Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0904183	05/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gigi Wood Davis, Do Family Practice	1010 Wayne Rd, Suite 100, Savannah, TN	

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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the automated white blood cell (WBC) differential analyte in 2017 event two, 2017 event three, and 2018 event one, resulting in the second unsuccessful PT occurrence for the WBC differential. (Refer to D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's 2017 and 2018 proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance for three consecutive proficiency testing events for the automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for the WBC differential. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory automated WBC differential scores: 2017 event two 0%, 2017 event three 0%, 2018 event one 0%. 2. Review of the 2017 PT event two evaluation report revealed unacceptable scores for WBC differential for 'Failure to Participate.' 3. Review of the 2017 PT event three evaluation report revealed unacceptable scores for Granulocyte % for sample numbers HEM-11, HEM-12, HEM-13, HEM-14, HEM-15, Lymphocyte % for sample numbers HEM-11, HEM-12, HEM-13, HEM-14, HEM-15 and Mono/Mid % for sample numbers" HEM-11, HEM-12, HEM-13, HEM-14, HEM-15. 4. Review of the 2018 PT event one evaluation report revealed unacceptable scores for Granulocyte % for sample number HEM-01, HEM-02, HEM-03, HEM-04, HEM-05; Lymphocyte % for sample number HEM-01, HEM-02, HEM-03, HEM-04, HEM-05; Mono/Mid % for sample number HEM-01, HEM-02, HEM-03, HEM-04, HEM-05; resulting in the second unsuccessful PT occurrence for the WBC differential.
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: The laboratory director failed to maintain compliance with successful white blood cell (WBC) differential proficiency testing (PT) for three events in a row and failed to follow the approved allegation of compliance (AOC) for the WBC differential, resulting in the second unsuccessful PT occurrence for the WBC differential. (Refer to D6019)
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), the laboratory's 2017 event two, 2017 event three, and 2018

	event proficiency testing (PT) evaluation reports and the laboratory's January 25, 2018 PT desk review survey Allegation of Compliance (AOC), the laboratory director failed to maintain compliance with successful PT and failed to follow the approved AOC for the WBC differential, resulting in the second unsuccessful PT occurrence for the WBC differential. The findings include: 1. Review of the CMS 155 report and the laboratory's 2017 events two and three, and 2018 event one PT evaluation reports revealed the WBC differential scores as follow: 2017 event two = 0%, 2017 event three = 0%, 2018 event one = 0%. 2. Review of the laboratory's AOC dated January 25, 2018, in reference to a previous failure to maintain compliance with successful PT, signed by the laboratory director on February 16, 2018, revealed the following statement: "What measure has been taken to correct deficiency-To be careful in reporting results on API to include values of mono, gran, & mid. All Lab personal informed & understand." Corrections to be monitored by laboratory director with each proficiency testing event.