

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1086159	<b>(X3) Date Survey Completed</b> 06/07/2018
<b>Name of Provider or Supplier</b> Victory Medical Center	<b>Street Address, City, State</b> 2110 W Ben White Blvd, Austin, TX	
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>D0000</b>	An initial CLIA inspection was performed on June 7, 2018. The laboratory was found to be in compliance with all Conditions for Participation in the CLIA regulations at 42 CFR 493.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Beckman Coulter hematology analyzer documentation and interview with facility personnel, the laboratory failed to retain all analytic records from the verification study signed on April 14, 2018. The findings included: 1. Based on a review of the verification studies for the Beckman Coulter AcT 2 Diff hematology analyzer, the laboratory performed a correlation study with another laboratory to assess the accuracy of the instrumentation. From the verification summary: "In this study the laboratory will be validating Analytic Accuracy. This will be done by proving agreement between test result and "true" result. This will be completed utilizing two methods. The first method is Comparison of results between new method and "reference' method. A patient sampling will be tested, and the results achieved in our laboratory will be compared to the results obtained by the current reference testing laboratory." Based on review of the correlation study, the laboratory had evaluated the data, but had not retained the analytic records from performing the testing on the Beckman Coulter AcT 2 Diff hematology analyzer. 2. In an interview at 10:15 hours on 6/7/2018 in the laboratory, Testing Person 1 stated the laboratory was unaware of the requirement to maintain the verification study analytic records and had likely shredded them.</p>

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of Beckman Coulter hematology analyzer verification study documentation, the analyzer reference manual, and interview with facility personnel, the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population in verification study signed on April 14, 2018. The findings included: 1. Based on a review of the verification studies for the Beckman Coulter AcT 2 Diff hematology analyzer, approved on April 14, 2018 by the laboratory director: "The reportable range and reference ranges will be gathered from the package inserts and used until it is determined the patient population demands the setting of our own acceptable range." 2. Based on review of the Beckman Coulter AcT 2 Diff reference manual (PN 4237515BA (August 2010)), on page 4-10, the manufacturer provides the following ranges: "A normal range study was conducted to assess the Reference Ranges for the AcT diff 2 analyzer. Whole-blood samples were collected from 50 donors (equal numbers of males and females). The selection of donors was consistent with guidelines stated in NCCLS, C28-A. See Table 4.12." From Table 4.12 Normal Population Study Value: White blood cell count (WBC) Reference/Normal Values: 3.38 - 8.68 x 1000 cells per microliter Value: Red blood cell count (RBC) Reference /Normal Values: 3.75 -5.25 x 1,000,000 cells per microliter Value: Hemoglobin (Hgb) Reference/Normal Values: 11.69 - 15.82 grams per deciliter Value: Hematocrit Reference/Normal Value: 34.69 - 45.88 percent/ratio Value: Platelet count Reference /Normal Value: 116.10 - 329.27 x 1000/ microliter 3. Based on random review of patient results (Accession: 3876), the laboratory was using the following reference /normal values: Value: White blood cell count (WBC) Reference/Normal Values: 3.5 - 10.5 x 1000 cells per microliter Value: Red blood cell count (RBC) Reference /Normal Values: 4.32 - 5.72 x 1,000,000 cells per microliter Value: Hemoglobin (Hgb) Reference/Normal Values: 13.8 -17.2 grams per deciliter Value: Hematocrit Reference/Normal Value: 38.8 - 50.0 percent/ratio Value: Platelet count Reference /Normal Value: 150 -450 x 1000/ microliter 4.. In an interview at 10:55 hours on 6/7 /2018 in the laboratory, the Laboratory Director stated the laboratory's reference ranges had been set up in the laboratory information system prior to the verification study and the exact source of the reference ranges was not known at the time of the survey.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on review of Beckman Coulter hematology analyzer verification study documentation, the analyzer reference manual, and interview with facility personnel, the laboratory director failed to ensure the laboratory verified that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population in verification study signed on April 14, 2018. Refer to D5421.