| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D2103468 | 06/04/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Vascular Health Clinics | 2125 Ridgewood Drive, Midland, 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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to verify the accuracy of testing for the hematology PFA-100 platelet function testing at least twice annually for one (April to June) of one testing events in 2018. Findings include: 1. On June 4, 2018 at 11:50 AM, record review for the verification of accuracy of the PFA-100 platelet function testing revealed there was no documentation to show the testing was completed for one (April to June) of one testing events in 2018. 2. During the interview on June 4, 2018 at 11:50 AM, testing personnel #1 as listed on the CMS-209 confirmed the event from April to June 2018 was not performed and documented. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on procedure review and interview, the laboratory failed to establish and follow written procedures for the chemistry and hematology testing for 19 (November 2016 to June 2018) of 19 months of testing. Findings include: 1. On June 4, 2018 at approximately 1:30 PM, review of the "Lab Policy & Procedure Manual" and the lack |

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| | of documentation throughout the surveying process revealed the laboratory did not have procedures for the following: a. Operating procedures for the Beckman Coulter AcT diff 2 hematology analyzer - daily operating, maintenance, quality control, troubleshooting, and calibration. b. Competency c. Temperature - room temperature, refrigerator, and freezer monitoring d. Humidity monitoring e. Corrective action - temperatures out of range and control material out of range f. Reagent open expiration date, storage, and use g. Quality Assurance that monitors the general, pre-analytic, analytic, and postanalytic test systems h. Retention of medical records, patient records, laboratory testing i. Calibration and/or calibration verification j. Maintenance function checks for: centrifuge, thermometers, and pipettes 2. During the interview on June 4, 2018 at approximately 3:00 PM, testing personnel #1 as listed on the CMS-209 confirmed the lab did not have policies and procedures for the above findings. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to perform and document performance specifications for the Easyra chemistry analyzer for 14 (April 2017 to June 2018) of 15 months of patient testing. Findings include: 1. On June 4, 2018 at 11:30 AM, record review of the chemistry Easyra analyzer revealed there was no documentation to show the new instrument performance specifications (accuracy, precision, and reportable range) was validated for 14 (April 2017 to June 2018) of 15 months prior to reporting patient results. 2. On June 4, 2018 at 11:30 AM, record review revealed the laboratory had implemented a new instrument in April of 2017. When queried, testing personnel #1 as listed on the CMS-209 was not able to provide the surveyor documentation to show the performance specifications were performed and documented prior to reporting patient test results. 3. During the interview on June 4, 2018 at 11:30 AM, testing personnel #1 confirmed the performance specifications were not performed and documented before reporting out patient testing. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>. Based on lack of documentation and interview, the laboratory failed to perform and document the function checks as required by the manufacturers for the room temperature, refrigerator, and the humidity readings for 19 (November 2016 to June |

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| | 2018) of 19 months of operation for the chemistry and hematology instrumentation. Findings include: 1. On June 4, 2018 at 2:40 PM when queried, testing personnel #1 as listed on the CMS-209 was unable to provide the surveyor the documentation to show the room temperature, refrigerator, and the humidity readings were performed and documented for 19 of 19 months of testing. 2. During the interview on June 4, 2018 at 2:40 PM, testing personnel #1 as listed on the CMS-209 was unable to provide the surveyor the documentation requested. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to perform quality control as required for the hematology PFA-100 platelet function instrument each day of patient testing for nine (September 2017 to June 2018) of nine months of operation. Findings include: 1. On June 4, 2018 at 2:30 PM, record review for the PFA-100 platelet function instrument revealed the laboratory did not run at least two levels of control material each day of patient testing for nine (September 2017 to June 2018) of nine months. 2. On June 4, 2018 at 2:30 PM when queried, testing personnel #1 as listed on the CMS-209 was not able to provide the surveyor with documentation to show two different levels of control material had been performed and documented prior to running patient samples. 3. During the interview on June 4, 2018 at 2:30 PM, testing personnel #1 confirmed two different levels of controls had not been performed each day of patient testing and that an individualized quality control plan had not been implemented to decrease the number or frequency of running controls. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to establish a system to ensure the Medica Easyra instrument calculated chemistry tests low density lipoprotein (LDL) and the estimated glomerular filtration rate (eGFR) values reported |

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| | using calculations were accurately sent from point of entry to the final report periodically for accuracy for 19 (November 2016 to June 2018) of 19 months of operation. Findings include: 1. On June 4 2018 at 12:32 PM, record review for the Medica Easyra chemistry instrument identified two chemistry tests that requires a calculated final result. 2. On June 4, 2018 at 12:32 PM, record review revealed there was no documentation to show the laboratory had verified the accuracy of the instrument generated calculations for the LDL and the eGFR for 19 (November 2016 to June 2018) of 19 months of operation. 3. During the interview on June 4, 2018 at 12:32 PM, testing personnel #1 as listed on the CMS-209 confirmed the calculations were not checked periodically. . |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to ensure the six month competency assessment for one (#1) of one testing personnel performing moderately complex chemistry and hematology testing in 2017. Findings include: 1. On June 4, 2018 at 11:45 AM, record review revealed no documentation for the six month competency assessment for one of one testing personnel as follows: a. no six month competency - hematology Beckman Coulter AcT diff 2 due in 2017 b. no six month competency - hematology PFA -100 analyzer c. no six month competency - Easyra chemistry analyzer 2. During the interview on June 4, 2018 at 11:45 AM, testing personnel #1 as listed on CMS-209 confirmed the six month competency assessment was not completed. |