

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658265	(X3) Date Survey Completed 06/23/2022
Name of Provider or Supplier Immuno Reference Lab	Street Address, City, State 562 Avenida Munoz Rivera, San Juan, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of referred samples log sheets review and interview with the laboratory director, it was determined that the laboratory did not ensure the proper conditions of specimen transportation. The findings include: a. On 6/23/2022 at 1:57 PM, the logsheet used to document the samples collected at the referral laboratories were reviewed. The laboratory carriers must document the following information: arrival hour to the referral laboratory, departure hour, number of samples stored at room temperature, refrigerated or frozen, total of samples collected and the portable refrigerators temperatures. b. Review of the laboratory logsheet routes on 6/23/2022 at 2:00 pm, showed that on 6/21/2022 and 6/22/2022 none of the carriers documented the temperatures of any of the portable refrigerators. A total of twelve different routes were reviewed. c. The laboratory director was interviewed on 6/23/2022 at 2:15 pm, about the findings, and she stated that a route supervisor was in charge of the evaluations of the logsheets , but no remedial action was taken about the temperature missing values.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on lack of IQ 200 calibration records, IQ200 system procedures manual review and general supervisor interview on June 23, 2022, it was determined that the laboratory failed to perform at least every 30 days the calibration of the IQ 200 system for the urinalysis microscopic exams from January 2021 to June 23, 2022. The findings include: 1. The laboratory processed and reported the urine microscopic exams by the IQ 200 system. 2. On June 23, 2022 at 12:38 PM, the procedures manual was reviewed, it establishes that the calibration of the IQ 200 system must be performed every 30 days. 3. On June 23, 2022 at 1:18 PM, the IQ 200 calibration records were requested, however, the laboratory did not have available the calibration records for the IQ 200 system from January 2021 to June 23, 2022. 4. On June 23, 2022 at 2:42 PM, the general supervisor confirmed that the IQ 200 calibration records were not available. 5. The laboratory processed and reported 24,288 patients specimens for urine microscopic exam by the IQ 200 system from January 2021 to June 23, 2022.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on quality control records review, laboratory procedure manual and laboratory general supervisor interview; it was determined that the laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. The findings include: a. The laboratory performed Immunoglobulin (IgM) by Cobas 8000 system. b. Quality control records were reviewed on June 23, 2022 at 11:06 am, from November 1, 2021 to November 30, 2021. c. The laboratory procedure manual (PM) was reviewed on June 23, 2022 at 11:20 AM, the PM stated, that if more than 6 control values, fails above or below the one standard deviation (1 SD), the laboratory must take and document a corrective action. d. Review on June 23, 2022 at 11:30 AM, of the Immunoglobulin (IgM) quality control graphs from November 1, 2021 to November 12, 2021, showed that the laboratory failed to take and document corrective action when the control material for IgM exceeded the laboratory limits with a trend above 1 SD in more than 10 plots and more than two

consecutive plots are above 2 SD. 74 patient samples were processed and reported. e. The laboratory general supervisor confirmed on June 23, 2022 at 12:00 PM, that no corrective actions were taken.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review , at random, of endocrinology and general immunology patient test records, manufacturer instructions and interview with the laboratory director on June 23, 2022, it was found that the laboratory did not document the procedural controls when the laboratory tested patient's samples for Human Horizon Gonadotropin (hCG) and Mycoplasma pneumoniae tests. The findings include: a At 11:37 am, on June 23, 2022, the manufacturer's instructions (insert) for hCG test was reviewed. The insert showed that an internal positive procedural control was included in each patient testing card. The manufacturer stated that the procedural control indicates that specimen contains detectable levels of hCG. b. At 11:42 AM on 6/23/2022 the hCG patient worksheet showed that the laboratory did not document the procedural control result with each patient cartridge. The laboratory only document the daily external quality control results. c. At 12:05 pm , on June 23, 2022, the manufacturer's instructions (insert) for Mycoplasma pneumoniae was reviewed. The insert showed that an internal positive procedural control was included in each patient testing card. The manufacturer stated that the procedural control was used as a validation tool. d. At 12:10 PM on 6/23/2022 the Mycoplasma pneumoniae patient worksheet showed that the laboratory did not document the procedural control result with each patient testing card. The laboratory only document the daily , external quality control, results. e. Information about the total number of patients processed and reported for Mycoplasma pneumoniae, from 5/18/2022 to 6/22/2022 , was requested to the laboratory director. At 1:00 PM the laboratory director stated that a total of 2,459 patients test were tested, but no documentation of the procedural control was performed. d. Information about the total number of patients processed and reported for hCG, from 1/3/2022 to 6/22/2022 , was requested to the laboratory director. At 1:00 PM the laboratory director stated that a total of 227 patients test were tested, but no documentation

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 lack of IQ 200 calibration records, IQ200 system procedures manual review

and general supervisor interview on June 23, 2022, it was determined that the laboratory director failed to ensure compliance with the requirements for urinalysis. Refer to D 5437 (The laboratory did not perform at least every 30 days the calibration of the IQ 200 system for the urinalysis microscopic exams from January 2021 to June 23, 2022).

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on testing personnel records review and laboratory director interview on June 23, 2022, it was found that the laboratory director did not make sure that two out two new the testing personnel, had the necessary training before beginning to perform patient tests. The findings include: 1. On June 23, 2022 at 9:30 am, testing personnel records showed that the laboratory hired two out two new the testing personnel in June 2022. One of the them was hired on June 13, 2022 and the other on June 20, 2022. 2. The laboratory did not not document record related for these testing personnel training. 3. On June 23, 2022 at 9:45 am, the laboratory director confirmed that the two new testing personnel processed patient specimens but the laboratory did not document the training.