

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2137962	<b>(X3) Date Survey Completed</b>  05/20/2019
<b>Name of Provider or Supplier</b>  Cbs Labs Of Tampa Llc	<b>Street Address, City, State</b>  1916 W Dr Martin Luther King Jr Blvd, Tampa, FL	
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>	<p>An announced CLIA recertification survey was conducted at CBS Labs of Tampa on 05/14/2019 - 05/20/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. An Immediate Jeopardy situation was identified and the laboratory was notified at 02:00 PM on 05/20/19. The laboratory failed to complete performance verification for Bio - Rad D-10 Hemoglobin A1C instrument and to have the performance verification for Bio - Rad D-10 Hemoglobin A1C instrument and the Beckman Coulter Unicel DxI 600 instrument that performs testing for prostate specific antigen(PSA)horionic gonatropin(HCG), folate, Vitamin B12, thyroxine (T4), free thyroxine (FT4), triiodothyronine (T3), free triiodothyronine (FT3), triiodothyronine uptake (T3 uptake), and thyroid stimulating hormone (TSH) approved by the Laboratory Director. (See D5400) The following Conditions were cited: D5400 Analytic Systems 493.1250 D6000 Moderate Complexity Laboratory Director 493.1403</p>
<b>D2121</b>	<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: Based on review of American Proficiency Institute (API) proficiency testing results and interview with the Technical Consultant #B, the laboratory failed to score at least 80% for White Blood Cell in 1 (2018 Hematology 2nd Event) Event out of 5 (3rd testing event 2017, 2018 1st, 2nd, 3rd Events, and 2019 1st Event) testing events reviewed in the specialty of Hematology. Findings Included: Review of API Hematology proficiency testing results revealed a score of 60% for White Blood Cell for the 2nd Event for 2018. Interview on 05/15/16 at 10:15 AM the Technical Consultant #B confirmed the proficiency testing failure.</p>

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE
	CFR(s): 493.1236(c)(1)
	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.
	<p>This STANDARD is not met as evidenced by:  Based on review of American Proficiency Institute (API) proficiency testing , and interview with the Technical Consultant #B, the laboratory failed to ensure the accuracy of ammonia and hemoglobin A1C testing twice a year for 2018 for the subspecialty of Routine Chemistry. Findings Included: Review of API proficiency testing results for 2018 revealed that ammonia and hemoglobin A1C results were not included in the 2018 proficiency testing records. Interview on 05/15/19 at 10:00 AM, Technical Consultant #B confirmed that the laboratory did not enroll ammonia and hemoglobin A1C analytes for 2018 API proficiency or verify twice annually to confirm accuracy.</p>
D5400	ANALYTIC SYSTEMS
	CFR(s): 493.1250
	<p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p>
	<p>This CONDITION is not met as evidenced by:  Based on record review and interview with the Technical Consultant, the laboratory failed to follow Beckman Coulter manufacturer's instructions for the Unicel DxI 600 maintenance requirements (See D5411), failed to define the acceptable range for the measure of resistance (Ohms) for the de-ionized water, (See D5413), and failed to have completed the Bio-Rad D-10 Hemoglobin A1C performance verification and to have the performance verification for the Bio-Rad D-10 Hemoglobin A1c and the Beckman Coulter Unicel DxI 600 approved by the Laboratory Director. (See D5421)</p>
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
	CFR(s): 493.1252(a)
	<p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p>
	<p>This STANDARD is not met as evidenced by:  Based on record review and interview with the Technical Consultant #B, the laboratory failed to follow Beckman Coulter manufacturer's instructions regarding the maintenance requirements for the Beckman Coulter Unicel DxI 600 chemistry analyzer . Findings included: Record review of the Beckman Coulter Maintenance logs for the Beckman Coulter Unicel DxI 600 analyzer revealed that the maintenance</p>

logs included a 5000 test interval maintenance and a 10,000 test interval maintenance. The maintenance records showed that the 5000 tests was reached 12/07/18 and the 10000 tests was reached 03/13/19. As of 5/16/19 the maintenance for 5000 tests and 10000 tests had not been performed and the number of tests was 12,825. Interview on 05/16/19 at 2:00 PM, the Technical Consultant confirmed the 5000 test interval maintenance and 10000 test interval maintenance had not been performed.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview with Testing Personnel #D, the laboratory failed to define the acceptable range for the measure of resistance (which is measured in Ohms) for the De-ionized water for the Beckman Coulter AU680 from 11/18 to 05/15/19. Findings Included: Review of De-ionized Water Check logs for the laboratory found that there was not a defined range for the Ohms for the de-ionized water but the Ohms had been documented. Review of de-ionized water procedures revealed that the laboratory did not have manufacturer's instructions available at time of survey. Review of the laboratory's "Chemistry Distilled Water Q. C. procedure did not include the acceptable range for the Ohms for the de-ionized water. Interview on 05/16/19 at 12:30 PM Testing Personnel #D confirmed that the De-ionized Water Check logs and the "Chemistry Distilled Water Q.C. procedure did not include the acceptable range.

