Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	10D2137962	06/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cbs Labs Of Tampa Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at CBS Labs of Tampa, LLC on 06/21/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Technical Consultant the laboratory failed to record the open date and expiration date on the CBC (Complete Blood Count) and Retic Controls. Findings Included: Observations during the tour of the laboratory on 06/21/2021 at 2:17 PM revealed that the open CBC controls (Level 1-Lot#123173760, Level 2-Lot#1331183760, and Level 3-143193760) and the open Retic Controls (Level 1-Lot # 153202230, Level 2-Lot#163212230, and Level 3-Lot#17322223) did not have an open date written on them or the date of amended expiration. Review of the manufacturers' instructions for the CBC and Retic controls stated that once open, the controls are only good for 16 days. On 06/21/21 at 3:00 PM, the Technical Consultant confirmed that the open date was not recorded or the new expiration date 16 days post opening on the CBC or Retic controls.
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 observations, record review, and interview with the Technical Consultant the laboratory failed to store Chemistry controls and calibrators per the manufacturers' instructions for 192 out of 373 days in 2020 and 2021. Findings Included: During a tour of the laboratory on 06/21/21 at 3:00 PM a freezer was observed with a temperature of -19 degrees Celsius. The acceptable range on the temperature log was -20 degrees Celsius/-5 degrees Celsius. Observations of the chemistry controls and calibrators stored in the freezer revealed that they should be stored between -20 and -70 degrees Celsius. Review of temperature logs for 2021 and 2020 revealed 192 days out of 373 days the temperature was warmer than the acceptable range for storage of -20 to -70 degrees Celsius. In January 2020 the temperature was out of acceptable range 21 out of 23 days: 2 (-18), 3(-18), 6(-19), 7(-19), 9(-19), 10(-19), 13(-18), 14 (-19), 15(-18), 16(-18), 17(-19), 20(-18), 21(-18), 22(-19), 23(-19), 24(-19), 27(-19), 28(-18), 29(-18), 30(-18), and 31(-19). In February 2020 the temperature was out of acceptable range 20 out of 21 days: 3(-18), 4(-19), 6(-18), 7(-18), 10(-19), 11(-19), 12 (-18), 13(-18), 14(-18), 17(-17), 18(-18), 19(-18), 20(-19), 21(-18), 24(-17), 25(-17), 26(-17), 27(-18), and 28(-18). In March 2020 the temperature was out of acceptable range 21 out of 21 days: 2(-18), 3(-17), 4(-18), 5(-18), 6(-17), 8(-18), 9(-18), 10(-17), 11(-17), 12(-19), 15(-18), 16(-18), 17(-19), 18(-19), 19(-19), 22(-18), 23(-18), 24 (-18), 27(-18), 30(-18), and 31(-18). In April 2020 the temperature was out of acceptable range 22 out of 22 days: 1(-18), 2(-18), 3(-18), 6(-19), 7(-19), 8(-18), 9 (-18), 10(-18), 13(-18), 14(-18), 15(-19), 16(-19), 17(-19), 20(-18), 21(-19), 22(-18), 23(-19), 24(-18), 27(-18), 28(-18), 29(-18), and 30(-18). In May 2020 the temperature was out of acceptable range 21 out of 21 days: 1(-18), 4(-19), 5(-18), 6(-19), 7(-19), 8 (-18), 11(-18), 12(-18), 13(-18), 14(-19), 15(-18), 18(-18), 19(-18), 20(-18), 21(-18), 22(-18), 25(-19), 26(-18), 27(-18), 28(-18), and 29(-18). In June 2020 the temperature was out of acceptable range 22 out of 22 days: 1(-18), 2(-18), 3(-18), 4(-18), 5(-18), 8 (-18), 9(-18), 10(-18), 11(-18), 12(-18), 15(-18), 16(-18), 17(-18), 18(-18), 19(-18), 22 (-18), 23(-18), 24(-18), 25(-18), 26(-18), 29(-18), and 30(-18). In July 2020 the temperature was out of acceptable range 18 out of 23 days: 1(-18), 2(-18), 3(-18), 6 (-18), 7(-18), 8(-18), 9(-18), 10(-18), 13(-18), 14(-18), 15(-18), 16(-19), 17(-18), 23 (-19), 24(-19), 29(-19), 30(-19), and 31(-19). In August 2020 the temperature was out of acceptable range 20 out of 21 days: 3(-18), 4(-18), 5(-18), 6(-18), 7(-18), 11(-19), 12(-18), 13(-18), 14(-18), 17(-19), 18(-19), 19(-18), 20(-18), 21(-18), 24(-18), 25 (-18), 26(-18), 27(-18), 28(-18), and 31(-18). In September 2020 the temperature was out of acceptable range 22 out of 22 days: 1(-19), 2(-19), 3(-19), 4(-19), 7(-19), 8 (-19), 9(-18), 10(-19), 11(-18), 14(-19), 15(-19), 16(-19), 17(-19), 18(-19), 21(-19), 22 (-19), 23(-19), 24(-18), 25(-19), 28(-19), 29(-19), and 30(-19). In February 2021 the temperature was out of acceptable range 1 out of 20 days: 8(-19). In April 2021 the temperature was out of acceptable range 2 out of 19 days: 2(-19) and 8(-19). In June 2021 the temperature was out of acceptable range 2 out of 15 days: 8(-19) and 16 (-18). Interview on 06/21/21 at 2:45 PM with the Technical Consultant confirmed that the temperature was not in accordance with the manufacturer's temperature range for storage of the Chemistry controls and calibrators.

D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant the laboratory failed to document why controls were ran multiple times on the Chemistry analyzers for 2 out of 2 years (2019-2021) reviewed. Findings Included: Review of quality control records for the Beckman Coulter AU680 and Unicel DxI600 Chemistry analyzers revealed days when the quality control (QC) were ran multiple times with no corrective action documented. QC was ran on the Beckman Coulter AU680 on 12/04/19 at 12:21 PM and 4:55 PM (2 times) on all analytes with no corrective action noted. On the Unicel DxI600, QC was ran on 12/02/19 at 2:35 PM, 2:35 PM, and 3:30 PM (3 times) on all analytes with no corrective action noted. Review of the policy and procedure (implemented 10/2016 and last signed by the Laboratory Director on 02/01/21) revealed under quality control that "All corrective actions must be documented by the technologist operating the analyzer." Interview on 06/21/21 at 6:10 PM with the Technical Consultant confirmed that there was no explanation or corrective action documented to indicate why the controls were ran multiple times.