| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D0984811 | 08/28/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| John R Medical Clinic | 26505 John R Street, 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 |
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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>. Based on review of the American Association of Bioanalysts (AAB) final proficiency testing reports, it was determined that the laboratory failed to successfully participate in a CMS approved proficiency testing program for the bacteriology sub-specialty. Findings include: Review of AAB proficiency testing reports showed unsatisfactory performance for two (the 3rd event of 2018 and the 2nd event of 2019) of three proficiency testing events for the bacteriology sub-specialty. Refer to D2026 and D2028. |
| **D2026** | BACTERIOLOGY |

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| | CFR(s): 493.823(d)<br><br>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform and document remedial action for unsatisfactory bacteriology proficiency testing scores for 2 (the 3rd event of 2018 and the 2nd event of 2019) of 2 events. Findings include: 1. A review of the American Association of Bioanalysts (AAB) final reports revealed the following scores for the bacteriology subspecialty: a. the 3rd event of 2018 had a score of 40% b. the 2nd event of 2019 had a score of 50% 2. When requested on 8/28/19 at 11:35 am, documented remedial actions for the failed events was not made available. 3. An interview on 8/28/19 at 11: 35 am with the GS confirmed remedial actions had not been performed and documented. |
| **D2028** | BACTERIOLOGY<br>CFR(s): 493.823(e)<br><br>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>. Based on review of the American Association of Bioanalysts (AAB) final proficiency testing reports, it was determined the laboratory failed to achieve an overall testing event score of satisfactory performance for 2 (the 3rd event of 2018 and the 2nd event of 2019) of 3 consecutive testing events for the bacteriology sub-specialty. Findings include: 1. A review of AAB proficiency testing reports showed unsatisfactory performance in bacteriology for the following events: PT Event Score 3rd of 2018 40 2nd of 2019 50 |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, record review, and interview with the General Supervisor (GS), the laboratory failed to ensure protection from biohazardous materials for one observation. Findings include: 1. An observation on 8/28/19 at 11:01 am by the surveyor revealed Testing Personnel #1 (TP1) performed Complete Blood Count (CBC) testing without the use of gloves. 2. A record review of the laboratory's "e- |

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| | Compliance Training Bloodborne Pathogens" policy exposed a section titled "Gloves" states, "gloves must be worn when it is reasonable to anticipate hand contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, when performing vascular access procedures, and when handling or touching contaminated items and surfaces." 3. An interview on 8/28/19 at 11:01 am with the GS confirmed gloves were not worn during CBC testing. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. A. Based on record review and interview with the General Supervisor (GS), the laboratory failed to retain hematology quality control results for 2 (August 2017 to August 2019) of 2 years. Findings include: 1. A record review of Complete Blood Count (CBC) quality control from the Abbott CD-1800 hematology analyzer revealed a lack of quality control data between August 2017 and August 2019. 2. An interview on 8/28/19 at 12:55 pm with the GS confirmed quality control results from the Abbott CD-1800 hematology analyzer were not available. B. Based on record review and interview with the General Supervisor (GS), the laboratory failed to retain instrument raw data for quality control records or calibrations for 2 (August 2017 to August 2019) of 2 years. Findings include: 1. A record review of quality control and calibration records revealed only hand-transcribed results were available for the following tests: a. Glucose b. Triglycerides c. High Density Lipoproteins d. Total Cholesterol 2. An interview on 8/28/19 at approximately 10:50 am with the GS confirmed only hand-transcribed results were available and the instrument did not produce printed copies. This is a repeat deficiency from the 5/12/15 and the 2/22/11 surveys. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, record review, and interview with the General Supervisor (GS), the laboratory failed to label patient culture plates with the patient name and unique identifier for 3 of 3 plates observed. Findings include. 1. On 8/28/19 at 9:20 am, the surveyor observed 3 urine cultures that lacked patient names. 2. A review of the laboratory's policy "Examination of Urine for Bacteria" revealed a section stating, "label the bottom of the media plate with patients name, number, and date." 3. During the interview on 8/28/19 at 9:51 am, the GS confirmed culture plates were not labeled according to the laboratory's procedure. |

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| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform and evaluate the chemistry calibration verification at least once every 6 months as required. Refer to D5439. 2. The laboratory failed to perform two levels of microalbumin/creatinine quality control at least each day of patient testing. Refer to D5447. 3. The laboratory failed to perform valid quality control for High Density Lipoprotein (HDL) testing. Refer to D5481. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform and evaluate the chemistry calibration verification at least every 6 months as required for 2 (2018 and 2019) of 2 years. Findings include: 1. A record review of calibration records revealed the following tests were last calibrated 8 /9/17: a. Total Cholesterol b. Glucose c. High Density Lipoprotein d. Triglycerides 2. An interview on 8/28/19 at 10:50 am with the GS confirmed the lack of calibration data from 2018 and 2019 for the above tests. This is a repeat deficiency from the 5/12 /15 and the 1/21/09 surveys. |

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| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform two levels of microalbumin/creatinine quality control at least each day of patient testing for 3 (patient #11, patient #12, and patient #14) of 3 patients reviewed. Findings include: 1. A record review of the "DCA 2000 analyzer Microalbumin/Creatinine reagent kit package insert revealed a section titled "Quality Control" which states, "Run two DCA 2000 Microalbumin/Creatinine controls for each new lot of reagent kits. Thereafter, run one control per kit of 10 reagent cartridges and also run one control at scheduled intervals to assess and maintain operator proficiency. Establish a quality control program which includes proper sample collection and handling practices, acceptable limits on controls, on-going evaluation of control results, proper storage of reagent cartridges, etc." 2. When requested on 8/28/19 at 1:00 pm, the General Supervisor did not provide an established Individualized Quality Control Plan (IQCP) for the DCA 2000 Microalbumin/Creatinine test. 3. A review of patient charts revealed microalbumin /creatinine testing was performed on the following patients without acceptable quality control testing: a. Patient #11 performed on 8/15/18 b. Patient #12 performed on 7/23 /18 c. Patient #14 performed on 4/23/18 4. An interview on 8/28/19 at 1:03 pm with the GS confirmed quality control for microalbumin/creatinine was not performed each day of patient testing and the laboratory did not have an established IQCP. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform valid quality control for High Density Lipoprotein (HDL) testing for 143 of 180 days. Findings include: 1. A record review of HDL quality control testing Levey-Jennings charts revealed 143 days when quality control was unacceptable. a. 7/17/17- 9/22/17 b. 9/25/17- 11/15/17 c. 11/16/17- 1/22/18 d. 1/24 /18- 2/22/18 e. 3/19/18- 3/20/18 f. 3/21/18- 5/18/18 g. 6/15/18- 8/2/18 2. A review of the laboratory's "Quality Control Data Interpretation Procedure" revealed a section stating, "Do 10 consecutive control values fall on the same side of the mean? (Yes = Rejection)." 3. An interview on 8/28/19 at 11:00 am with the GS confirmed quality control was out according to laboratory-specified criteria. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c) |

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| | The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to include the test result in the test report for 1 (patient #14) of 15 patient charts audited. Findings include: 1. A patient chart audit revealed patient #14 had a microalbumin test ordered and performed on 4/23/18. The chart did not include the test report. 2. An interview on 8/28/19 at 1:03 pm with the GS confirmed the test report was missing from the patient's chart. |