Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1010918	08/08/2022
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
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: . Based on observation and interview with the Technical Consultant (TC), the laboratory failed to ensure specimen collection tubes had not exceeded their expiration dates for 9 blood specimen collection tubes in the laboratory's phlebotomy supply cart. Findings include: 1. The surveyor observed the phlebotomy supply cart in the hallway outside of the laboratory's storage room at 9:37 am on 8/8/22. The following blood collection tubes were found to have exceeded their expiration dates: a. All sodium citrate blue-top tubes i. BD Vacutainer lot number 0316282 expiration date 8/31/21, two tubes total. ii. BD Vacutainer lot number 1259182 expiration date 6 /30/22, two tubes total. iii. BD Vacutainer lot number 1288653 expiration date 7/31 /22, one tube total. b. All dipotassium ethylenediaminetetraacetic acid (K2EDTA) navy-top tubes: i. BD Vacutainer lot number 1137444 expiration date 5/31/22, two tubes total. c. All dipotassium ethylenediaminetetraacetic acid (K2EDTA) pink-top tubes: i. BD Vacutainer lot number 1014130 expiration date 6/30/22, two tubes total. 2. An interview on 8/8/22 at 9:42 am with the TC confirmed the blood collection tubes listed above had exceeded their expiration dates. ***This is a repeated deficiency from the 7/15/16 recertification survey***
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to include the address of the laboratory where qualitative toxicology testing was performed for 8 (Patients 15244, 17297, 18508, 20105, 21312, 31649, 27148, and 24321) of 12 patient test reports reviewed. Findings include: 1. A review of patient qualitative toxicology test reports revealed 8 of 12 did not indicate the address of the laboratory where testing had been performed: a. Patient 15244 received testing on 6/2/21. b. Patient 17297 received testing on 7/20/21. c. Patient 18508 received testing on 8/30/21. d. Patient 20105 received testing on 10/7/21. e. Patient 21312 received testing on 11/5/21. f. Patient 24321 received testing on 1/25/22. g. Patient 27148 received testing on 3/2/22. h. Patient 31649 received testing on 6/27/22. 2. An interview on 8/8/22 at 10:13 am with the TC confirmed the laboratory did not include the address of the laboratory where qualitative toxicology testing had been performed for the patients listed above on the test report.
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 the Technical Consultant, the laboratory failed to ensure the quality assurance manager, performing the duties of a Technical Consultant, had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of peforming testin 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 with the Technical Consultant, the laboratory failed to ensure personnel performing the technical consultant duty of performing testing personnel competency assessments was qualified for 1 (quality assurance manager) of 2 personnel performing testing personnel competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed Testing Personnel #1 had a competency assessment performed in June 2022 by the quality assurance manager. 2. The surveyor requested the qualifications of the quality assurance manager on 8/8/22 at 4:54 pm and the documentation was not made available. 3. An email received on 8/12/22 at 10:00 am from the Technical Consultant revealed the quality assurance manager did not have the qualifications to perform the duties of a technical consultant.