Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300744	08/15/2018
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the CASPER reports (#153/#155), and a review of American Association of Bioanalysts (AAB) proficiency testing evaluations for Hematology, the surveyor determined the laboratory failed to successfully participate in proficiency testing (PT) for Platelets (Plts) for three of five testing events, Event #3, 2016; Event #3, 2017 and Event #1, 2018. These failures resulted in a non-initial unsuccessful proficiency testing performance for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored the following for three of five testing events: a) The laboratory scored 20 % (percent) for Plts for Event #3, 2016. b)

	The laboratory scored 60 % for Plts for Event #3, 2017. c) The laboratory scored 60 % for Plts for Event #1, 2018. 2. The surveyor confirmed the above noted failures by reviewing the AAB proficiency testing evaluations for Hematology. 3. The surveyor attempted to contact the laboratory personnel on 8/15/18 (Wednesday) at 11:05 AM; however the attempt was not successful. The only testing personnel works only on Mondays (per the receptionist). The Laboratory Director was not available.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of the CASPER reports (#153/#155), and a review of American Association of Bioanalysts (AAB) proficiency testing evaluations for Hematology, the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing (PT) for Platelets (Plts) for three of five testing events, Event #3, 2016; Event #3, 2017 and Event #1, 2018. These failures resulted in a non-initial unsuccessful proficiency testing performance for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored the following for three of five testing events: a) The laboratory scored 20 % (percent) for Plts for Event #3, 2016. b) The laboratory scored 60 % for Plts for Event #3, 2017. c) The laboratory scored 60 % for Plts for Event #1, 2018. 2. The surveyor confirmed the above noted failures by reviewing the AAB proficiency testing evaluations for Hematology. 3. The surveyor attempted to contact the laboratory personnel on 8/15/18 (Wednesday) at 11:05 AM; however the attempt was not successful. The only testing personnel works only on Mondays (per the receptionist); and the Laboratory Director was not available.
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 the CASPER reports (#153/#155), and a review of American Association of Bioanalysts (AAB) proficiency testing evaluations for Hematology, the surveyor determined the Laboratory Director failed to ensure the laboratory successfully participated in proficiency testing (PT) for Platelets (Plts) for three of five testing events, Event #3, 2016; Event #3, 2017 and Event #1, 2018. These failures resulted in a non-initial unsuccessful proficiency testing performance for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored the following for three of five testing events: a) The laboratory scored 20 % (percent) for Plts for Event #3, 2016. b) The laboratory scored 60 % for Plts for Event #3, 2017. c) The laboratory scored 60 % for Plts for Event #1, 2018. 2. The surveyor confirmed the above noted failures by reviewing the AAB proficiency testing evaluations for Hematology. 3. The surveyor attempted to contact the

	laboratory personnel on 8/15/18 (Wednesday) at 11:05 AM; however the attempt was not successful. The only testing personnel works only on Mondays (per the receptionist); and the Laboratory Director was unavailable.
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 the CASPER reports (#153/#155), and a review of American Association of Bioanalysts (AAB) proficiency testing evaluations for Hematology, the surveyor determined the Laboratory Director failed to ensure a quality assessment program was maintained in a manner to identify and correct errors, occurring in pre-analytic/analytic/post analytic processes of proficiency testing specimens and possibly patient specimens. This is evidenced by the laboratory's repeated failures of proficiency testing as follows: The laboratory failed to successfully participate in proficiency testing (PT) for Platelets (Plts) for three of five testing events, Event #3, 2016; Event #3, 2017 and Event #1, 2018. These failures resulted in a non-initial unsuccessful proficiency testing performance for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored the following for three of five testing events: a) The laboratory scored 20 % (percent) for Plts for Event #3, 2016. b) The laboratory scored 60 % for Plts for Event #3, 2017. c) The laboratory scored 60 % for Plts for Event #1, 2018. 2. The surveyor confirmed the above noted failures by reviewing the AAB proficiency testing evaluations for Hematology. 3. The surveyor attempted to contact the laboratory personnel on 8/15/18 (Wednesday) at 11: 05 AM; however the attempt was not successful. The only testing personnel works only on Mondays (per the receptionist); and the Laboratory Director was unavailable. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor