

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2023608	(X3) Date Survey Completed 09/17/2019
Name of Provider or Supplier Christus Trinity Clinic	Street Address, City, State 700 Davey Crockett Drive, Suite 500, New Boston, TX	
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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2018 and 2019 and staff interview, the laboratory failed to attain an acceptable score for hematology testing of monocytes/Mid percentage in the third event of 2018 and for red blood cell (RBC) count and Monocytes/Mid percentage in the second event 2019 using the Abbott Emerald analyzer. Findings: 1. API proficiency testing documentation for 2018 and 2019 was reviewed. Scores for Monocytes/Mids in the second event 2019 were as follows: Monocytes/Mids (%) Sample Reported Expected Score HEM-11 6.6 2.6-6.0 Unacceptable HEM-12 5.7 3.6-6.8 Acceptable HEM-13 4.1 2.2-4.3 Acceptable HEM-14 6.0 2.3-6.0 Acceptable HEM-15 6.8 1.4-6.7 Unacceptable 2. The resulting score for Monocytes/Mids was 60%. This was confirmed in an interview at the site with the LD on 09-17-2019. 3. Scores for RBC count in the second event 2019 were as follows: Red Cell Count (X10¹²/Liter) Sample Reported Expected Score HEM-06 4.38 3.85-4.35 Unacceptable HEM-07 3.94 3.43-3.88 Unacceptable HEM-08 5.42 4.79-5.41 Unacceptable HEM-09 5.44 4.76-5.38 Unacceptable HEM-10 2.34 2.05-2.32 Unacceptable 4. The resulting score for RBC was 0. This was confirmed in an interview at the site with the laboratory director (LD-CMS form 209) on 09-17-2019. 5. Scores for Monocytes/Mids in the second event 2019 were as follows: Monocytes/Mids (%) Sample Reported Expected Score HEM-06 9.0 3.6-9.4 Acceptable HEM-07 10.3 3.7-9.0 Unacceptable HEM-08 5.8 3.6-6.1 Acceptable HEM-09 7.8 5.4-8.1</p>

Acceptable HEM-10 16.4 2.6-13.6 Unacceptable 6. The resulting score for Monocytes /Mids was 60%. This was confirmed in an interview at the site with the LD on 09-17-2019. .

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

. Based on surveyor observation, review of laboratory policy, review of patient reports and staff interview, the laboratory failed to include its verified reference ranges for hematology testing on the patient report generated in the laboratory information system (LIS). Findings: 1. A comparison of hematology reference ranges found in laboratory policy with reference ranges included in patient reports showed the following: Measured parameters listed. White blood cells (WBC) Red blood cells (RBC) Hemoglobin (Hgb) Hematocrit (HCT) Platelets (PLT) Granulocytes or Neutrophils (GRAN) Lymphocytes (LYM) Monocytes, eosinophils and basophils (MID) Hematology Reference (Normal) Ranges Parameter Policy LIS WBC (X10³/uL) 4.5-11.0 4.1-10.9 RBC (X10³/uL) 4.1-5.30 4.2-6.3 Hgb (g/dL) 12.0-16.0 12-18 HCT (%) 36-46 37-51 PLT (X10³/uL) 130-400 140-440 GRAN (X10³/uL) 2.2-9.0 2-7.8 LYM (X10³/uL) 0.5-4.0 0.6-4.1 MID (X10³/uL) 0.2-2.3 0-1.8 GRAN % 47.8-81.8 37-92 LYM % 10.1-36.5 10-58.5 MID % 5.4-19.2 0.1-24 2. In an interview at the site on 09-17-2019, testing person 2 (TP2-CMS form 209) stated that to his knowledge the ranges in the LIS had been the same since its installation. 3. In an interview at the site on 09-17-2019 the laboratory director, who also serves as the technical consultant (TC-CMS form 209), stated she did not know where the ranges found in the LIS had come from and confirmed they did not match the reference ranges listed in laboratory policy. .