

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2049864	(X3) Date Survey Completed 02/22/2024
Name of Provider or Supplier Southern Lab Partners, Llc	Street Address, City, State 2732 7th Avenue South, Birmingham, AL	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, corrective action document, and an interview with the Laboratory Director (LD), the laboratory failed to ensure PT results were submitted before the postmark due date. This was noted for one of three Microbiology PT events reviewed in 2023. The findings include: 1. A review of the API PT records revealed a score of 0% and "Failure to participate" on 2023 Microbiology Event 3 for C. diff (Clostridioides difficile) and HSV (Herpes Simplex Virus) 1/2 with a deadline date of 9/26/2023. 2. At 3:57 AM on 2/22/2024, The LD confirmed the PT results were not submitted.</p>
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>

This STANDARD is not met as evidenced by:
 Based on a review of the Beckman Coulter DxI 600 validation records and an interview with the Laboratory Director, the laboratory failed to evaluate data used for validation of Vitamin B12, Prolactin, Progesterone, Sensitive Estradiol, Follicle-stimulating Hormone (FSH), Leutinizing Hormone (LH), and Testosterone. This was noted from the time of validation approval, 11/17/2023, to the date of the current survey, 2/22/2024. The findings include: 1. A review of the validation for the above listed analytes revealed three runs of a level 1 and level 3 control to establish precision and accuracy of each analyte. No evidence of an evaluation of the raw data provided was available for review at the time of survey. 2. During an interview on 2/21/2024 at 11:30 AM, the Laboratory Director confirmed the above findings.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
 Based on reviews of the Beckman Coulter DxH 520 calibration records, quality control records, the Beckman Coulter DxH 520 User Manual, and an interview with the Laboratory Director, the laboratory failed to follow the manufacturer's instructions for calibration frequency. This was noted one out of four opportunities for calibration from the date of the last survey, 2/15/2022, to the date of the current survey, 2/22/2024. This is a repeat deficiency. The findings include: 1. A review of Beckman Coulter DxH 520 calibration records revealed calibrations performed on 3/25/2022, 11/22/2022, and 10/2/2023. No evidence of a calibration in the first half of 2023 was available for review. 2. A review of the Beckman Coulter DxH 520 quality control (QC) records revealed only the daily instrument printouts. The laboratory had not implemented a mechanism to monitor for QC shifts and trends over time. 3. A review of Beckman Coulter DxH 520 User Manual revealed "You should verify the calibration status. If verification fails, proceed with calibration." To verify calibration the user manual states "When controls show evidence of unusual trends (all levels demonstrate similar parameter recovery)." 4. During an interview on 2/21/2024 at 3:45 PM, the Laboratory Director confirmed the laboratory was not reviewing for QC shifts or trends, and had no other mechanism (such as submitting QC data to a comparative peer review program) to determine if calibration was needed during this time period (November 2022 - October 2023).

D5439

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

Based on a review of Beckman Coulter AU480 Calibration Verification (CalVer) records, a review of calibration reports, a review of Policies and Procedures, and an interview with the Laboratory Director, the laboratory failed to perform calibration verification every six months per CLIA regulations. This was noted from the date of the previous survey, 2/15/2022, to the date of the current survey, 2/21/2024. The findings include: 1. A review of the AU480 Calibration Verification records revealed a CalVer Performed on 11/9/2022 for Albumin, Alkaline Phosphatase (ALP), Alanine Transaminase (ALT), Aspartate Transferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Cholesterol, Creatinine Kinase (CK), Chloride (Cl), Carbon dioxide (CO₂), Creatinine, Direct Bilirubin, High-density Lipoprotein (HDL), Glucose, Potassium (K), Magnesium (Mg), Sodium (Na), Total Bilirubin, Total Protein, Triglycerides, and Uric Acid. No other CalVer records for the AU480 were available for review. 2. A review of calibration reports for the above listed analytes revealed each analyte to only have two calibration factors performed with routine calibration. 3. A review of the Polices and Procedures revealed the following under "Calibration Verification Exceptions", "...Calibration Verification is met if running 3 or more levels of calibrator..." 3. During and interview on 2/21/2024 at 2:27 PM, the Laboratory Director confirmed CalVers are not being performed every six months as specified in the laboratory's policy.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

performance and environmental conditions, and variance in operator performance. (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the current Application for Certification (CMS-116), a review of Policies and Procedures, a review of Qiagen Rotor-Gene quality control (QC) records, and an interview with the Laboratory Director, the laboratory failed to establish a cut off value for Gardnerella Vaginalis. This was noted for five out of five months reviewed from August 2023 to December 2023. The findings include: 1. A review of the CMS-116 form revealed the laboratory is performing Urinary Tract Infection panels on the Qiagen Rotor-Gene. Gardnerella Vaginalis is among the organisms being tested and reported for patient testing. 2. A review of the Qiagen Rotor-Gene quantitation reports revealed Gardnerella Vaginalis to be among the rotated organisms used for a positive control. 3. A review of the Qiagen Rotor-Gene procedure revealed no evidence of a cut off value to indicate an acceptable QC result for Gardnerella Vaginalis. 4. During an interview on 2/22/2024 at 12:00 PM, the Laboratory Director confirmed the above findings.