

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0673305	(X3) Date Survey Completed 01/23/2018
Name of Provider or Supplier Hosp Metropolitan San German	Street Address, City, State Calle Javilla #8, San German, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on hematology preventive maintenance records review from January 2016 to January 23, 2018 and laboratory director interview on January 23, 2018 at 10:55 AM, it was determined that the laboratory failed to follow manufacturer's instructions for the preventive maintenance of Sysmex 1800i and Sysmex XS 1000i analyzer. The findings include: 1. The laboratory did not perform the monthly preventive maintenance of the Sysmex 1800i analyzer from February 2017 to December 2017 and the Sysmex XS 1000i analyzer on January 2017, February 2017, April 2017, June 2017 to December 2017. 2. The testing personnel and laboratory director confirmed on January 23, 2018, that the laboratory did not perform and document the preventive maintenance of Sysmex 1000i and Sysmex XS 1000i analyzer those months. 3. The laboratory perform 160,627 patients tests from January 1, 2017 to December 31, 2017. 4. This deficiency was cited on January 27, 2016 survey.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p>

This STANDARD is not met as evidenced by:
Based on urinalysis quality control records review in 2016-2017 and laboratory director interview on January 23, 2018 at 11:35 AM, it was determined that the laboratory failed to follow the written policies to evaluate twice a year the relationship of the test urinalysis performed by the systems ARKRAY Au4050 and Clinitek Advantus. The findings include: 1. The laboratory performed urinalysis by the systems ARKRAY Au4050 and Clinitek Advantus. 2. Quality controls records were reviewed since January 2016. 3. The laboratory director stated on January 23, 2018 that the laboratory written procedures established to evaluate each six months the relationship between two system that perform the same test. 4. The laboratory did not perform the comparison of the urinalysis tests by two different systems since 2016.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on quality assessment (QA) records review in 2016-2017 and laboratory director interview on January 23, 2018 at 11:35 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The finding includes: 1. The laboratory failed to follow the written policies to evaluate twice a year the relationship of the test urinalysis performed by the systems ARKRAY Au4050 and Clinitek Advantus.. Refer to D5775. 2. The laboratory failed to follow manufacturer's instructions for the preventive maintenance of Sysmex 1800i and Sysmex XS 1000i analyzer. Refer to D5429.

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 hematology and urinalysis quality control records review in 2016-2017 and laboratory director interview at 11:35 AM on January 23, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory failed to follow the written policies to evaluate twice a year the relationship of the test urinalysis performed by the systems ARKRAY Au4050 and Clinitek Advantus. Refer to D5775. 2. The laboratory failed to follow the manufacturer's instructions for the preventive maintenance of Sysmex 1800i and Sysmex XS 1000i analyzer. Refer to D5429.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review in 2016-2017 and laboratory director interview on January 23, 2018 at 11:35 AM, it was determined that laboratory director failed to ensure compliance with quality assessment requirements. The finding includes: 1. The laboratory failed to follow the written policies to evaluate twice a year the relationship of the test urinalysis performed by the systems ARKRAY Au4050 and Clinitek Advantus. Refer to D5791.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on personnel records review and laboratory director interview on January 23, 2018 at 11:48 AM, it was determined that the laboratory failed to follow the written procedures to monitor and ensure the competency evaluations of the Clinical Consultant. The finding includes: 1. The personnel records showed that the laboratory director did not evaluate annually the competence of the Clinical Consultant. The last competence in records was performed on January 1, 2015. 2. This deficiency was cited on January 27, 2016 survey.

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

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.

This STANDARD is not met as evidenced by:

1. Based on urinalysis quality control records review in 2016-2017 and laboratory director interview on January 23, 2018 at 11:35 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: a. The laboratory failed to follow the written policies to evaluate twice a year the relationship of the test urinalysis performed by the systems ARKRAY Au4050 and Clinitek

Advantus. Refer to D5775. 2. Based on hematology preventive maintenance records review from January 2016 to December 2017, laboratory testing personnel and laboratory director interview on January 23, 2018 at 10:58 AM, it was determined that the testing personnel failed to follow the preventive maintenance of the hematology analyzer (Sysmex 1800i and Sysmex XS 1000i). The finding includes: a. The laboratory failed to follow the manufacturer's instructions for the preventive maintenance of Sysmex 1800i and Sysmex XS 1000i analyzer. Refer to D5429.