Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2102839	11/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Greystone Family Medicine Pc	6930 Cahaba Valley Road Suite 102, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to maintain a record of attestation, signed by the Laboratory Director and testing personnel, for Hematology, Event #3, 2017. This affected one of six testing events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records for Hematology Event #3, 2017 revealed an attestation statement was not included in the records retained. 2. During an interview of November 21, 2019 at 3:14 PM, TP #1 reviewed the proficiency testing records and confirmed the attestation statement for the above mentioned event was not included in the records.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)

	The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records, a review of the test menu, and an interview with Testing Personnel (TP #1), the surveyor determined the laboratory failed to self-evaluate results returned ungraded from API, for Hematology Event #1, 2019. This affected one of six testing events reviewed by the surveyor. The finding include: 1. During the initial tour of the laboratory on November 21, 2019 at 1:00 PM, the testing personnel stated the laboratory performed PPM (Provider Performed Microscopy), including urine sediment examinations, KOH (Potassium Hydrogen Peroxide), and vaginal wet preparations. 2. A review of the API proficiency testing records revealed the laboratory was enrolled to participate in testing of the above mentioned analytes. A review of the records for Event #1 of 2019 revealed when API returned the scores for the event, the KOH and urine sediment examination were not graded. The laboratory did not self-evaluate the testing of these analytes to ensure the accuracy of the laboratory's reporting. The Technical Consultant documented a note in the records for the staff to print the data summaries. However, no data summaries were included in the proficiency testing records. 3. In an interview of November 21, 2019 at 3:15 PM, the surveyor reviewed the note and proficiency testing records with TP #1. TP #1 stated she attempted to print the data summaries as instructed by the Technical Consultant, however she was not able to print them. TP #1 further stated she attempted to contact API, but was unsuccessful. The data summaries were never printed, and the laboratory never self-evaluated the test results.