

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658160	(X3) Date Survey Completed 07/14/2023
Name of Provider or Supplier Lab Clinico Ortega	Street Address, City, State Calle Georgetti #64, Naranjito, 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Erythrocyte sedimentation rate (ESR) quality control records(year 2022-2023), patient's test record review and laboratory director interview on July 14,2023 at 11:15 AM, it was determined that the laboratory failed to check the manufacturer's stated values of control material used since January 5, 2022 to July 13, 2023. The findings include: 1. The laboratory uses the Sedimat 15 system to perform Erythrocyte sedimentation rate patient's samples an the Polymedco SED-CHEK 2 control material level I and II. (Reviewed on July 14,2023 at 11:15 AM). 2. The ESR quality control records, showed that the laboratory did not check the manufacturer's stated values for the following lot's numbers prior to place it in routine use: (Reviewed on July 14,2023 at 11:20 AM). A. Control Lot: 11001211 Normal /11001211 Abnormal Use date: January 5,2022 to June 29,2022 Patients processed: 167 B. Control Lot: 11501221 Normal/ 11501221 Abnormal Use date: July 5,2022 to June 28,2023 Patients processed: 336 C. Control Lot: 11503221 Normal/ 11503221</p>

	<p>Abnormal Use date: July 5,2023 to July 13,2023 Patients processed: 9 3. The laboratory director confirmed that the laboratory did not check the manufacturer's stated values prior to place it in routine use. (Reviewed on July 14,2023 at 11:25 AM). 4. The laboratory performed and reported 512 out of 512 patient's specimen were tested for ESR from January 5, 2022, to July 13, 2023.</p>
<p>D5775</p>	<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> <p>This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) written procedures, QA records review (year 2022-2023) and laboratory director interview on July 14,2023 at 10:10 AM, it was determined that the laboratory failed to evaluate and define, twice a year, the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Coulter Act 5 diff AL system since February 2,2022. (Reviewed on July 14, 2023,2023 at 10:10 AM). 2. The hematology differential comparison records and quality assurance review were reviewed from February 2022 to July 14, 2023. (Reviewed on July 14, 2023 at 10:15 AM). 3. The laboratory written procedures showed that the comparison procedures must be performed twice a year. (Reviewed on July 14,2023 at 10:18 AM). 4. Review of the QA records on July 14,2023 at 10:23 AM, showed that the laboratory performed the hematology cell differential comparison procedures, during year 2022, only on December 2,2022. 5. The laboratory director confirmed on July 14, 2023 at 10:30 AM ,that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system.</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 hematology quality control records review and laboratory director interview on July 14, 2023 at 11:35 AM, it was determined that laboratory director failed to ensure compliance with the requirements for ESR quality control procedures. Refer to D5469.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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 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 2022-2023 and laboratory director interview on July 14, 2023 at 10:40 AM, it was determined that laboratory director failed to ensure compliance with quality assessment requirements. Refer to D5775.