

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0704459	(X3) Date Survey Completed 10/05/2023
Name of Provider or Supplier Laboratorio Clinico Familiar Inc	Street Address, City, State Ave San Patricio #862 Las Lomas, 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 review of hematology written procedure manual and laboratory director interview on October 5, 2023 at 9:50 AM, it was determined that the laboratory did not update the hematology procedure manual to reflect the new Dxh 520 hematology instrument requirements. The findings include: 1. The laboratory performed hematology tests by Dxh 520 instrument since August 1, 2022. 2. Review of the hematology written procedure manual showed that no information regarding the following requirements for the Dxh 520 system were included: a. requirements for patient preparation, specimen collection, storage, preservation, transportation,</p>

processing and referral criteria for specimen acceptability and rejection. b. normal values c. limitations in the test methodology, including interfering substances d. pertinent literature references e. criteria to determine acceptable control results f. quality control procedures 3. The last revision of the hematology written procedure manual was performed on January 2013. 4. The laboratory director confirmed during interview on October 5, 2023 at 9:55 AM, that the laboratory did not have an updated hematology written procedure manual.

D5479

CONTROL PROCEDURES
CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory director interview on October 5, 2023 at 12:53 PM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control each day of patient and control testing. The findings include: 1. The laboratory performed (hCG) human chorionic gonadotropin by Instant view kit. 2. The manufacturer's instructions stated that the laboratory must monitor and document the internal control to ensure the validity of the hCG test performed. 3. The hCG test worksheet records showed on October 5, 2023 at 12:53 PM, that the laboratory did not document the observed results of the internal procedural control each day of patient and control testing. 4. The laboratory processed and reported 35 hCG patient samples from January 1, 2022 to October 5, 2023. 5. The laboratory director confirmed on October 5, 2023 at 12:58 PM, that the laboratory failed to monitor and document the internal control each day of patient and control testing.

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 Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory director interview on October 5, 2023 at 12:53 PM, it was determined that the laboratory director failed to ensure that the internal procedural control was monitored and documented. Refer to D5479.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must 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 review and laboratory director interview on October 5, 2023 at 9:50 AM, it was determined that the laboratory director did not update the hematology written procedure manual when the laboratory acquired the new Dxh 520 instrument on August 1, 2022. Refer to D5403.