| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 31D1073627 | 12/18/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Excel Medical Laboratory | 99-107 Glendale Avenue, Edison, NJ | |

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 |
|---|---|
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>a. Based on surveyor review of the Procedure Manual (PM), analyzer comparison data and interview with the General Supervisor (GS), the laboratory failed to follow their PM policy for "Intra-Instrument Correlation" for Hematology tests ran on the Cell-Dyn Ruby #1 and #2 on 2/12/19. The findings include: 1) The PM stated "3. The values obtained on both analyzers are compared. 4. The average difference between two analyzers should be less than 10%". 2) The values were not compared. 3) The average difference was not calculated. 4) The GS #3 listed on the CMS form 209 confirmed on 12/17/19 at 11:05 am the above mentioned procedure was not followed.<br>b. Based on surveyor review of the PM and interview with the GS, the laboratory failed to follow the procedure for Sample Collection and Preparation for Partial Thromboplastin Time (PTT) tests run on the ACL Elite analyzer from 11/16/17 to the date of survey. The finding includes: 1. The PM stated "Remove Plasma within sixty minutes of venipuncture." but a review of patients requisitions revealed Plasma wasn't removed until specimen was received by the laboratory. 2. Approximately 1500 tests were run and reported. 3. The GS #3 listed on CMS form 209 confirmed on 12/18/19 at 11:00 am that the laboratory did not follow the procedure for sample collection and preparation. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b) |

| | |
|---|---|
| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have all procedures needed for General Immunology tests on the date of the survey. The finding includes: 1. The laboratory failed to have a procedure for titering positive results for Anti-streptolysin O (ASO) and C-Reactive protein (CRP) tests. 2. The LD confirmed on 12/18/19 at 11: 10 am that the laboratory did not have the above procedures. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Manufacturer Package Inserts (MPI) and interview with the Technical Supervisor (TS), the laboratory failed to follow the MPI for BD BBL Sensi-Disc Antimicrobial Susceptibility Test Discs tests from 11/16/17 to the date of survey. The finding includes: 1. The MPI stated to perform a gram stain but the laboratory did not perform gram stains before performing susceptibility. 2. The TS #2 listed on CMS form 209 confirmed on 12/17/19 at 10:20 am that the laboratory did not follow the MPI. This deficiency was corrected on site 12/18/19. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the General Supervisor (GS), the laboratory failed to put a new expiration date on Hematology Control material used on the Cell-Dyn Ruby on the date of the survey. The GS #3 listed on CMS form 209 confirmed on 12/17/19 at 1:10 pm the laboratory failed to put a new expiration date on the control material. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of calibration records and interview with the General Supervisor (GS), the laboratory failed to perform and document calibration procedures at least once every six months for Hematology Testing on the Cell-Dyn Ruby #2 analyzer in the calendar year 2019. The finding includes: 1. There was no documented evidence that calibration was performed in the calendar year 2019 2. The GS confirmed on 12/17/19 at 11:30 am Calibration was not performed every six months. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records and interview with General Supervisor (GS), the laboratory failed to perform and document a positive titered level of controls on each day of patient testing for Immunology slide tests from 11/16/17 to the date of the survey. The findings include: 1. There was no documented evidence a positive titered control was performed when a positive patient result was tittered for Anti-Streptolysin O (ASO), Mononucleosis (Mono), Rheumatoid Factor (RF), Rubella, C-Reactive Protein (CRP), Rapid Plasma Reagin (RPR) tests. 2. Approximately one to three patients were run and reported each month QC was not done. 3. The GS #3 listed on CMS 209 confirmed on 12/18/19 at 10:30 am that a positive tittered control was not performed every day a patient a patient was titered. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>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-- 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document quality control for Bio Rad Tox/See urine drug screen test from 11/16/17 to the date of the survey. The finding includes: 1. The laboratory did not perform positive and negative QC on each day of patient testing. 2. The laboratory ran and reported approximately five patient samples a week. 3. The GS #3 listed on the CMS form 209 confirmed on 12/18/19 at 10:50 am that the laboratory did not perform and document quality control on each day of patient testing. |