

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0673783	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Sur -Med Medical Center, Corp	Street Address, City, State 8 Colon Pacheco, Salinas, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the general supervisor, the clinical consultant, the testing personnel records (years 2018-2019) and laboratory general supervisor interview on January 22, 2019 at 1:00 PM, it was determined that the laboratory failed to follow written policies to assess the clinical consultant, general supervisor competency and testing personnel. (MT#5985, MT#6785, Mt#5931 and MT#5857) (MD #6620). The findings include: 1. The general supervisor, clinical consultant and testing personnel records were reviewed on January 22, 2019 at 10:30 AM. 2. The laboratory schedule for testing personnel competence evaluation showed that it must be performed every year. 3. Review of the general supervisor, the clinical consultant and the testing personnel records, showed that the laboratory technical supervisor did not evaluate the personnel competence during year 2019.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on manufacturer's instructions, syphilis serology quality control records review (years 2018-2019) and laboratory general supervisor interview at 10:30 AM on January 22, 2020, 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 quality control records from January 2019 to January 21, 2020, the records showed that the laboratory processed and reported one thousand twenty two (1,222) RPR (Rapid plasma reagin) patient's tests in 2019 that was performed at temperatures below the range in 112 of 211 days. (19 C). 3. The laboratory processed and reported one thousand twenty two (1,222) RPR (Rapid plasma reagin) patient's samples those days. 4. The laboratory general supervisor confirmed that the laboratory performed RPR (Rapid plasma reagin) tests below the range established by the manufacturer's those days. (19C)</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review (years 2018-2019) and laboratory general supervisor interview at 10:30 AM on January 22, 2020, it was found that the laboratory director did not assure that quality control procedures related to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. The findings include: 1. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. The manufacturer's establishes that the RPR (Rapid plasma reagin) test must be performed at room temperature between 20 C to 30 C . Refer to D5411.</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review (years 2018-2019) and laboratory general supervisor interview at 10:30 AM on January 22, 2020, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D6177.</p>
<p>D6177</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on syphilis serology quality control records review (years 2018-2019) and laboratory general supervisor interview at 10:30 AM on January 22, 2020, it was determined that testing personnel failed to follow quality control procedures related to manufacturer's instructions.. The finding includes: 1. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. The manufacturer's establishes that the RPR (Rapid plasma reagin) test must be performed at room temperature between 20 C to 30 C . Refer to D5411.