

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658313	(X3) Date Survey Completed 06/12/2024
Name of Provider or Supplier Laboratorio Clinico Hyde Park	Street Address, City, State Calle Las Marias #238, Urb Hyde Park, Rio Piedras, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on hematology procedure manual records, Complete Blood Count (CBC) test report review and laboratory director interview on June 12, 2024 at 10:15 AM, it was determined that the laboratory failed to include in the written hematology procedure manual the CBC test reference intervals, when they processed and reported 7255 out of 7255 patient's results from January 1, 2023 to June 12, 2024. The findings include:</p> <ul style="list-style-type: none"> a. The laboratory performs hematology CBC tests by the Sysmex XS 800i instrument. b. On June 12, 2024 at 10:15 AM, review of the hematology procedure manual,

	<p>showed that there was no information regarding patient's CBC test report reference intervals (normal values). c. The laboratory processed and reported 7255 out of 7255 CBC patient's results from January 1, 2023 to June 12, 2024. d. The laboratory director confirmed on June 12, 2024 at 10:20 AM, that the hematology procedure manual did not include any information regarding the CBC test report reference intervals.</p>
<p>D5411</p>	<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: Based on laboratory temperature records, manufacturer's instructions review and laboratory director interview on June 12, 2024 at 10:45 AM, it was determined that the laboratory did not monitor nor take any remedial actions when the laboratory sample collection area showed temperatures outside the manufacturer's established range for the Ethylenediaminetetraacetic Acid (EDTA) sample collection tubes, when they processed 65 out of 65 Complete Blood Count (CBC) patients from May 13, 2024 to May 29, 2024. The findings include: a. On June 12, 2024 at 10:45 AM, the laboratory room temperature of the sample collection area was reviewed, and it showed that from May 13, 2024 to May 29, 2024 the recorded temperature was from 26 to 28 C. b. On June 12, 2024 at 10:48 AM, the manufacturer's instructions of the EDTA collection tubes showed that the required storage temperature range was from 4 to 25 C. c. From May 13, 2024 to May 29, 2024, the laboratory collected 65 out of 65 CBC patient samples on EDTA collection tubes. d. The laboratory director confirmed on June 12, 2024 at 10:50 AM, that since May 13, 2024 to May 29, 2024, the room temperature of the laboratory sample collection area was out of the established range.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory temperature records, manufacturer's instructions review and laboratory director interview on June 12, 2024 at 10:45 AM, it was determined that the laboratory director did not ensure that the required storage temperature for Ethylenediaminetetraacetic Acid (EDTA) collection tubes were observed and documented at the laboratory sample collection area. Refer to D5411.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on hematology procedure manual, Complete Blood Count (CBC) test report review and laboratory director interview on June 12, 2024 at 10:15 AM, it was determined that the laboratory director failed to ensure that the CBC reference ranges were included in the hematology written procedure manual. Refer to D5403.