Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300744	04/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bruce Pava Md	52 Medical Park Drive East Suite 317, 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 AAB (American Association of Bioanalysts) proficiency testing records and interviews with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the Laboratory Director (also serving as the Technical Consultant) and testing personnel signed the attestation statement for Hematology testing for Event #3, 2018. The laboratory failed to maintain a record of attestation for Event 1, 2018. This affected two of six testing events reviewed by the surveyor. This is a repeat deficiency. The facility failed to follow the Plan of Correction, submitted in May of 2017, as a result of the Recertification Survey, conducted on April 19, 2017. The findings include: 1. A review of the AAB proficiency testing records revealed the following: a) The attestation statement for Hematology testing, Event #3, 2018 was included with the records; however neither the Laboratory Director nor the testing personnel had signed the statement. TP #1 confirmed the above noted findings at 12:

	30 PM on 4/02/19. b) The proficiency testing records retained for Hematology testing, Event #1 of 2018, failed to include an attestation statement. TP #1 confined these findings at 12:26 PM on 4/02/19.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the Casper report, including the proficiency testing reporting to the national database, a review of the AAB (American Association of Bioanalysts) proficiency testing records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to obtain the results for Hematology testing, Event #2, 2017, resulting in the laboratory's failure to ensure a review and evaluation were performed. This affected one of six proficiency testing events reviewed by the surveyor. This is a repeat deficiency. The findings include: 1. A review of the AAB proficiency testing records revealed the laboratory failed to obtain results for the Hematology testing for Event #2, 2017, resulting in the laboratory's failure to assess the results to determine accuracy of testing and reporting. 2. A review of the Casper report for the laboratory revealed the laboratory scored eighty percent (80 %) for the Red Blood Cell Count, Hematocrit and Hemoglobin, which required review, evaluation, and implementation of corrective actions. There was no evidence provided a review was done. 3. In an interview on 4/02/2019 at 12:25 PM, TP #1 reviewed the folder with documents from Hematology testing, Event #2, 2017 and confirmed there were no results included.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of personnel records and quality assurance checklists, a review of proficiency testing records, a review of the policy and procedure manual, and interviews with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure: 1) Plans of Corrections from the Recertification Survey, conducted on April 19, 2017, were followed to assure attestation statements were signed and retained; and results from proficiency testing were obtained to determine the laboratory's accuracy of testing and reporting. This affected three of six testing events reviewed by the surveyor. 2) Laboratory testing personnel's competency was assessed at least annually, after the first year of employment. This affected three of three testing personnel. The findings include: 1. Refer to D6021. {Also refer to D2015 and 5211 (These are repeat deficiencies)} 2. Refer to D6030.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of personnel records and quality assurance checklists, a review of proficiency testing records, a review of the policy and procedure manual, and interviews with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure the quality of services provided, by failing to ensure the following: 1) Plans of Corrections from the Recertification Survey, conducted on April 19, 2017, were followed to assure attestation statements were signed and retained; and results from proficiency testing were obtained to determine the laboratory's accuracy of testing and reporting. This affected three of six testing events reviewed by the surveyor. 2) Laboratory testing personnel's competency was assessed at least annually, after the first year of employment. This affected three of three testing personnel. The findings include: 1. Refer to D2015 and 5211. These are repeat deficiencies. 2. Refer to D6030.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, a review of the personnel and quality assurance records, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure policies and procedures were established to ensure testing personnel of moderate complexity testing maintained their competency. The Laboratory Director (also serving as the Technical Consultant) further failed to assess the personnel's competency annually, after the first year of employment. This affected three of three testing personnel for May 2017 - April 2, 2019. The finding include: 1. A review of the personnel records, found in the 2018 manual, revealed laboratory personnel assessment records for the three testing personnel (listed on the CMS Laboratory Personnel Report). The dates on these records were 1/3/18, handwritten over areas which had been covered with white-out (liquid paper). Underneath the date on the assessment for TP #1 was clearly visible the year, 2017; and the assessment was not signed by the Laboratory Director. The director's name was written on the competency assessment by TP #1 (See interview at 10:50 AM). 2. The personnel records, found in the 2019 manual, revealed laboratory

	personnel assessment records for the three testing personnel. The dates at the top of these records were 2/23/15, with dates of 2/14/19 on the signature lines, which had also been covered with white-out. 3. At 10:30 AM, TP #1 stated the competency assessments, dated 2018, were not the same as those used in 2017, because she maintained each year's assessments in separate manuals, specific for the year. A review of the 2017 manual revealed there were no competency assessments maintained; although TP #1 stated each of the three manuals (2017-2019) contained assessments for that year. 4. The assessments for TP #2 and #3 had been signed by TP #1. TP#1 had written the laboratory director's name on one of two assessments for herself, which she confirmed at 10:50 AM on 4/02/2019. 5. The policy and procedure manual failed to include a policy or procedure on how personnel competencies were to be done or the frequency of occurrence. 6. A review of the monthly quality assurance checklists for 2018 and 2019 revealed a category, entitled Personnel Policies Were Followed, with the following items check-marked (indicating performance): all personnel who perform tests had documented training; and all personnel who perform tests have read the procedure manual for those tests. TP #1 confirmed, during the exit summation at 1:30 PM, the above statements were the extent of the laboratory's personnel policies and procedures.