

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0987006	(X3) Date Survey Completed 07/28/2023
Name of Provider or Supplier Centro De Salud Integral En Orocovis	Street Address, City, State Carr Pr-155, Sector El Desvio, Orocovis, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology DxH 560 instrument performance verification results and laboratory supervisor interview on July 28, 2023 at 11:33 A.M., it was determined that the laboratory failed to evaluate the instrument's obtained results. The findings include: 1. The laboratory acquired the DxH 560 hematology system since December 2022. 2. On July 28, 2023 at 11:28 A.M., the instrument performance verification procedures were reviewed and showed that it was performed on December, 2022, and that the laboratory director did not evaluate and sign the performance verification of the DxH 560 hematology system prior to begin to test patient samples. 3. The laboratory supervisor confirmed on July 28, 2023 at 11:33 A. M., that the laboratory director did not evaluate and sign the performance verification of the DxH 560 hematology system. 4. The laboratory processed and reported 3,779 hematology tests from March 1, 2023 to July 27, 2023.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the urinalysis quality control records on July 28, 2023 at 11:50 am, it was determined that the laboratory did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 6,035 patients were processed and reported from January 1, 2022 to July 25, 2023. The findings include: 1. The urinalysis quality control records were reviewed on July 28, 2023 at 11:50 am. 2. The laboratory did not include or document a negative control material for urinalysis microscopy test. 3. The laboratory supervisor confirmed on July 28, 2022 at 11:55 am, that no negative microscopy control was implemented from January 1, 2022 to July 25, 2023, when 6,035 patients were processed and reported.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on hematology quality control records review from March 1, 2023 to July 27, 2023, and laboratory supervisor interview on July 28, 2023 at 11:33 A.M., it was determined that the laboratory director failed to fulfill her responsibility to evaluate and sign the performance verification of the new hematology DxH 560 system. Refer to D5421.

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 urinalysis quality control records review from January 1, 2022 to July 25, 2023, and laboratory supervisor interview on July 28, 2023 at 11:55 A.M., it was determined that the laboratory technical supervisor failed to fulfill her responsibility to ensure that the laboratory follows the urinalysis quality control protocol. Refer to D5449.