Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2181522	04/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mi Health Clinic	4707 Mcleod Drive East, Saginaw, 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	The purpose of this unannounced survey was for complaint #MI00111704. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, 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: General Immunology was not met. Findings include: 1. The laboratory failed to establish performance specifications for the Ray Biotech SARS-CoV-2 IgM and the Healgen SARS-CoV-2 IgM/IgG combination assays to use capillary blood as the specimen source. Refer to D5423. 2. The laboratory failed to perform quality control procedures each day patient testing was performed using the Ray Biotech SARS-CoV-2 IgM and Healgen SARS-CoV-2 IgM/IgG combination assays. Refer to D5445.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Medical Director and the General Supervisor, the laboratory failed to establish a procedure for reporting results when the Ray Biotech SARS-CoV-2 IgM and Healgen SARS-CoV-2 IgM assays have discrepant results for 22 (Patients 4201, 4202, 4204, 4205, 4206, 4207, 4208, 4209, W4, W7, W9, W11, W14, W18, W19, W20, W21, W22, W23, W24, W26, and W28) of 32 patient charts audited. Findings include: 1. A record review of 32 patient testing work records revealed 22 demonstrated discrepancies between the Ray Biotech SARS-CoV-2 IgM and Healgen SARS-CoV-2 IgM assays. a. Patient 4201 had 1+ reactivity for the Healgen assay and 0 reactivity for the Ray Biotech assay. b. Patients 4202, 4204, 4205, 4206, 4207, 4208, 4209, W4, W26, W22, W7, W11, W19, W21, and W23 had 1+ reactivity for the Ray Biotech assay and 0 reactivity for the Healgen assay. c. Patients W20 and W14 had reactivity of 2+ for the Ray Biotech assay and 0 for the Healgen assay. d. Patients W18, W28, W24, and W9 had a reactivity of 2+ for the Healgen assay and 0 for the Ray Biotech assay. 2. A record review of the laboratory established "COVID-19 IgM Antibody Detection", "COVID-19 IgM/IgG Antibody Detection", and "Michigan Health Clinics Standard Operating Procedures for COVID-19 Testing and Reporting" procedures revealed a lack of procedure describing how testing personnel is to resolve discrepancies between the two SARS-CoV-2 IgM assays before reporting patient test results. 3. A phone interview on 4/23 /2020 at 3:00 pm with the Medical Director and the General Supervisor confirmed the laboratory did not have an established procedure to resolve discrepancies between the two SARS-CoV-2 IgM testing kits before reporting patients.
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 record review and interviews, the laboratory failed to establish performance specifications for the Ray Biotech SARS-CoV-2 IgM and the Healgen SARS-CoV-2 IgM/IgG combination assays to use capillary blood as the specimen source for 20 (4/3/2020 to 4/23/2020) of 20 days the laboratory has been accepting patient specimens. Findings include: 1. A record review of the laboratory's established "Internal Validation of Qualitative IgM and IgG Detection Kits Ray-Biotech Testing of SARS-CoV-19 (IgM & IgG)" and "Internal Validation of Qualitative IgM and IgG Detection Kits Healgen Testing of SARS-CoV-19 (IgM & IgG)" verification of performance data showed it was approved by the Laboratory Director on 4/1/2020 2. A phone interview on 4/21/2020 at 11:00 am with the Medical Director revealed the laboratory started accepting specimens for testing on 4/3/2020. 3. A record review of the laboratory's established "Internal Validation of Qualitative IgM and IgG Detection Kits Ray-Biotech Testing of SARS-CoV-19 (IgM & IgG)" revealed a section stating, "100 whole blood samples were tested after the approval of the Institution Review Board (IRB). The blood samples were transferred from tubes with anticoagulant (EDTA) previously collected from patients tested for Covid-19 with RT-PCR. Since our intention was to perform the test on plasma from patients, our validation procedure addressed only plasma samples. No validation was done concerning serum, whole blood, or capillary blood samples." 4. A record review of the laboratory's established "Internal Validation of Qualitative IgM and IgG Detection Kits Healgen Testing of SARS-CoV-19 (IgM & IgG)" revealed a section stating, "90 whole blood samples were tested after the approval of the Institution Review Board (IRB). The blood samples were transferred from tubes with anticoagulant (EDTA) previously collected from patients tested for Covid-19 with PCR. Since our intention was to perform the test on plasma from patients, our validation procedure addressed only plasma samples. No validation was done concerning serum, whole blood, or capillary blood samples." 5. A phone interview on 4/21/2020 at 11:10 am with the General Supervisor revealed the laboratory uses both capillary and venous specimens for SARS-CoV-2 IgM and IgG testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to perform quality control procedures each day patient testing was performed using the Ray Biotech SARS-CoV-2 IgM and Healgen SARS-CoV-2 IgM/ IgG combination assays for 1 (4 /20/2020) of 5 days patient testing was performed. Findings include: 1. A record review of the laboratory's "COVID-19 IgM Antibody Detection" procedure revealed a section stating, "Plasma from patients with PCR confirmed positive and negative SARS-COV-2 infection will be used as controls. Positive and negative control plasma will be frozen at -20 degrees Celsius for up to 3 months in 35 ul aliquots in labeled plastic bullets. Controls can be frozen at -80 degrees Celsius for long-term storage.

