

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2069996	(X3) Date Survey Completed 05/10/2018
Name of Provider or Supplier Community Health Promotion Center	Street Address, City, State Rd 190, Km 1 8, Carolina, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on test reports records (years 2017 TO 2018), laboratory tests volumes records review and general supervisor interview on May 10, 2018 at 11:10 AM, it was determined that the laboratory failed to indicate the laboratory name in the following tests results reports from November 8, 2017 to May 9, 2018: complete blood cells (CBC), comprehensive metabolic panel (CMP), urinalysis, Rheumatoid Arthritis (RA), C reactive protein (CRP) and rapid plasma reagin (RPR). The findings include: 1. The laboratory names is Community Health Promotion Service Center. 2. On May 10, 2018 at 11:10 AM, the test reports records(years 2016,2017) showed that the laboratory did not indicate the laboratory name in the following tests results reports from November 8, 2017 to May 9, 2018: CBC, CMP, urinalysis, RA, CRP and RPR. 3. The general supervisor confirmed on on May 10, 2018 at 11:12 AM, that the laboratory tests results reports did not indicate the laboratory name from November 8, 2017 to May 9, 2018. 4. From November 8, 2017 to May 9, 2018, the annual volume records showed that the laboratory processed and reported the following patients tests reports: a. 921 out of 921 CBC results reports b. 306 out of 306 CMP results reports c. 397 out of 397 urinalysis results reports d. 11 out of 11 RA results reports e. 16 out of 16 CRP results reports f. 313 out of 313 results reports RPR</p>

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 test reports records (years 2017 TO 2018), laboratory tests volumes records review and general supervisor interview on May 10, 2018 at 11:10 AM, it was determined that the laboratory director failed to ensure that the report test results indicate the laboratory name in the following tests results reports from November 8, 2017 to May 9, 2018: complete blood cells (CBC), comprehensive metabolic panel (CMP), urinalysis, Rheumatoid Arthritis (RA), C reactive protein (CRP) and rapid plasma reagin (RPR). Refer to D 5805.