should be stored frozen at -20 degrees C." 7. An interview on 9/16/24 at 10:17 am with Technical Consultant #1 confirmed the specimen freezer temperatures were out of range.
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, interview, and record review with Testing Consultant #1 (TC1) the laboratory failed to label 2 testing reagents on the Siemens Viva-ProE instrument. Findings include: 1. The surveyor observed on 9/16/2024 at 9:24 am that hydrochloric acid (HCL) reagent and probe cleaner on Siemens Viva-ProE instrument was not labeled with open date or expiration date. 2. An interview with TC1 on 9/16 /2024 at 9:25 am confirmed that reagents on the instrument were not labeled. 3. A review of the "Laboratory's General Laboratory Policies", Section "Reagents, Controls, Test Kits, Media, Etc.," it states, "All reagents, controls, test kits, media, etc. are marked with appropriate, date received, date opened, date initially used, and the expiration date ..."
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to ensure the Laboratory Director, performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings

	include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and interview Technical Consultant #1 (TC1), the laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel's competency assessments was qualified. Findings include: 1. A review of the laboratory's personnel competency assessment records revealed that Laboratory Director (LD) performed competency assessments in 2024, 2023, and 2022 for TC1. 2. A record review of the Laboratory Director's credentials revealed that the LD was not qualified to perform duties of the Technical Consultant. 3. A review of the laboratory's "Personnel Training and Qualifications" policy revealed a section stating, "Personnel must be evaluated by the technical consultant at least semiannually during the first year of employment. Thereafter, testing personnel are

	evaluated yearly." 4. An interview with TC1 on 09/16/2024 at 10:00 am confirmed LD performed the competency assessments for TC1 and was not qualified to be the laboratory's Technical Consultant.