

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0962638	(X3) Date Survey Completed 05/19/2022
Name of Provider or Supplier Greystone Internal Medicine	Street Address, City, State 101 Missionary Ridge Suite 200, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) Proficiency Testing (PT) records, the laboratory's Protocol for Proficiency Testing, and an interview with the Technical Consultant (TC), the laboratory failed to document corrective action for events scoring eighty percent (80 %) for RBC (Red Blood Cell Count), HCT (Hematocrit), MCV (Mean Corpuscular Volume), RDW (Red Cell Distribution Width), and MCH (Mean Corpuscular Hemoglobin). This affected two of seven events reviewed by the surveyor from 2020 - 2022. This is a repeat deficiency. The findings include: 1. A review of the API records revealed the laboratory scored 80% and failed to document corrective actions on the following: a) 2020 Hematology 1st Event - MCH b) 2020 Hematology 3rd Event - RBC, HCT, MCV, RDW, and MCH 2. A review of the laboratory's Protocol for Proficiency Testing under Reviewing PT Results revealed, "...3. If any analyte is missed ... 6. Document all corrective action...". 3. During a phone interview on 05/19/2022 at 10:50 AM, the Technical Consultant confirmed the laboratory failed to perform corrective for 2020 1st and 3rd Events.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the maintenance records, the CELL-DYN Emerald Operator's Manual, and an interview with the Technical Consultant, the laboratory failed to document maintenance as defined by the manufacturer. This was noted from the previous survey (11/21/2019) to March 2021 (when the laboratory ceased using the analyzer for patient testing). The findings include: 1. A review of the maintenance records revealed December 2019 through March 2021 maintenance documents could not be located. 2. A review of the CELL-DYN Emerald Operator's Manual in Section 9, Service and Maintenance, revealed the following: a) "...Monthly Maintenance Bleach Cleaning - Cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected..." b) "...Semi-Annual Maintenance Lubricating the Pistons - For optimal operation, the Syringe Pistons should be lubricated every six months as described below..." 3. During a phone interview on 05/19/2022 at 12:06 PM, the Technical Consultant confirmed the laboratory could not locate the CELL-DYN Emerald maintenance records.

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 a review of calibration records, the CELL-DYN Emerald Operator's Manual, and an interview with the Director of Operations, the laboratory failed to perform and document calibrations for the CELL-DYN Emerald following the manufacturer's recommended frequency. This was noted for two of two calibrations due in 2020. The findings include: 1. A review of the CELL-DYN Emerald Hematology analyzer records revealed no documentation of 2020 calibrations. The last documented calibration was performed on November 20, 2019. The laboratory ceased patient testing on the analyzer in March 2021. 2. A review of the CELL-DYN Emerald Operator's Manual in Section 6 "Calibration" revealed, "Calibration verification criteria include: ...At least every six months..." 3. During an interview on 05/19/2022 at 12:06 PM, the Director of Operations confirmed the laboratory could not locate any 2020 CELL-DYN Emerald calibration records.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

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:
 Based on a review the CELL-DYN Emerald CBC (Complete Blood Count) Quality Control (QC) records, patient logs, and an interview with the Director of Operations, the laboratory failed to perform CBC QC each day of patient testing. This was noted for one day out of six months reviewed by the surveyor from December 2019 to November 2020. The findings include: 1. A review of the CELL-DYN Emerald QC records revealed no QC was performed on December 10, 2019. 2. A review of the patient logs revealed the laboratory performed seven patients CBC's on December 10, 2019. 3. During an interview on May 19, 2022 at 1:41 PM, the Director of Operations confirmed the above findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on a review of the policy and procedure manual, a review of the American Proficiency Institute (API) proficiency testing records, CELL DYN Emerald CBC (Complete Blood Count) Quality Control (QC) records, calibration records, maintenance records, and an interview with the Director of Operations, the laboratory failed to maintain a Quality Assessment program to monitor, identify, and correct problems, occurring within the analytic process. This affected the survey review period of November 21, 2019 - March 2021 (when patient testing on the CELL-DYN Emerald ceased). The findings include: 1. A review of the policy and procedure manual revealed a Quality Assurance (QA) Plan to monitor areas, as follows: Proficiency Testing, Personnel, Patient Test Management, Quality Control, Communications, Complaints, and Quality Assurance. 2. A review of the API records revealed the laboratory scored 80% and failed to document corrective actions on the following surveys: a) 2020 Hematology 1st Event - MCH (Mean Corpuscular Hemoglobin) b) 2020 Hematology 3rd Event - RBC (Red Blood Cell), Hct (Hematocrit), MCV (Mean Corpuscular Volume), RDW (Red Cell Distribution Width), and MCH (Mean Corpuscular Hemoglobin). (Refer to D5221.) 3. A review of the CELL-DYN Emerald records revealed QC was not performed on December 10, 2019; seven patients CBCs (Complete Blood Counts) were performed on that date. (Refer to D5447.) 4. A review of the CELL-DYN Emerald records revealed no calibration documentation for 2020. (Refer to D5437.) 5. A review of the CELL-DYN Emerald records revealed no documentation of maintenance from December 2019 through March 2021 (when patient testing on the analyzer ceased). (Refer to D5429.) 6. During an interview on 05/19/2022 at 12:42 PM, the Director of Operations confirmed the laboratory had failed to perform reviews to assure the quality of the analytic systems, as per the Quality Assessment protocol.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the Director of Operations, the Technical Consultant failed to ensure annual evaluations were performed by a qualified personnel for Hematology Complete Blood Count (CBC). This was noted for two of two Testing Personnel listed on the CMS - 209 Laboratory Personnel Report. The findings include: 1. A review of the personnel records revealed Laboratory Personnel Evaluations signed and evaluated by employees, not qualified as Technical Consultant, for both Testing Personnel #1 and the Technical Consultant (also, Testing Personnel). The following was noted: a) Technical Consultant's annual evaluations were performed on 06/01/2020 and 09/17/2021 by an employee at a different location. b) Testing Personnel #1's annual evaluations were performed on 11/30/2020, 03/03/2021, and 03/03/2022 by an employee who performed waived testing only. 2. During an interview on 05/16/2022 at 12:15 PM, the Director of Operations confirmed the annual evaluations for both the Technical Consultant and Testing Personnel #1 were performed by employees who did not at minimum meet the Technical Consultant requirements.