

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658283	(X3) Date Survey Completed 03/24/2021
Name of Provider or Supplier Auxilio Mutuo Hospital Clinical Lab	Street Address, City, State Ave Ponce De Leon Pda 37, Hato Rey, 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
D5010	<p>VIROLOGY CFR(s): 493.1205</p> <p>If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of virology Real Time Polymerase Chain reaction (RT-PCR) written procedures, refrigerator two point monitoring temperature electronic log, patient log test results review and interview with the laboratory general supervisor on March 24, 2021, at 10:41, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for virology tests (RT-PCR SARS -CoV-19 storage) Refer to D 5401. The laboratory did not follow the written instructions for specimen storage in 15 out of 15 testing dates.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory Real Time Polymerase Chain reaction (RT-PCR) written procedures, refrigerator two point monitoring temperature electronic log, patient log test results review and interview with the laboratory general supervisor on March 24, 2021, at 10:41 am, it was found that the laboratory did not follow the written</p>

instructions related to storage of the RT-PCR patient specimens. The findings include:

- a. The laboratory performed RT-PCR tests with the Applied Biosystems 7500 Fast DX instrument since March 15, 2021. . The reagents were provided by GSD NovaPrime-SARS-CoV-2. The laboratory processed samples from Monday to Friday.
- b. On March 24, 2021 , at 10:41 am, the RT-PCR written procedure was reviewed. The written procedure stated that the samples may be stored up to 24 hours at 2-4 C. If the sample will be processed after 24 hours , the sample must be stored at -80 C. c. Review of the electronic refrigerator temperature log showed that on 10 out of ten days (March 15, 2021 at 2:00 am to March 24, 2021 2:00 am) the laboratory maximum readings up to of 5.6 C and minimums down to -2.6 C. None of the observed temperatures were within the required 2-4 C. d. The patient log test results showed that the laboratory performed 331 patient samples since March 15, 2021. Six out of 331 were positive ones and 325 out of 331 were negatives. e. Review of patient log test results showed that 4 out of 331 were processed more that 24 hours after sample collection, but the laboratory was not able to present any evidence that those samples were stored at -80 C. Sample Id Collection date Processing date 1003285442 3/17/2021 3/19/201 1003285503 3/17/2021 3/19/2021 1003285774 3/17/2021 3/19 /2021 1003285085 3/17/2021 3/19/2021 d. The laboratory general supervisor stated on 3/24/2021 at 12:05 PM, that the laboratory was aware of some kind of problems with the refrigerator temperatures, but they still used it to stored the RT-PCR samples. e. The laboratory did not take any remedial action in order to avoid the store of RT-PCR samples at refrigerator.

D5451

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on general immunology quality control records (years 2020-2021), patient's testing records log review (years 2020-2021) and laboratory general supervisor interview on March 24, 2021 at 11:30 AM, it was determined that the laboratory failed to include , at least once a day, a negative control material and a control material with tittered reactivity when patients specimens were tested for Rheumatoid Arthritis (RA) latex quantitative method (BioKit reagent) The findings include: 1. The laboratory used Biokit reagent kit to perform Rheumatoid Arthritis (RA) latex quantitative patient's sample tests. 2. Review of RA records from January 2020 to March 23, 2021, showed that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when thirty out of four hundred patients specimens were processed and reported for RA quantitative test in the following days: Date Patient ID Results 1/3/2020 MGJ R 1:64 dils 1/19 /2020 LGR R 1:4 dils 2/5/2020 CZL R 1:8 dils 2/8/2020 RAG R 1:16 dils 2/15/2020 FMM R 1:8 dils 2/16/2020 HVR R 1:64 dils 3/10/2020 MGJ R 1:4 dils 4/14/2020 CCL R 1:8 dils 5/5/2020 MRR R 1:4 dils 5/19/2020 MCC R 1:8 dils 5/22/2020 MTH R 1:32 dils 6/15/2020 HRF R 1:4 dils 7/02/2020 MTH R 1:64 dils 7/27/2020 FGG R 1:64 dils 8/17/2020 MMC, AJB R 1:4 dils 8/20/2020 NGV R 1:32 dils 9/10/2020 WCA R 1:4 dils 9/17/2020 LNC R 1:4 dils 9/29/2020 AJM R 1:4 dils 10/26/2020

