

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1086589	(X3) Date Survey Completed 08/28/2018
Name of Provider or Supplier Laboratorio Clinico Pitahaya	Street Address, City, State Carr Pr-924 Km 2 Hm 8 Bo Collores, Humacao, 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
D5307	<p>TEST REQUEST CFR(s): 493.1241(d)</p> <p>The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on tests requisition records, patients tests results records review and general supervisor interview on August 28, 2018 at 11:00 AM, it was determined that the laboratory failed to ensure that the patients tests requisition were available in the laboratory. The findings include: 1. On August 28, 2018 at 11:00 AM, the tests requisition records showed that one out of eight patients tests requisition was not available in the laboratory. 2. The patients tests results records showed that the specimens of this patient was collected on August 23, 2018 and was referred to Laboratorio Clinico Rodriguez for sedimentation rate test and for a lipid panel. 3. The general supervisor confirmed on August 28, 2018 at 11:00 AM, that this patient tests requisition was not available in the laboratory.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on quality control records review for the urine microscopic examination and interview with the general supervisor (testing personnel) on August 28, 2018 at 10:20 AM, it was determined that the laboratory failed to include at least once a day a negative (normal) control material when 478 out of 478 patient urine microscopic specimens were examined from January 1, 2017 to August 28, 2018. The findings include: 1. The laboratory did not include at least once a day, a negative (normal) control material when patient urine microscopic specimens were examined from January 1, 2017 to August 28, 2018. 2. The general supervisor confirmed on August 28, 2018 at 10:20 AM, that the laboratory did not include at least once a day the normal urine microscopic control material when patients urine microscopic specimens are examined. 3. The laboratory examined 478 out of 478 patient urine microscopic specimens from January 1, 2017 to August 28, 2018.

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 quality control records review for the urine microscopic examination and interview with the general supervisor (testing personnel) on August 28, 2018 at 10:20 AM, it was determined that the laboratory director (technical consultant) failed to ensure that the laboratory comply with the analytic system requirement for the examination of the patient urine microscopic specimens. The finding includes: 1. Refer to D 5449 (The laboratory did not include at least once a day, a negative (normal) control material when patient urine microscopic specimens were examined from January 1, 2017 to august 28, 2018).

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on quality control records review for the urine microscopic examination and interview with the general supervisor (testing personnel) on August 28, 2018 at 10:20 AM, it was determined that the testing personnel failed to include at least once a day a negative (normal) control material when 478 out of 478 patient urine microscopic specimens were examined from January 1, 2017 to august 28, 2018. Refer to D 5449.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on tests requisition records, patients tests results records review and general supervisor interview on August 28, 2018 at 11:00 AM, it was determined that the laboratory director failed to ensure that the patients tests requisition were available at the laboratory. Refer to D 5307.