

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0028568	<b>(X3) Date Survey Completed</b>  12/05/2023
<b>Name of Provider or Supplier</b>  Family Medical Clinic Of Harrogate, Pc	<b>Street Address, City, State</b>  170 Beech St, Suite 1, Harrogate, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Citation One: Based on observation of the laboratory, review of the laboratory's policy, quality control (QC) records, patient test log and patient Complete Blood Count (CBC) test result reports, and interview with the lead testing person, the laboratory failed to follow the quality control procedures policy in October 2022. The findings include: 1. Observation of the laboratory on 12.05.2023 at 10:20 a.m. revealed a Beckman Coulter DXH-520 (serial number BC121191) hematology analyzer in use for CBC patient testing. 2. Review of the laboratory's Systems Management policy under the section titled, "Quality Control Procedures" revealed the following, "This laboratory always tests assayed controls as follows: Three levels, (low, normal, and high) each day of patient testing. All levels must be acceptable prior to testing or patient samples". 3. Review of quality control records revealed one of three levels of quality control (normal level) was unacceptable on 10.15.2022. 4. Review of patient test log and patient CBC test result reports revealed nine CBC patient samples were ran and reported on 10.15.2022 when one of three levels of quality control was unacceptable. 5. Interview on 12.05.2023 at approximately 1:30 p. m. with the lead testing person confirmed the laboratory failed to follow the Quality Control Procedures policy in October 2022. Citation Two: Based on observation of the laboratory, review of the laboratory's policy, random review of patient test records from 12.04.2023 and 12.05.2023, and interview with the lead testing person, it was revealed that the laboratory failed to follow their Abnormal WBC Differential Counts Instrument Flag policy in December 2023. The findings include: 1. Observation of the</p>

laboratory on 12.05.2023 at 10:20 a.m. revealed a Beckman Coulter DXH-520 (serial number BC121191) hematology analyzer in use for CBC patient testing. 2. Review of the laboratory's Abnormal WBC Differential Counts Instrument Flags policy revealed the following statement, "When the analyzer flags a result, the CBC will be rerun to verify the flag". 3. A random review of patient test reports from the Beckman Coulter DXH-520 hematology analyzer from 12.04.2023 and 12.05.2023 revealed the following three of ten results with a CBC flag: Date 12.04.2023; Patient 40396; PLT1 flag; no documentation of sample rerun Date 12.05.2023; Patient 19221; Abnormal Diff, Suspect Diff, LY/MO Overlap, H&H Check Failed flags; no documentation of sample rerun Date 12.05.2023; Patient 36403; PLT1 flag; no documentation of sample rerun 4. Interview on 12.05.2023 at approximately 1:30 p.m. with the lead testing person confirmed the laboratory failed to follow the Abnormal WBC Differential Counts Instrument Flags policy when three of ten patient's CBC results were flagged with no documentation of sample rerun in December 2023. Word Key: Complete Blood Count = CBC White Blood Cell = WBC Platelet = PLT Differential = Diff Lymphocyte = LY Monocyte = MO Hemoglobin and Hematocrit = H&H

**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 observation of the laboratory, review of patient test reports and interview with the lead testing person, the laboratory failed to have an effective system in place to ensure patient CBC test result flags were identified and addressed in December 2023. The findings include: 1. Observation of the laboratory on 12.05.2023 at 10:20 a.m. revealed a Beckman Coulter DXH-520 (serial number BC121191) hematology analyzer in use for CBC patient testing. 2. Review of ten CBC patient test results revealed the following three of ten patient's CBC test results that flagged on the analyzer printout, but the flags were not present on the LIS or EMR printouts: Date: Patient number: 12.04.2023 40396 12.05.2023 19221 12.05.2023 36403 3. Interview on 12.05.2023 at approximately 11:30 a.m., the lead testing person was asked to describe how patient CBC results are reviewed. She stated that patient CBC results are reviewed on the LIS by laboratory personnel and if no flags are present the results are released to the EMR for provider review. Interview further confirmed three of ten patient CBC results reviewed had unidentified flags present on the analyzer result printouts that were not present on the LIS and EMR result printouts. This confirmed the above findings. Word Key: Complete Blood Count = CBC Laboratory Information System = LIS Electronic Medical Record = EMR