	Thaw controls at room temperature. Controls will be tested as follows: Every new kit lot received, after receipt of a new shipment of the same lot, monthly. Negative QC [quality control] must produce a negative result. Positive QC must produce a positive or weak positive result. Record results on QC log." 2. A record review of the laboratory's procedure "COVID-19 IgG/IgM Antibody Detection" revealed a section stating, "Plasma from patients with PCR confirmed positive and negative SARS-COV-2 infection will be used as controls. Positive and negative control plasma will be frozen at -20 degrees Celsius for up to 3 months in 35 ul aliquots in labeled plastic bullets. Controls can be frozen at -80 degrees Celsius for long-term storage. Thaw controls at room temperature. Controls will be tested as follows: Every new kit lot received, after receipt of a new shipment of the same lot, monthly. Negative QC must produce a negative (0) result. Positive QC must produce a positive or weak positive (1+ or 2+) result. Record results on QC log." 3. A phone interview on 4/20/2020 at 1: 49 pm with the Medical Director revealed the Ray Biotech and Healgen assays did not have the Food and Drug Administration (FDA) Emergency Use Authorizations (EUA) and the assays were laboratory-developed. 4. A record review of the laboratory's "COVID-19 IgG/IgM Antibody Detection QC log" revealed quality control was not performed on 4/20/20. 5. A record review of laboratory work records revealed 253 patients were tested on 4/20/2020. 6. The surveyor requested the laboratory's approved Individualized Quality Control Plan (IQCP) for both the Ray Biotech and Healgen assays on 4/21/2020 at 11:12 am and it was not made available prior to survey exit. 7. A phone interview on 4/21/2020 at 11:12 am with the General Supervisor confirmed quality control testing was not performed each day of patient testing.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (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 Medical Director and General Supervisor, the laboratory failed to perform quality control testing that produced graded reactivity for the Ray Biotech SARS-CoV-2 IgM and Healgen SARS-CoV-2 IgM/IgG combination assays for 7 (4/3/2020, 4/9/2020, 4/10/2020, 4/15/2020, 4/16 /2020, 4/21/2020, and 4/22/2020) of 7 days quality control testing was performed. Findings include: 1. A record review of the laboratory's "COVID-19 IgM Antibody Detection" procedure revealed a section stating, "Plasma from patients with PCR confirmed positive and negative SARS-COV-2 infection will be used as controls. Positive and negative control plasma will be frozen at -20 degrees Celsius for up to 3 months in 35 ul aliquots in labeled plastic bullets. Controls can be frozen at -80 degrees Celsius for long-term storage. Thaw controls at room temperature. Controls will be tested as follows: Every new kit lot received, after receipt of a new shipment of the same lot, monthly. Negative QC [quality control] must produce a negative result. Positive QC must produce a positive or weak positive result. Record results on QC log." 2. A record review of the laboratory's procedure "COVID-19 IgG/IgM Antibody Detection" revealed a section stating, "Plasma from patients with PCR

	confirmed positive and negative SARS-COV-2 infection will be used as controls. Positive and negative control plasma will be frozen at -20 degrees Celsius for up to 3 months in 35 ul aliquots in labeled plastic bullets. Controls can be frozen at -80 degrees Celsius for long-term storage. Thaw controls at room temperature. Controls will be tested as follows: Every new kit lot received, after receipt of a new shipment of the same lot, monthly. Negative QC must produce a negative (0) result. Positive QC must produce a positive or weak positive (1+ or 2+) result. Record results on QC log." 3. A record review of patient testing reports revealed the laboratory is reporting graded results of 0, 1+, and 2+. 4. A record review of the laboratory's "COVID-19 IgG /IgM Antibody Detection QC Log" and "COVID-19 IgM Antibody Detection QC Log" revealed the following days did not have graded quality control performed: a. 4/3 /2020 b. 4/9/2020 c. 4/10/2020 d. 4/15/2020 e. 4/16/2020 f. 4/21/2020 g. 4/22/2020 5. A phone interview on 4/23/2020 at 3:00 pm with the Medical Director and General Supervisor confirmed the laboratory did not perform quality control with graded reactivity and does report graded test results.
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 Medical Director and General Supervisor, the laboratory failed to ensure the patient test results recorded as part of the work record were accurately entered into patient final reports for 16 (Patients 4201, 4202, 4204, 4205, 4206, 4207, 4208, 4209, W4, W7, W11, W19, W21, W23, W24, and W26) of 32 patient charts audited. Findings include: 1. A record review of patient work records and the corresponding final reports revealed the following patient testing work records were not accurately entered into the final reports: a. Patients 4201, 4204, 4205, 4207, 4208, 4209, W7, W11, W19, W21, W23, W26 work records stated 1+ reactivity for IgM and the final reports stated 2+ reactivity for IgM. b. Patients 4202 and W4 work records stated 1+ for IgM and 2+ for IgG and the final reports stated 2+ reactivity for IgM and 2+ reactivity for IgG. c. Patient 4206 work record stated 1+ reactivity for IgG and the final report stated 2+ reactivity for IgG. d. Patient W24 work record stated 0 for IgM and 2+ for IgG and the final report stated 2+ reactivity for IgM and 2+ reactivity for IgG. 2. A phone interview on 4/23/2020 at 3:00 pm with the Medical Director and the General Supervisor confirmed the laboratory had not accurately entered the work record results into the patients' final reports.