Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0365804	07/08/2021
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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to verify the performance specifications. Refer to D5421. 2. The laboratory failed to document sample test reactions as part of the verification of performance specifications for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5427. 3. The laboratory failed to determine if calibration verification procedures performed met the laboratory's acceptable limits. Refer to D5439 A. 4. The laboratory failed to perform calibration verification procedures at least once every 6 months for Total Iron Binding Capacity testing. Refer to D5439 B. ***This is a repeated Condition from the 6/3/19 recertification survey***
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to verify the performance specifications for 2 (Testosterone and Prostate Specific Antigen) of 8 assays on the laboratory's Beckman Access II instrument. Findings include: 1. A review of the laboratory's "Test Check List" revealed Testosterone and Prostate Specific Antigen (PSA) were listed as part of the laboratory's test menu. 2. An interview on 7/8/21 at 1:04 pm with TC1 confirmed the Testosterone and PSA assays were added to the test menu since the previous survey. 3. The surveyor requested the laboratory's verification of performance specification data for the Testosterone and PSA assays at 1:04 pm on 7/8/21 and it was not made available. 4. A review of the laboratory's patient testing logs revealed a total of 45 patient testing dates between 1/8/21 and 7/1/21 with 14 patients tested with the Testosterone assay and 69 patients tested with the PSA assay. 5. An interview on 7/8 /21 at 2:00 pm with TC1 confirmed the laboratory did not verify the performance specifications compared to the manufacturer for the Testosterone and PSA assays. ***This is a repeated deficiency from the 12/19/16 recertification survey***
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to document sample test reactions as part of the verification of performance specifications for the Healgen COVID-19 IgG/IgM Rapid Test Cassette for 20 of 20 samples tested. Findings include: 1. A review of the laboratory's "Results of Verification Study" revealed the laboratory tested 10 known positive samples and 10 known negative samples and did not document the reactions from each sample cassette tested. 2. A review of the laboratory's "New Method Validation Policy" revealed it did not include a policy for documenting sample test reactions as part of the verification of performance specifications. 3. An interview on 7/8/21 at 9:39 am with TC1 confirmed the laboratory did not document sample test reactions for the verification of performance specifications for the Healgen COVID-19 IgG/IgM Rapid Test Cassette.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
. A. Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to determine if calibration verification procedures performed met the laboratory's acceptable limits for 2 (11/29/19 event and 6/25/20 event) of 4 calibration verification events. Findings include: 1. A review of the laboratory's calibration verification documentation revealed the following analytes listed on the laboratory's test menu did not have calibration verification evaluated to determine if the results were within acceptable limits: a. 11/29/19 calibration verification testing event i. Uric Acid ii. Alanine Aminotransferase (ALT) b. 6/25/20 calibration verification testing event i. Carbon Dioxide (CO2) ii. Blood Urea Nitrogen (BUN) iii. Aspartate Transaminase (AST) 2. The surveyor requested the calibration verification evaluations for the the analytes listed above on 7/8/21 at 11:18 am and they were not made available. 3. A review of the laboratory's "Calibration Verification" policy revealed a section stating, "The calibration verification will be monitored on the monthly QA Review sheet." and did not specify the laboratory's acceptable limits for calibration verification. 4. An interview on 7/8/21 at 11:33 am with TC1 confirmed the laboratory did not ensure calibration verification procedures for the analytes listed above were within acceptable limits. B. Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to perform calibration verification procedures at least once every 6 months for Total Iron Binding Capacity testing for 2 (July 2019 to June 2021) of 2 years. Findings include: 1. A review of the laboratory's calibration verification documentation revealed a lack of records showing the performance of calibration verification procedures for Total Iron Binding Capacity (TIBC) testing at least every 6 months in 2019 and 2020. Below is the list of dates when calibration verification was performed for other chemistry analytes, but not TIBC: a. 11/29/19 b. 6/25/20 c. 12/29/20 2. A review of the laboratory's "Calibration Verification" procedure revealed a section stating, "Calibration verification will be performed every six months. Calibration verification will be performed on all analytes that have less than a three point calibrator." 3. An interview on 7/8/21 at 11:23 am with TC1 revealed the TIBC assay uses two calibrators and calibration verification for the assay had not been performed at least every 6 months. *** This is a repeated deficiency from the 6/3/19 recertification survey***