Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2059616	08/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Shaddai	Carr 2, Km 99 Bo Cocos, Quebradillas, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on hematology quality control records review (year 2022-2023) and interview with the laboratory director on August 4, 2023 at 12:30 P.M. , it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. Refer D5469 1. The laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial control material used by the Cell Dyn 1700 instrument since July 2022.) 2. The laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from July 2022 to August 2023.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review (year 2023) and laboratory director interview on August 4, 2023 at 11: 00 A.M., , it was determined that the laboratory failed to follow the manufacturer's

	instruction when 127 out of 127 patient specimen were tested for Mycoplasma by Immuno Card Meridian method. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On August 4, 2023 at 11:05 A.M., the Mycoplasma testing records showed that the laboratory did not monitor nor documented the room temperature when it processed Mycoplasma patients specimens. 3. The laboratory director confirmed on August 4, 2023 at 11:10 A.M., that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 127 out of 127 patient specimen for mycoplasma test out of the manufacturer's temperature ranged in year 2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (year 2022-2023) and interview with the laboratory director on August 4, 2023 at 10:45 A.M., it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (lipid panel and glucose) tests processed by the Daytona system. The findings include: 1. The laboratory used the Daytona system to perform lipid panel and glucose tests. 2. Review of routine chemistry calibration verification records showed that the laboratory did not perform the lipid panel and glucose calibration verification procedure since June 2022. 3. The laboratory director confirmed on August 4, 2023 at 10:55 A.M., that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests. The laboratory processed and reported since June 2022 the following patient samples : 822 lipid panel and 23 glucose test.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on hematology quality control values review (July 2022-August 2023) and interview with the laboratory director on August 4, 2023 at 11:30 A.M. , it was found that the laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial control material used by the Cell Dyn 1700 instrument since July 2022. The findings include: a. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used since July 2022. b. The Cell Dyn 1700 system showed the quality control (low , normal and high) , however, the laboratory director confirmed that the laboratory did not evaluate any control in Levey Jenny graphs since July 2022, due the laboratory did not have printer. c. The hematology lot number used were : Lot : 23530422, 23530423, 23530424 (7/22/2022 - 8/26/2022) 31560422, 31560423, 3156024 (02/23 /2023- 8/4/23) d. The laboratory did not have any recorded information (paper or electronically) of the lot numbers used from 8/27/022 to 2/22/202.. e. The laboratory processed and reported 1,261 Complete blood cell (CBC) in 2022. f. During the survey performed on August 4, 2023, the laboratory director confirmed that the laboratory did not evaluate control results to detect any outliers, shifts or trends in control values since July 2022. 2. Based on complete cell count (CBC) quality control records review in Cell Dyn system and interview with the laboratory director on August 4, 2023 at 12 : 00 P. M , it was determined that the laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from July 2022 to August 2023. The finding include : a. The CBC quality control records showed that the laboratory did not verify the new lots of CBC control materials (lot 350307-42 and 350307-43) prior to placed in routine on April 1, 2022 and February 2023, respectively. b. The laboratory director confirmed on August 4, 2023 at 12: 15. P.M. that the laboratory did not verify those new lots of CBC control materials prior to placed in routine. c. The laboratory processed and reported 1,261 Complete blood cell (CBC) in 2022.
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 review of hematology quality control records review on August 4, 2023 at 1: 00 P.M. it was determined that the laboratory director failed to fulfill her responsibilities with the hematology analytic requirements. Refer to D6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on hematology, routine chemistry and general Immunology quality control records review (year 2022-2023) on August 4, 2023 at 12:30 P.M. and laboratory director interview on August 4, 2023 at 12:30 P.M. , it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include : 1.The laboratory failed to follow the manufacturer's instruction when 127 out of 127 patient specimen were tested for Mycoplasma by Immuno Card Meridian method. (Refer to D5405) 2. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (lipid panel and glucose) tests processed by the Daytona system. (Refer to D5439) 3. The laboratory did not evaluate nor define the statistical values of all the lot numbers of the commercial control material used by the Cell Dyn 1700 instrument since July 2022. (Refer to D5469) 4. The laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from July 2022 to August 2023. (Refer to D5469)