Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0365804	01/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Forum Medical Clinics, Pc	25625 Schoenherr Road, Warren, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to follow its policy to ensure optimum integrity of patient Complete Blood Count (CBC) specimens prior to testing for 7 (Patients 2, 17, 47, 99, 67, 38, and 34) of 13 patient test reports reviewed. Findings include: 1. A review of the laboratory's "Medonic M Series Hematology Analyzer Procedure Manual" revealed a section titled "Specimen Requirements/Patient Preparation" stating, "For optimum results, the sample should be gently mixed for 10-15 minutes on a mixer, and should be analyzed between 15 minutes and 6 hours stored at room temperature. Failure to mix properly or count in the required time limit may produce erroneous results" 2. A review of 13 patient CBC test reports revealed the following patients had CBC testing performed beyond 6 hours from the collection date and time: a. Patient #2 had their specimen collected on 3/10/22 at 10:20 am and their CBC performed on 3/11/22 at 2:04 pm. b. Patient #17 had their specimen collected on 4/6/22 at 3:24 pm and their CBC performed on 4/7/22 at 10:46 am. c. Patient #47 had their specimen collected on 7/11 /22 at 9:47 am and their CBC performed on 7/12/22 at 11:27 am. d. Patient #99 had their specimen collected on 8/9/22 at 3:40 pm and their CBC performed on 8/10/22 at 11:51 am. e. Patient #67 had their specimen collected on 9/20/22 at 11:36 am and their CBC performed on 9/21/22 at 10:18 am. f. Patient #38 had their specimen collected on 11/7/22 at 8:54 am and their CBC performed on 11/8/22 at 11:20 am. g. Patient #34 had their specimen collected on 12/5/22 at 9:51 am and their CBC performed on 12/6/22 at 11:25 am. 3. An interview on 1/5/23 at 11:49 am with the

	Technical Consultant confirmed the patients listed above had been tested beyond the established optimum stability of patient specimens.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to follow its policy to assess competency for its urine qualitative toxicology testing for 1 (Testing Personnel #1) of 1 testing personnel performing testing. Findings include: 1. A review of the laboratory's personnel competency records revealed a lack of competency assessment for Testing Personnel #1 for the performance of urine qualitative toxicology testing using the Medica EasyRA analyzer. 2. A review of the laboratory's "Employee Evaluations" policy revealed a section stating, "All new lab employees will have a competency evaluation after their initial training, at the 6 month interval and every year thereafter." 3. An interview on 1/5/23 at 12:12 pm with the Technical Consultant revealed the laboratory started testing using the Medica EasyRA test system in January 2022 and competency assessments for Testing Personnel #1 had not been performed according to the laboratory's policy.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Technical Consultant, the laboratory failed to establish maintenance protocols for mechanical pipettes and a centrifuge for 2 (December 2020 to December 2022) of 2 years reviewed. Findings include: 1. A tour of the laboratory on 1/5/23 at 11:01 am revealed two mechanical Thermo Scientific Finnpipette pipettes used in reagent preparation and a Druker Diagnostics centrifuge used in specimen preparation. 2. The surveyor requested maintenance documentation for the mechanical pipettes and centrifuge on 1/5/23 at 11:16 am and it was not made available. 3. An interview on 1/5/23 at 1:01 pm with the Technical Consultant revealed the laboratory had not established procedures for maintaining mechanical pipettes and the centrifuge.