Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1098313	02/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Puerto Rico Women And Children's Hospital	Carr Pr-2 Km 11 Hm 6, Bayamon, 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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Clinitek Advantus manufacturer's instructions, urinalysis room temperature records (years 2021 and 2022) review, and technical supervisor interview on February 10, 2023 at 12:55 PM, it was determined that the laboratory failed to follow the Clinitek Advantus instructions for optimum operating temperature when 2192 out of 2334 urinalysis patients specimens were processed and reported from January 1, 2021 to December 31, 2022. The findings include: 1. On February 10,1023, at 12:55 P.M., review the Clinitek Advantus manufacturer's showed that the optimum operating require temperature range is from 22 C to 26C. Furthermore, it indicated that temperatures below 22C could result in decreased readings for urobilinogen and leukocytes (esterase); temperatures above 26C could increase for them. 2. On February 10,1023, at 12:57 P.M., the urinalysis room temperature records showed that 72 out of 365 days during the year 2021 the laboratory processed and reported 995 urinalysis patient specimens at temperature range of 18.6 C to 21.9C: 1/20/21-1/25/21, 2/20/21-2/25/21,3/20/21-3/25/21,4/20/21-4/25/21,5/20/21-5/25/21,6/20/21-6/25/21,7/20/21-7/25/21,8/20/21-8/25/21,9/20/21-9/25/21,10/20/21-10/25/21,11/20/21-11/25/21,12/20/21-12/25/21. Also, the records showed that the laboratory processed and reported 1,339 urinalysis patient's specimens in 65 out of 365 days during the year 2022 at the same range: 1/5/22-1/10/22,2/5/22-2/10/22,3/5/22-3/10/22,4/5/22-4/10/22, 5/5/22-5/10/22,6/5/22-6/10/22,7/5/22-7/10/22,8/5/22-8/10/22,9/5/22-9/10/22,10/5/22-10/10/22,12/5/22,12/7/22-12/10/22. 3. On February 10,1023, at 1:01 P.M., the technical supervisor , confirmed that the laboratory processed and reported those

	urinalysis patients specimens at temperature range from 18.6 C to 21.9C. Also the technical supervisor stated that she did not verify the urobilinogen or leukocyte (esterase) tests when the urinalysis tests were performed when the temperatures below the 22 C. 4. The laboratory processed and reported 2192 out of 2334 patient samples for urinalysis testing from January 1, 2021 to December 31, 2022.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on DxH 800 Instrument maintenance records review (from year 2021 and 202), manufacturer's preventive manual and interview with the laboratory supervisor on February 10, 2023 at 1:44 pm, it was determined that the laboratory failed to follow the established manufacturer's preventive maintenance of every six months, when 10,851 out of 10,851 hematology patient samples were processed and reported from January 1, 2021 to December 31, 2021; and 14,362 out of 14,362 hematology patient samples were processed and reported from January 1, 2022 to December 31, 2022. The findings include: 1. On February 10, 2023, at 11:15 am, the Dxh instrument manufacturer's preventive manual stated that the laboratory must perform every six months, the following maintenance procedure: Cleaning the STM. 2. On February 10, 2023, at 11:30 am, the DxH 800 instrument preventive maintenance records showed that the laboratory did not perform the preventive maintenance of every six months from January 1, 2021 to December 31, 2022. 3. On February 10, 2023 at 1:44 pm, the laboratory supervisor confirmed that the laboratory failed to perform the DxH 800 instrument preventive maintenance of every six months from January 1, 2021 to December 31, 2021, and from January 1, 2022 to December 31, 2022.
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 Clinitek Advantus manufacturer's instructions, urinalysis room temperature records, DxH 800 Instrument maintenance records, manufacturer's preventive manual records review and laboratory technical supervisor interview on February 10. 2023 at 1:44 PM, it was determined that laboratory failed to ensure compliance with the requirements for hematology and urinalysis analytic systems. Refer to D 5405 (The laboratory did not follow the Clinitek Advantus instructions for optimum operating temperature). Refer to D 5411 (The laboratory not followed DxH 800 Instrument maintenance instructions).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)

	The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on DxH 800 Instrument maintenance records, manufacturer's preventive manual review and interview with the technical supervisor on February 10, 2023 at 1: 44 pm, it was determined that the technical supervisor .failed to ensure compliance with the requirements for analytic systems. Refer to D 5405 (The laboratory did not follow the Clinitek Advantus instructions for optimum operating temperature). Refer to D 5411 (The laboratory not followed DxH 800 Instrument maintenance instructions).
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory technical supervisor interview on February 10, 2023 at 12:55 PM, it was determined that the technical supervisor failed to provide annually the competence evaluation to five out six testing personnel that performed the high and moderate complexity tests since December 2021. The findings include: 1. On February 10, 2023 at 12:55 PM, review the personnel records showed that the technical supervisor did not evaluate annually the competence of five out six testing personnel; that include at least the following requirements: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. The five out of six personnel records showed that the competence evaluation were performed in December 2021. 3. On February 10, 2023 at 1:03 PM, the technical supervisor confirmed that the testing personnel competency were performed in December 2021.
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: Based on DxH 800 Instrument maintenance records, manufacturer's preventive manual review and technical supervisor interview on February 10, 2023 at 1:44 PM, it was determined that testing personnel failed to follow quality control procedures. Refer to D 5405 (The laboratory did not follow the Clinitek Advantus instructions for optimum operating temperature). Refer to D 5411 (The laboratory not followed DxH 800 Instrument maintenance instructions).