Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0894888	08/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aguadilla Medical Services Lab	Carr Est Pr-2, Km 129 Hm 5, Bo Victoria, Aguadilla, 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
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 (QA) activities records review and laboratory supervisor interview, it was determined that laboratory failed to evaluate and monitor the General Laboratory system requirements since January 2021. The findings include: 1. On August 9, 2022 at 9:43 AM, the laboratory QA record was requested. No QA records was presented, nor found by the laboratory personnel. 2. Since January 2021 the laboratory did not evaluate practices related to: Patient confidentiality, Specimen identification and integrity, complaint investigation, communications and personnel competency. 3. The laboratory supervisor confirmed on August 9, 2022 at 11:22 AM, that those evaluations were not performed nor documented.
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 (QA) records and laboratory supervisor interview, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for pre-analytic systems. The findings include: 1. On August 9, 2022 at 9:43 AM, the laboratory QA record was requested. No QA records was presented, nor found by the laboratory personnel. 2. Since January 2021 the laboratory did not evaluate practices related to: Test request, specimen sumbmission and handling, specimen referral. 3. The laboratory supervisor confirmed on August 9, 2022 at 11:22 AM, that those evaluations were not performed nor documented.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the Urinalysis microscopic quality control review it was determined that the laboratory did not include and not document the negative microscopic control material when 1,116 patient were processed and reported from January 2021 to December 2021. The findings include: 1. The Urinalysis quality control was review on August 9, 2022 at 11:06 am. No negative quality control material was documented. 2. The laboratory supervisor confirmed on August 9, 2022 at 11:09 am that no microcopy negative control was included from January 2021 to December 2021 when 1,116 patient were processed and reported under the microcope.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality assesment (QA) record review and laboratory supervisor interview, it was determined that laboratory failed to to evaluate and monitor the analytic system requirements since January 2021. The findings include: 1. On August 9, 2022 at 9:43 AM, the laboratory QA record was requested. No QA records was presented, nor found by the laboratory personnel. 2. Since January 2021 the laboratory did not evaluate practices related to: Test procedures, accurate and reliable test system, equipment, instruments, reagents, materials, specimen and reagent storage conditions, systemn maintenance and function checks, verification of method performance speifications, calibration, control procedures, comparison of test results, test records, corrective actions. 3. The laboratory supervisor confirmed on August 9, 2022 at 11:22 AM, that those evaluations were not performed nor documented.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on Quality assessment (QA) records review and laboratory supervisor interview, it was determined that the laboratory failed to monitor and evaluate the requirements for post analytic systems (test report and turn around time) since January 2021. The findings include: 1. On August 9, 2022 at 9:43 AM, the laboratory QA record was requested. No QA records was presented, nor found by the laboratory personnel. 2. Since January 2021 the laboratory did not evaluate practices related to: test report and turn around time. 3. The laboratory supervisor confirmed on August 9, 2022 at 11:22 AM, that those evaluations were not performed nor documented.
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 quality control records review, quality assesment and laboratory supervisor interview on August 9, 2022 at 12:00 pm, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6093 and D 6094.
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 Urinalysis microscopy quality control records review laboratory supervisor interview, it was determined that laboratory director failed to ensure that a negative control material were included when the laboratory processed urine microscopy tests. Refer to D5445.
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 Assesment (QA) records reviewed and laboratory supervisor interview, it was determined that laboratory director failed to ensure compliance with QA requirements. Refer to D5291, D5391, D5791 and D5891.