Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2137962	09/10/2025
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 on 09/09/2025-09/10/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D2016 493.803 (a)(b)(c) Condition: Successful Participation
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and staff interview, the lab failed to successfully participate in proficiency testing for creatinine (test event 3 of 2024 and 1 of 2025) and urine sediment (test event 3 of 2024 and 1 of 2025) for the specialty of Chemistry. See D2096.

D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory had unsuccessful performance for two out of three test event for the analytes creatinine (test event #3 of 2024 and #1 of 2025) and urine sediment (test event #3 of 2024 and #1 of 2025) for the specialty of Chemistry (subspecialties of Routine Chemistry and Urinalysis). Findings included: 1. Proficiency testing Performance Summary documents were reviewed for the specialty of Chemistry. The results for the analyte creatinine (Routine Chemistry) reflected a score of 20% for test event (TE) #3 for 2024 and 60% for TE #1 of 2025. The results for the analyte urine sediment (Urinalysis) reflected a score of 50% for TE #3 for 2024 and 50% for TE #1 for 2025. 2. The Technical Consultant confirmed the above data on 09/09/2025 at 12:10 p.m.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have a uni-directional workflow for molecular amplification procedures from 02/14/2024 to 09 /2025. Findings included: 1. A tour of the lab was conducted on 09/09/2025 at 9:55 a. m. The layout of the lab failed to allow for uni-directional flow. 2. Review of validation binder for Molecular revealed testing was approved to begin, by Lab Director signature, 02/15/2024. 3. The Laboratory's Policy and Procedure Manual, policy titled "Do's and Don'ts, signed by the Laboratory Director on 08/03/2023 was reviewed. The policy stated, under Organization of workspace and equipment, that the workspace should be organized to ensure work flows in one direction. There was no layout/map of how the workspace and equipment would be organized to ensure uni-directional flow. 4. Interview with the Technical Supervisor on 09/09/2025 at 11:10 a. m. confirmed the above.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer for sub-speciality Syphilis Serology for 2023-2025. Findings included: 1. The laboratory performed qualitative Syphilis Serology using Arlington Scientific Rapid Plasma Reagin (RPR) card testing. The manufacturer instructions stated the accuracy of the needle dispensing reagent was to be checked to ensure 30 plus or minus 1 drop in 0.5 ml and the automatic rotator speed of 100 plus or minus 5 rpm each day of testing. 2. The RPR Quality Control Daily records for 3 /2025, 4/2025, and 5/2025 failed to document the accuracy of the needle dispensing reagent was checked to ensure 30 plus or minus 1 drop in 0.5 ml each day of testing and for 5/2025 the automatic rotator speed was 100 plus or minus 5 rpm each day of testing. 3. The Technical Consultant on 9/10/2025 at 1:00 p.m., confirmed the laboratory had not been documenting following the RPR manufacturer instructions for accuracy of reagent needle volume and automatic rotor speed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to, for commercially assayed control material, verify the stated value by the laboratory prior to being put into use for General Immunology, Routine Chemistry, Endocrinology, Toxicology, and Hematology Complete Blood Count (CBC) for 2023 to 2025. Findings included: 1. Quality Control (QC) Records for 2023-2025 for General Immunology, Routine Chemistry, Endocrinology, Toxicology, and CBC failed to include documentation of verifying the assayed commercial control material's stated values prior to use. 2. The Policy and Procedure Manual with an approval date of 08/02/2023, was reviewed. No policy was found regarding verifying assayed control material prior to use. 3. The Technical Consultant on 9/10/2025 at 11:00 a.m. confirmed the laboratory did not have documentation or a policy to verify the stated values of assayed commercial QC material for the General Immunology, Routine Chemistry, Endocrinology, Toxicology, and Hematology CBC for 2023 to 2025.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2)

	Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy or to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that were part of the Laboratory Director's responsibilities. The Laboratory Director failed to document a 6 month onsite visit from 1/2025 to 9/2025. Findings included: 1. The Policy and Procedure Manual, which had an approval date of 08/02/2023 was reviewed. No policy was found regarding documenting the Laboratory Director being on site every 6 months to include evidence of performing activities that were part of the Laboratory Director's responsibilities. 2. The Laboratory Director confirmed on 09/10/2025 at 2:30 p.m., via phone, that he was not aware of this requirement to add a procedure or to perform and document an onsite visit at least every 6 months.