HBC R 1:16 dils 11/19/2020 IRP R 1:64 dils 12/8/2020 ECR R 1:16 dils 1/6/2021 RTS R 1:4 dils 1/8/2021 ALH R 1:2 dils 2/4/2021 MOL R 1:4 dils 2/8/2021 MNF R 1:2 dils 2/18/2021 AMP R 1:32 dils 2/22/2021 DRR R 1:4 dils 3/0/2021 JGR R 1:32 dils 3. The laboratory processed and reported thirty (30) RA patient's samples with tittered reactivity those days. 4. The laboratory general supervisor confirmed on March 24 at 11:30 AM, that the testing records showed that the laboratory did not perform nor document the control procedures those days.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
Based on "Bio Flex 2200" (Bio Rad) test system documents review and interview with laboratory testing personnel on March 24, 2021 at 11:18 AM, it was determined that the laboratory director failed to evaluate the performance specifications of the "Bio Flex 2200" (Bio Rad) test system since July 10, 2020. The findings include: 1. The laboratory used the "Bio Flex 2200" test system (Bio Rad) to perform the following tests since July 10, 2020: HIV Ag, HIV Ab, EBV, HSV, Measles, Mumps, VZV, Rubella, TOXO Gondi, Cytomegalovirus, Vitamin D and Syphilis IgG. 2. The data obtained during the validation process of the test system "Bio Flex 2200" (Bio Rad), was not evaluated or reviewed by the laboratory director, before reporting the results of the patients.

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 test results, and temperature records review on March 24, 2021, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory virology services for RT-PCR COVID-19 tests requirements. Refer to D6087 and 6100

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

	<p>Based on RT-PCR -COVID-19 written procedures , temperature records review and interview with the general supervisor on March 24, 2021 at 10:41 am, it was found that the laboratory director did not assure that the RT-PCR COVID-19 patient samples were stored at the established storage temperature. The finding includes: a. The RT-PCR written procedures established that the RT-PCR patient sample must be stored between 2 - 4 C. b. Review of the temperatures records showed that temperatures as high as 5.6 and low as -2.3 C were recorded since March 15, 2021. c. The general supervisor established, during interview, that the refrigerator was showing temperature fluctuations since January 2021.</p>
<p>D6100</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10)</p> <p>The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).</p> <p>This STANDARD is not met as evidenced by: Based on RT-PCR SARS-CoV-2 patient's test records, temperature monitoring records review and interview with the laboratory general supervisor on March 24, 2021, it was found that the laboratory director did not ensure, the day to day onsite supervision, of the general supervisor (Medical Technologist -FR) related to COVID -19 RT-PCR patients samples storage. The finding includes: a. The RT-PCR patient' a tests records showed that, from March 15, 2021 to March 24, 2021; 331 out of 331 samples were stored outside the established temperature range of 2 - 4 C. b. There were no evidence of any remedial action taken by the general supervisor to ensure the proper sample storage. Refer to D 5401.</p>
<p>D6148</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4)</p> <p>The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records and written RT-PCR procedures instructions on March 24, 2021, it was determined that the general supervisor did not ensure that the patient's samples, collected for COVID-19 RT-PCR , were stored at the required temperature range prior to testing. The findings include: a. On March 24, 2021 at 10: 41 am , the COVID-19 RT-PCR written instructions, were reviewed. The instructions showed that the samples must be stored between 2-4 C. b. The temperature records since March 15, 2021 showed that the samples were stored outside the range limits. c. The general supervisor did not take any remedial actions to ensure the required specimen storage</p>