Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0365804	06/03/2019
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to retain 1) the chemistry instrument maintenance logs and 2) the chemistry, endocrinology, and immunology quality control records for 2 (May 2017 to May 2019) of 2 years reviewed. Findings include: 1. Record review of the monthly maintenance logs revealed lack of documentation as follows: a. "Mindray BS-200 Maintenance Log" - no June, July, and August 1st-17th 2017 b. Beckman Coulter Access 2 maintenance log - no June and July 2017 2. Record review of the chemistry, endocrinology, and immunology quality control records revealed lack of documentation for the daily quality control for the following patient audits as follows: a. August 3-4, 2017 Patient 8966 - no lipid ("CHOL, TRIG, HDL, and LDL") controls b. October 27, 2017 Patient 9763 - no "CMP" and Vitamin D controls c. December 13, 2017 Patient 5147 - "CMP" and "hs-CRP" controls d. February 14, 2018 Patient 5522 - "Cystatin-C" controls e. May 15, 2018 Patient 6312 - "Cystatin-C" controls 3. During the interview on June 3, 2019 at 12:00 pm, 12:47 pm, and 2:50 pm, the TC acknowledged the maintenance logs and quality control records were not retained for two years. ***Repeat Deficiency from 12/19/16 survey***
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to review, evaluate, and provide corrective action take for the hematology and chemistry proficiency testing results for 3 (3rd event 2017 and 2nd and 3rd events in 2018) of 6 events reviewed that received grades less than 80%. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) proficiency testing final reports revealed no documentation of corrective action for 3 of 6 events as follows: a. 3rd event 2017 - hematology b. 2nd event 2018 - chemistry - cholesterol (20%) and total protein (40%) c. 3rd event 2018 - chemistry - albumin (0%), chloride (40%), and high density lipoprotein (20%) 2. During the interview on June 3, 2018 at 9:56 am, the TC acknowledged the laboratory did not have any documentation for the corrective action taken for the hematology and chemistry analytes that were below the 80% acceptable range. ***Repeat Deficiency from 12/19/16 survey ***
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 Technical Consultant (TC), the laboratory failed to have a written request for patient testing from an authorized person for the hematology, chemistry, and immunology testing for 1 (medical record number 8413) of 17 patient charts audited. Findings include: 1. Record review of patient chart audits revealed the laboratory did not have a written request for the testing performed for 1 of 17 charts audited and the following testing was completed: a. "CBC with Diff" b. "CMP" c. "hs-CRP" d. Uric Acid e. Homocysteine f. "Lipid Panel" 2. During the interview on June 3, 2019 at 2:50 pm, the TC confirmed the written order was not scanned into the laboratory information system and was not available on the day of the survey.
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 follow their written procedure for the "Temperature and Humidity Log" readings. Refer to D5401. 2. The laboratory failed to perform and document the weekly maintenance on the

	"Hematology Maintenance" log. Refer to D5429. 3. The laboratory failed to perform and document the calibration verification for the Mindray BS-200 chemistry analyzer at least every six months. Refer to D5439. 4. The laboratory failed to perform quality control as required for the chemistry endocrinology testing. Refer to D5445. The cumulative effect of the failure of the laboratory to meet the requirements of 493.1251 through 493.1289 constitutes condition-level noncompliance.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on procedure review, observation, lack of documentation, and interview with Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to follow their written procedure for the "Temperature and Humidity Log" for 2 (May 2017 to May 2019) of 2 years of reagent storage. Findings include: 1. Tab 1 of the "Lab Manual" under "Temperature and Humidity Log" , the policy states to record temperatures daily. 2. On June 3, 2019 at 8:55 am during a tour of the laboratory the surveyor observed the following reagents stored in the Whirlpool refrigerator: a. Endocrinology reagents - Free Thyroxine (Free T4), Thyroid Stimulating Hormone (TSH), and Vitamin D reagent + calibrator. b. Chemistry reagents - Hemoglobin A1C control set, chemistry control set + calibration set, Folate reagent, Vitamin B12 reagent + calibrator, and Ferritin reagent + calibrator. 3. The "Temperature and Humidity Log" revealed lack of documentation to show the temperature reading was recorded daily as the refrigerator did not have a thermometer to monitor the temperature range. 4. On June 3, 2019 at 1:16 pm, the TP acknowledged the refrigerator did not have a thermometer so actual temperatures were not being read and recorded daily. ***Repeat Deficiency from 12/19/16 survey***
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document the weekly maintenance on the "Hematology Maintenance" log for 2 (March and April 2019) of 24 months reviewed. Findings include: 1. Record review of the "Hematology Maintenance" log revealed three tasks to be performed weekly as follows: a. "Empty Waste" b. "Change water for eye wash" c. "Clean microscope" 2. Record review of the "Hematology Maintenance" logs revealed for two (March and April 2019) months the weekly maintenance was not recorded for 3 of the 4 weekly tasks. 3. During the interview on June 3, 2019 at 1: 03 pm, the TC acknowledged the maintenance was not performed as required.

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: . Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to perform and document the calibration verification for the Mindray BS-200 chemistry analyzer at least every six months for 2 (May 2017 to May 2019) of 2 years. Findings include: 1. No documentation was found to show the calibration verification of the Mindray BS-200 chemistry analyzer had been performed and documented every six months as follows: a. October 2017 - no documentation b. April and October 2018 - no documentation c. April 2019 - no documentation 2. When requested on June 3, 2019 at 12:06 pm, the TC acknowledged the laboratory did not perform calibration verifications since the instrument was put into use.
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 interview with the Technical Consultant (TC), the laboratory failed to perform quality control as required for the chemistry and endocrinology testing for 2 (medical record number 5522 and 6312) of 17 patient

	charts audited. Findings include: 1. Review of the quality control records revealed a lack of documentation of controls run for the following tests performed: a. 5522 - 02 /14/18 lack of control documents for Cystatin-C b. 6312 - 05/15/18 lack of control documents for Cystatin-C, thyroid stimulating hormone, and free thyroxine 2. During the interview on June 3, 2019 at 2:50 pm, the TC and Testing Personnel (TP) acknowledged two different levels of external controls had not been performed on the day of testing. ***Repeat Deficiency from 12/19/16 survey***
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, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to provide patient test reports for 1 (medical record number {MRN} 8413) of 17 patient charts audited. Findings include: 1. Record review of patient test reports revealed lack of documentation of the final report for 1 of 17 patient charts audited failed to be scanned into the laboratory information system (LIS) from 03/06/2019 for MRN 8413. 2. On 06/03/2019 at 2:50 pm when queried, Testing Personnel (TP) was not able to provide the surveyor the final patient testing results. 3. During the interview on June 3, 2019 at 2:50 pm, the TC and TP acknowledged the patient final test report was not scanned into the LIS system.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant (TC), the laboratory failed to ensure the final American Proficiency Institute (API) proficiency testing (PT) reports were reviewed by the appropriate testing personnel for 2 (May 2017 to May 2019) of 2 years reviewed. Findings include: 1. Record review of the API hematology and chemistry proficiency testing reports revealed the appropriate testing personnel (TP) did not review the final results as follows: a. hematology and chemistry 3rd event 2017 b. hematology and chemistry 1st-3rd events in 2018. 2.

	During the interview on June 3, 2019 at 9:56 am, TC confirmed the TP did not review the final PT results. ***Repeat Deficiency from 12/19/16 survey***