Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1068770	08/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Soos Pediatrics Pc	102 Bowling Lane, Dublin, GA	

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
D0000	A proficiency testing desk review was completed on August 27, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 automated red blood cell count (RBC) and hematocrit (HCT) in 2017 event two, 2018 event one and 2018 event two, resulting in the second unsuccessful occurrence for RBC and HCT. (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 review of the laboratory's 2017 and 2018 proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance for three of four consecutive proficiency testing events for automated red blood cell count (RBC) and hematocrit (HCT) resulting in the second unsuccessful PT occurrence for RBC and HCT. The findings include: 1. Review of the 2017 event two evaluation report from the American Academy of Family Physicians (AAFP) revealed unacceptable scores for RBC and HCT on for sample numbers HD 7, 8 and 10 resulting in scores of 40% for both analytes. 3. Review of the 2018 event one evaluation report from the American Association of Bioanalysts (AAB) revealed unacceptable scores for RBC and HCT on sample numbers 1 ,2,3,4 & 5, resulting in scores of 0% for both analytes. 4. Review of the 2018 event two evaluation report revealed unacceptable scores for RBC on samples numbers 1,3,4 &5 resulting in a score of 20 % and unacceptable scores on HCT for sample numbers 1,2,3,4 & 5, resulting in a score of 0 % .
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 RBC and HCT proficiency testing (PT) for three of four consecutive events, resulting in the second unsuccessful PT occurrence for RBC and HCT. (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 laboratory's 2017 and 2018 proficiency testing (PT) evaluation reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance for three of four consecutive proficiency testing events for RBC and HCT, resulting in the second unsuccessful PT occurrence for RBC and HCT. The findings include: 1. Review of the 2017 event two evaluation report from the American Academy of Family Physicians (AAFP) revealed unacceptable scores

	for RBC and HCT on for sample numbers HD 7, 8 and 10 resulting in scores of 40% for both analytes. 3. Review of the 2018 event one evaluation report from the American Association of Bioanalysts (AAB) revealed unacceptable scores for RBC and HCT on sample numbers 1 ,2,3,4 & 5, resulting in scores of 0% for both analytes. 4. Review of the 2018 event two evaluation report revealed unacceptable scores for RBC on samples numbers 1,3,4 &5 resulting in a score of 20 % and unacceptable scores on HCT for sample numbers 1,2,3,4 & 5, resulting in a score of 0 % .