Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1055410	01/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Forsyth Pediatrics Oak Ridge	2205 Oak Ridge Road Suite Bb, Oak Ridge, NC	

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 review of 2017 and 2018 API (American Proficiency Institute) proficiency testing results 1/11/19 and the deficiency cited at D2131, the laboratory failed to successfully participate in proficiency testing for the specialty of hematology in two of three consecutive testing events.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two

	consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 API (American Proficiency Institute) proficiency testing records, review of 2017 and 2018 hematology records, interview with the TC (technical consultant) 1/11/19, and telephone interview with an API representative 2/5 /19, the laboratory failed to achieve satisfactory performance for the specialty of Hematology in two of three consecutive testing events, resulting in unsuccessful performance. Findings: 1. Review of 2017 and 2018 API proficiency testing records, review of 2017 and 2018 hematology records, and interview with the TC during the on-site survey 1/11/19 revealed: a. The laboratory received a score of 0% for failure to participate on the 2018 Hematology/Coagulation 1st event. b. The laboratory installed a Medonic M Series hematology analyzer 7/10/18. The TC stated during interview at approximately 11:00 a.m. that the laboratory's hematology proficiency module was not compatible with their Medonic M Series analyzer so they had to enroll in a different module. She stated they were instructed by API to report results for the 2018 Hematology/Coagulation 2nd event as "Discontinued" because there were no more samples available in the proficiency testing module they just enrolled in. c. Results for the 2018 Hematology/Coagulation 3rd event were printed during the survey by the TC. The report did not include any hematology results for the 3rd event. The TC stated during interview at approximately 11:15 a.m. that the testing personnel failed to submit hematology results for the 3rd event by the submission deadline, so they should have received a score of 0%. 2. During a telephone interview 2/5/19 at approximately 3:30 p.m., an API representative confirmed that the laboratory canceled their enrollment in the Hematology 3 proficiency module and enrolled in the Hematology 3S proficiency module on 7/11/18. The Hematology 3S module is compatible with testing on the Medonic M Series analyzer. The API representative verified that proficiency samples for the Hematology/Coagulation 3rd event were shipped to the laboratory, but no results were received by the submission deadline. She stated that the laboratory received a score of 0% for failure to participate, but the score did not appear on the report because the laboratory is now enrolled in a different module and their system only registers failures if the laboratory has a reporting history for the module.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 quality assessment records and interview with the TC (technical consultant) 1/11/19, the laboratory failed to retain all quality assessment records for at least two years. Review of 2017 and 2018 quality assessment records revealed there were no records available for quality assessment activities performed from January 2017 through July 2017. A "QUALITY ASSESSMENT INCIDENT MANAGEMENT FORM" completed by the TC 9/6/17 stated that the 2017 quality assessment monitor records were sent to the laboratory's sister facility for the

	laboratory director's review and signature, but were not returned. During interview at approximately 12:10 p.m., the TC confirmed that the records were missing. She stated the records were probably lost in inter-office mail.