Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0715747	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lbs Medical Service Corp	Calle C Aa-5 Urb Alturas De Rio Grande, Rio Grande, PR	

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	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at LBS Medical Service Corp on January 16, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on January 16, 2025.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory director on January 16, 2025 at 9:00 AM; it was determined that the laboratory failed to monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications since January 2023. The findings include: 1. The QA was requested and review on January 16, 2025 at 8:40 AM. The QA showed that the laboratory did not monitor the following general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications since January 2023. 2. The Laboratory director confirmed on January 16, 2025 at 9:00 AM that the laboratory failed to monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications since January 2023.

D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory director on January 16, 2025 at 9:00 AM; it was determined that the laboratory failed to monitor the preanalytic systems activities related to: test request, specimen submission, handling and referral, since January 2023. The findings include: 1. The QA was requested and review on January 16, 2025 at 8:40 AM. The QA showed that the laboratory did not monitor the following preanalytic systems activities related to: test request, specimen submission, handling and referral, since January 2023. 2. The Laboratory director confirmed on January 16, 2025 at 9:00 AM, that the laboratory failed to monitor the preanalytic systems activities related to: test request, specimen submission, handling and referral, since January 2023.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the Urinalysis quality control record and interview with the laboratory director interview on January 16, 2025 at 10:20 AM; it was determined that the laboratory did not meet the quality control requirements for manual microscopic urinalysis examination in the following days: September 3, 2024; August, 20, 2024; August 9, 2024; July 15, 2024; May 16, 2024; April 24, 2024; April 25, 2024; April 23, 2024; April 19, 2024; April 17, 2024; April 16, 2024; April 15, 2024; April 11, 2024; April 9, 2024. The finding include : 1. The urinalysis quality control records were reviewed on January 16, 2025 at 10:14 AM. The laboratory had established to use commercial control for manual microscopic urinalysis examinations. 2. The quality control records showed that the laboratory did not performed the negative or positive control material for the microscopic urinalysis control material in the following days: September 3, 2024; August, 20, 2024; August 9, 2024; July 15, 2024; May 16, 2024; April 24, 2024; April 25, 2024; April 23, 2024; April 19, 2024; April 17, 2024; April 16, 2024; April 15, 2024; April 11, 2024; April 9, 2024. 3. The laboratory confirmed on January 16, 2024 at 10:20 AM; that the laboratory did not performed the quality control records for manual microscopic urinalysis examinations
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the Human chorionic gonadotropin (hCG) quality control review and laboratory director interview on January 16, 2025 at 10:40 AM; it was determined that the laboratory did not documented the procedural control for each patient samples in the following days: March 18, 2024 (one patient), July 15, 2024 (two patient), August 19, 2024 (one patient), October 1, 2024 (one patient). The findings include: 1. On January 16, 2025 at 10:33 AM; the quality control record of hCG was reviewed and showed that the laboratory did not documented the procedural control for each patient samples in the following days: March 18, 2024 (one patient), July 15, 2024 (two patient), August 19, 2024 (one patient), October 1, 2024 (one patient). 2. The laboratory director confirmed on January 16, 2025 at 10:40 AM that the laboratory did not documented the procedural control for each patient samples in the following days: March 18, 2024 (one patient), July 15, 2024 (two patient), August 19, 2024 (one patient), October 1, 2024 (one patient).
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory director on January 16, 2025 at 9:00 AM; it was determined that the laboratory failed to monitor the analytic systems activities related to: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, specimen and reagent storage conditions, equipment, instrument, test, systems maintenance and function checks, control procedures, comparison of test results; corrective actions and test records, since January 2023. The findings include: 1. The QA was requested and review on January 16, 2025 at 8:40 AM. The QA showed that the laboratory did not monitor the following analytic systems activities related to: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, specimen and reagent storage conditions, equipment, instrument, test, systems maintenance and function checks, control procedures, comparison of test results; corrective actions and test records, since January 2023. 2. The Laboratory director confirmed on January 16, 2025 at 9:00 AM, that the laboratory failed to monitor the analytic systems activities related to: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, specimen and reagent storage conditions, equipment, instrument, test, systems maintenance and function checks, control procedures, comparison of test results; corrective actions and test records, since January 2023.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of

	postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory director on January 16, 2025 at 9:00 AM; it was determined that the laboratory failed to monitor the postanalytic systems activities related to: test report, turn-around time, since January 2023. The findings include: 1. The QA was requested and review on January 16, 2025 at 8:40 AM. The QA showed that the laboratory did not monitor the following postanalytic systems activities related to: test report, turn-around time, since January 2023. 2. The Laboratory director confirmed on January 16, 2025 at 9:00 AM, that the laboratory failed to monitor the postanalytic systems activities related to: test report, turn-around time, since January 2023.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the quality control records, quality assessment records and interview with the laboratory director on January 16, 2025 at 12:20 PM; it was determined that the laboratory director (sole personnel) did not ensure that the quality control and quality assessment that were establish were follow. Refer to D5293, D5393, D5449, D5481, D5793 and D5893.