

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0962638	(X3) Date Survey Completed 11/21/2019
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 records and an interview with the Director of Operations, the surveyor determined the laboratory staff failed to ensure results were obtained from API for Hematology Event #2, 2017. The laboratory failed to ensure the results were reviewed and evaluated, and corrective actions were taken for the eighty percent (80 %) score for the RBC (Red Blood Cell Count). This affected one of six testing events, reviewed by the surveyor. The findings include: 1. A review of Casper 0096 D for the laboratory, revealed the laboratory scored 80 % for the RBC for Hematology Event #2 of 2017. A review of the proficiency testing records at the labortaory revealed the laboratory failed to obtain the results for API, failed to perform an evaluation/review, and hence, failed to implement and document corrective actions for the RBC score of less than one hundred percent. 2. At 10:55 AM on November 21, 2019, the Director of Operations reviewed the proficiency testing manual for the missing results for Event #2, 2017 and did not find them.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
Based on a review of the policy and procedure manual, a review of the temperature and humidity logs, a review of the calibration records and interviews with the Director of Operations, the surveyor determined 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 September 2017 - November 21, 2019. The findings include: 1. A review of the policy and procedure manual revealed a QA (Quality Assurance) Plan to monitor areas: Proficiency Testing, Personnel, Patient Test Management, Quality Control, Communications, Complaints, Quality Assurance. 2. A review of the temperature and humidity logs revealed the laboratory staff did not monitor and document humidity or room temperature (Emerald Cell-Dyn operating system) for January - November 21, 2019. 3. At 11:30 AM on November 21, 2019, the Director of Operations reviewed the logs and confirmed the staff had not documented humidity or room temperature in 2019. At 12:17 PM, the Director of Operations confirmed the new testing personnel had not been checking the parameters as mentioned. 4. A review of the calibration records revealed no quality control had been tested after the calibration performed on February 27, 2018 at 12:50 PM. 5. At 12:22 PM on November 21, 2019, the Director of Operations stated the quality control should be run after the calibration to ensure the calibration worked. 6. At 12:28 - 12:45 PM on November 21, 2019, the surveyor inquired of the Director of Operations the laboratory's procedures for ensuring quality assurance for system processes. The Director of Operations (D of O) stated the tests are ordered electronically, but the CBC (Complete Blood Count) results are input manually. The D of O further stated the staff monitors ten medical charts each month; however none of the monitoring is documented. The D of O confirmed there was no documentation of QA audits.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of the personnel records and an interview with the Director of Operations, the surveyor determined the laboratory failed to ensure the individual, hired to serve as the technical consultant, presented with the necessary documentation (evidence of at least two years of laboratory experience or training in non-waived testing) to ensure she met the qualifications of Technical Consultant. This affected the survey review period of September 2017 - date of the survey (November 21, 2019). The findings include: 1. A review of the personnel files revealed the individual listed on the CMS form #209 (CLIA Laboratory Personnel Report) had not presented the documentation to show prior laboratory training/experience of at least two years in non-waived testing. 2. At 10:00 AM on 11/21/2019, the surveyor inquired of the Director of Operations, the listed Technical Consultant's (TC) qualifications, and asked for verification the individual had at least two years experience and/or training in non-waived testing. The CLIA regulation regarding TC qualifications was discussed, at this time. The Director of Operations confirmed the personnel records did not include the documentation of training/experience of the TC. At 12:45 PM, no documentation of prior laboratory experience/training was provided for the surveyor's review.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the Director of Operations, the surveyor determined the laboratory failed to ensure the individual, hired to serve as the technical consultant, presented with the necessary documentation (evidence of at least two years of laboratory experience or training in non-waived testing) to ensure she met the qualifications of Technical Consultant. This affected the survey review period of September 2017 - date of the survey (November 21, 2019). The findings include: 1. Refer to citation, D6033.