| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 24D0667501 | 12/13/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Entira Family Clinics North St Paul | 2601 Centennial Dr Suite 100, North Saint Paul, MN | |

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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| **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 observation, document review and interview with laboratory personnel, the laboratory failed to demonstrate a new Hematology analyzer could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 6 during a tour of the laboratory on 12/13/18 at 1:15 p.m. 2. A Cell Dyn Emerald Hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began Hematology testing using this analyzer in June 2018 as indicated in the performance verification documents and confirmed by laboratory personnel. 2. Laboratory performance verification (PV) studies completed to verify the reportable range of the analytes below did not reach the upper or lower limits of the reportable range adopted by the laboratory. See below. Analyte* PV Adopted HCT 9.2-64.6 6.0-75.0 MCV 88.6-111.6 49-115 3. In an interview on 12/13/18 at 3:50 p.m., Technical Consultant 1 and Technical Consultant 2 confirmed the laboratory's PV did not verify the upper or lower limit of the reportable ranges adopted from the manufacturer's literature. *Note HCT - Hematocrit MCV - Mean Corpuscular Volume |
| **D5805** | TEST REPORT |

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| | CFR(s): 493.1291(c)<br><br>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 document review and interview with laboratory personnel, the laboratory failed to ensure the name of the laboratory was indicated on the test report (c)(2). Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by Testing Personnel 6 during a tour of the laboratory on 12/13 /18 at 1:15 p.m. 2. The full name of the laboratory, Entira Family Clinics North Saint Paul, was not included on the patient test reports reviewed on date of survey. The laboratory name North Saint Paul was observed on 3 of 3 test reports. 3. In an interview on 12/13/18 at 4:30 p.m., Technical Consultant 1 confirmed the above finding. |
| **D6045** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(7)<br><br>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure all training for new testing personnel was performed and documented. Findings are as follows: 1. The laboratory performed non-waived Hematology (Heme) and Microbiology (Micro) testing as confirmed by Testing Personnel 6 during a tour of the laboratory on 12/13/18 at 1:15 p.m. 2. Initial training documents for 3 of 6 new testing personnel (TP) were not found during review of the laboratory's records or were incomplete. See below. The laboratory was unable to provide the missing documents upon request. Testing Personnel Training document issue TP4 No documents found TP8 Heme page blank TP9 Heme page missing 3. In an interview on 12/13/18 at 2:40 p.m., Technical Consultant 1 confirmed the above finding. |