**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 record review and interview with the Technical Consultant #B, the laboratory failed to complete the performance verification for the Bio - Rad D-10 Hemoglobin A1C instrument performed 09/27/18 and failed to have the Laboratory Director approve the Bio - Rad D-10 Hemoglobin A1C instrument performance verification and the performance verification performed 09/18/18 on the Beckman Coulter Unicel DxI 600 instrument. Findings included: A. Record review of the performance verification performed 09/27/18 for the Bio - Rad Hemoglobin A1C

instrument revealed that the linearity verification data had not been calculated and all sections of the performance verification for the Bio - Rad D-10 Hemoglobin A1C had not been approved by the Laboratory Director. Review of the Patient's Hemoglobin A1C result log revealed 1379 patient Hemoglobin A1C results were reported after 09/27/18. Interview on 05/15/19 at 02:00 PM, the Technical Consultant #B confirmed that the laboratory started patient testing 09/28/18 before the Laboratory Director approved the performance verification. The Technical consultant #B also stated that all abnormal hemoglobins were repeated and glucose values looked up before reporting but these steps were not in the Bio - Rad D-10 Hemoglobin A1C procedure. B. Review of the performance verification performed 09/18/18 for the Beckman Coulter Unicel DxI 600 revealed that the Laboratory Director had not approved the performance verification and the T3 uptake linearity study had only 1 data point. The laboratory has been testing patients since 10/2018. In the performance verification binder for the Beckman Coulter Unicel DxI 600 was a manufacturer instruction for T3 Uptake that stated the laboratory had to find their own specimens to determine linearity which had not been done at the time of survey. Review of the patient result log for T3 Uptake revealed the laboratory had tested 43 patients. Interview on 05/20/19 at 12:00 PM, the Technical Consultant #B confirmed that the laboratory had not performed a linearity study on T3 Uptake and did not have the Laboratory Director approve the completed performance verifications for the Beckman Coulter Unicel DxI 600.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance from 05/18 to 10/18. (See 6007) and to sign and approve the performance verification procedures for the Bio - Rad D-10 Hemoglobin A1C instrument and Beckman Coulter Unicel DxI 600 instrument. (See D6013),

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on record review and interview with the Laboratory Director, the Laboratory

Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, preanalytic and analytic from 05/18 to 10/18. Findings included: A. Review of the laboratory's procedure manual revealed a job description for the General Supervisor which included Technical Consultant responsibilities and evaluation criteria for assessment of employee training and competency. Interview on 05/14/19 at 0230, the Technical Consultant confirmed that the Laboratory Director did not document training and competencies for the Technical Consultants, #B. B. Record review of performance verifications revealed that the Bio - Rad D-Hemoglobin A1C instrument performance verification was performed 09/27/18 but had not been completed and the performance verification for the Bio - Rad Hemoglobin A1C instrument and Beckman Coulter Unicel DxI testing had not been approved by the Laboratory Director. Hemoglobin A1C patient testing had started 09/28/18 and patient testing on the Beckman Coulter Unicel DxI had started 10/23/18. Interview on 05/15/2019 at 02:00 PM the Technical Consultant #B confirmed the Bio-Rad D-10 Hemoglobin A1C instrument performance verification had not been completed. or approved by the Laboratory Director Interview on 05/20/19 at 12:00 PM the Technical Consultant #B confirmed the Beckman Coulter Unicel DxI 600 had not been approved by the Laboratory Director.

**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 record review and interview with the Laboratory Director, the Laboratory Director failed to approve the performance verification procedures for the Bio - Rad D-10 Hemoglobin A1C instrument and Beckman Coulter Unicel DxI 600. Findings included: Record review of the performance verification performed 09/27/18 for the Bio - Rad D-10 Hemoglobin A1C instrument revealed that the linearity verification data had not been calculated and all sections of the performance verification for the Hemoglobin A1C had not been approved by the Laboratory Director. Review of the performance verification performed 09/18/18 for the Beckman Coulter Unicel DxI 600 showed the Laboratory Director had not signed and approved. Interview on 05/20 /19 at 04:20 PM, Laboratory Director was unaware that the performance verifications had not been finished and approved.