Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658157	07/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Central De La Montana	Centro De Salud Integral En Naranjito Carr Pr-164, Naranjito, 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 (year 2018-2019), and interview with the laboratory director on July 9, 2019 at 11:00 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. The finding includes: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of Quality Assessment records (2018-2019), Quality Assessment (QA) written procedures review and laboratory director interview on July 9, 2019 at 12:30 P.M., it was determined that the laboratory failed to follow the written procedures to ensure the positive identification and optimum integrity of patient

	specimen from the time of collection or receipt through completion of testing and reporting of results. The findings include: 1. The laboratory written procedures establishes that the specimen identification and optimum integrity must be evaluated annually. 2. The laboratory director stated on July 9, 2019 at 12:30 P.M., that the laboratory did not perform an evaluation to ensure positive identification and optimum integrity of a patient's specimen that are under the laboratory control since 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual, quality assessment records review (2018-2019) and laboratory director interview on jULY 9, 2019 at 12:30 P.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for general laboratory systems: ensure the positive identification and optimum integrity of patient specimen . The findings include: 1. The laboratory quality assessment procedure manual establishes that the specimen identification and optimum integrity must be evaluated annually. 2. The laboratory director stated on July 9, 2019 at 12:30 P.M., that the laboratory did not perform an evaluation to ensure positive identification and optimum integrity of a patient's specimen that are under the laboratory control since 2017.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual, quality assessment records review (2018-2019) and laboratory director interview on July 9, 2019 at 12:15 P.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for pre analytic laboratory systems: test request. The findings include: 1. Review of the quality assessment procedure manual showed that evaluations to test requisitions must perform annually. 2. Review of the quality assessment records showed that the laboratory did not evaluate the test requisitions since 2017. 3. The laboratory director confirmed on July 9, 2019 at 12:15 P..M. that evaluations to test requisitions were not performed since 2017.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of hematology records and laboratory director interview on July 9, 2019 at 11:00 a.m. , it was determined that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). The findings include: 1. . The laboratory perform PT (Prothrombin time) and PTT (Partial thromboplastin time) tests by ACL ELITE PRO system. 2. The laboratory had in routine use on July 9, 2019 the following recombiplastin reagent: Lot. # N587757, exp. 5/2020. 3. The record showed that the laboratory began to use this new lot on October 2018. 4. Hematology records were reviewed since January 2018. The records showed that the laboratory did not document nor establish a normal population prothrombin (PT) mean for this recombiplastin new lot number used in October 2018. 5. The laboratory processed and reported 1,034 patient's samples since October 2018 with the incorrect INR. The laboratory uses the former laboratory PT mean of 12.0 secs. 6. The laboratory director stated on July 9, 2019 at 11:00 A.M, that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio).
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 manufacturer's instructions, syphilis serology quality control records review (year 2018-2019) and laboratory director interview at 11:20 A.M. on July 9, 2019, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. The findings include: 1. The manufacturer's establishes that the RPR (Rapid plasma reagin) test must be performed at room temperature between 20 C to 30 C . 2. Review of syphilis serology records from January 2019 to February 2019, the records showed that the laboratory processed and reported 761 RPR (Rapid plasma reagin) patient's tests that was performed at temperatures below 20 C during 35 days. 3. Review of syphilis serology records from May 2019 to June 2019, the records showed that the laboratory processed and reported 497 RPR (Rapid plasma reagin) patient's tests that was performed at temperatures below 20 C during 25 of 39 days. 4. The laboratory director confirmed that the laboratory performed RPR (Rapid plasma reagin) tests below the range established by the manufacturer's 74 days from January 2019 to June 2019.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that

	appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) written procedures, quality assessment records review (2018-2019) and laboratory director interview on July 9, 2019 at 12:15 P. M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate patient tests results for inconsistencies with patient information. The findings include: 1. The QA written procedures stated that the laboratory monitor and evaluate patient tests results for inconsistencies with patient information. 2. The quality assessment records showed that the laboratory did not evaluate nor document any test inconsistency since 2017. 3. The laboratory director stated on July 9, 2019 at 12:15 P..M. that information regarding test inconsistencies were not documented as established in the QA procedure manual since 2017.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on hematology quality control records review (2018-2019) and interview with the laboratory director on July 9, 2019 at 11:30 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements for hematology. The finding includes: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D6093.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 hematology and syphilis serology quality control records review from January 2018 to June 2019 and laboratory director interview at 11:30 AM on July 9, 2019, 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 instructions for calculating INR (International Normalized Ratio). Refer to D5401. 2. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. Refer to D5411.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 Quality Assessment (QA) records review (2018-2019) and laboratory director interview on July 9, 2019 at 12:30 P..M, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic and analytic systems. 2. The laboratory director confirmed on July 9, 2019 at 12:30 P.M., that failed to evaluate the requirements for laboratory general systems, preanalytic and analytic systems. Refer to D5291 and D5391.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of hematology and syphilis serology quality control records and interview with the laboratory director on July 9, 2019 at 12:00 P.M., it was determined that the testing personnel did not follow written policies for quality control procedures. The findings include: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401. 2. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. Refer to D5411.