Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1010918	05/24/2021
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
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on observation and interviews with the Office Manager and Technical Consultant, the laboratory failed to report SARS-CoV-2 test results as required for 27 tests performed since the laboratory started testing on 5/1/21. Findings include: 1. An observation by the surveyor on 5/24/21 at 9:10 am revealed the laboratory was performing SARS-CoV-2 testing using the Abbott BinaxNOW antigen test cards. 2. An interview with the Office Manager on 5/24/21 at 10:18 am revealed the laboratory is not reporting their SARS-CoV-2 testing results from the Abbott BinaxNOW antigen test cards to the health department. 3. An interview with the Technical Consultant on 5/24/21 at 10:57 am revealed the laboratory had tested 27 patients since the laboratory started testing on 5/1/21.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to have qualitative toxicology test requests from an authorized person for 7 (Patients

	14026, 1112, 4212, 7794, E2, 33, and 18) of 10 patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed the following patients had qualitative toxicology testing ordered and performed: a. Patient 14026 tested on 04/29/2021 b. Patient 1112 tested on 04/22/2020 c. Patient 4212 tested on 08 /03/2020 d. Patient 7794 tested on 11/10/2020 e. Patient E2 tested on 12/22/2020 f. Patient 33 tested on 06/21/2019 g. Patient 18 tested on 08/31/2019 2. An interview on 5/14/21 at 10:02 am with the Office Manager revealed the laboratory did not have test requests for the patients listed above for those testing dates.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to ensure test results were sent to the final report destination for 3 (Patients 1112, 33, and 18) of 10 patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed the following patients had qualitative toxicology testing ordered and performed: a. Patient 1112 tested on 04/22/2020 b. Patient 33 tested on 06/21/2019 c. Patient 18 tested on 08/31/2019 2. An interview on 5/14/21 at 10:02 am with the Office Manager revealed the laboratory did not have test reports for the patients listed above for those testing dates.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the Laboratory Director failed to ensure established quality assessment programs were maintained for 2 (May 2019 to May 2020) of 2 years. Findings include: 1. A review of the laboratory's Quality Assurance policy revealed a section stating, "The director will review all laboratory proficiency testing results and all quarterly and annual QA indicator monitoring done." 2. A review of the laboratory's records revealed a lack of quality assessment reviews from May 2019 to May 2021. 3. An interview on 5/24/21

	at 10:45 am with the Technical Consultant revealed the laboratory did not perform quarterly and annual quality assessment monitoring in accordance with the established policy.