Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0238676	01/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Pediatrics, Pa	1801 Doctors Drive, Sanford, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory proficiency testing (PT) enrollment records, and interview with office staff 01/11/18, the laboratory failed to enroll in a proficiency testing program for the 2018 calendar year. Review of PT enrollment records revealed no record of 2018 PT enrollment. Interview with office staff at approximately 11:00 a. m. confirmed the laboratory had not enrolled in a PT program for the 2018 calendar year. This deficiency was corrected on site at time of survey.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 College of American Pathologists (CAP)

	proficiency testing (PT) records 01/11/18, the laboratory failed to ensure that all attestation statements were signed as required by the personnel who performed the testing. Review of CAP Attestation Forms revealed the statement, ..."The laboratory director or designee and the testing personnel must sign on the result form." Review of 2016 CAP PT event FH1-C revealed the attestation statement was not signed by the testing personnel. Review of 2017 CAP PT event FH1-C revealed the attestation statement was not signed by the testing personnel.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 College of American Pathologists (CAP) proficiency testing (PT) records 01/11/18, the laboratory failed to verify the accuracy of the zero scores obtained in CAP PT events and failed to document corrective action for the zero scores obtained. Review of CAP "Original Evaluation", PT event FH1-A 2016, revealed the laboratory received a score of zero on 5 of 5 PT specimens for the regulated analyte "Cell ID/Flow Differential" due to lack of response. The CAP "Original Evaluation" signed by laboratory director states, "outstanding". There was no documentation that the laboratory's PT results obtained, but not submitted, were reviewed for accuracy. There was no documentation of corrective action. Review of CAP "Original Evaluation" PT event FH1-C 2017, revealed the laboratory received a score of zero on 5 of 5 PT specimens for the regulated analytes "Hematocrit" and "Hemoglobin" due to failure to provide a valid response code. The CAP "Original Evaluation" signed by laboratory director states, "called CAP forgot to put unit of measure for MCHC, HGB and HCT." There was no documentation that the laboratory's PT results were reviewed for accuracy. There was no documentation of corrective action.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 College of American Pathologists (CAP) proficiency testing (PT) records 01/11/18, the laboratory failed to evaluate unacceptable PT testing scores and failed to document any corrective action for the unacceptable PT testing scores. Findings: Review of CAP "Original Evaluation" PT event MC2-B 2016, revealed the laboratory received a score of unacceptable on 1 of 5 specimens, TC-06, for the regulated analyte "Throat Culture". The CAP "Original Evaluation" signed by the laboratory director states; "The error on one of the throat culture plates (read negative, but correct response was positive) not explainable since specimen discarded. Will watch for trends." There was no documentation of an evaluation of "trends". There was no documentation of corrective action. Review of

	CAP "Original Evaluation" PT event MC2-C 2016, revealed the laboratory received a score of unacceptable on 1 of 5 specimens, TC-11, for the regulated analyte "Throat Culture." The CAP "Original Evaluation" signed by the laboratory director states; "Reviewed, will continue to monitor". The was no documentation of how the unacceptable PT score was monitored. There was no documentation of corrective action.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment policy, review of 2016, 2017 and 2018 proficiency testing records 01/11/18, the laboratory failed to establish quality assessment policies and procedures to monitor, assess and correct problems associated with ongoing proficiency testing deficiencies within the general laboratory system. Review of laboratory quality assessment policy, entitled "Quality Assurance Program", revealed the statement, "The program will include the evaluation of patient preparation and specimen collection, preparation, preservation and transportation (pre-analytical), and test result interpretation and reporting (post-analytical)." The quality assessment policy fails to include an ongoing mechanism to monitor, assess and correct problems with proficiency testing deficiencies. Review of the 2016, 2017 and 2018 proficiency testing records revealed the following proficiency testing deficiencies within the laboratory system: 1. The failure to enroll in proficiency testing. See deficiency cited at D2000 and D6015. 2. The failure to evaluate unsuccessful or zero scores for proficiency testing. See deficiency cited at D5215 and D5221. 3. The failure to review proficiency testing results with testing personnel. See deficiency cited at D6018. 4. The failure of testing personnel to sign proficiency testing attestation forms. See deficiency cited at D2009. The laboratory quality assessment policy also states, "This policy shall be reviewed and re-evaluated yearly and changes made as deemed warranted by the Laboratory Director in consultation with other lab personnel." The policy was signed by previous laboratory director in July of 2015, there was no documentation of a yearly review by the laboratory director for 2016, 2017 or 2018.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of media package inserts, review of laboratory procedure manual and review of 2016 and 2017 laboratory refrigerator temperature logs 01/11/18, the laboratory failed to document corrective action for temperatures below the required acceptable limit for media storage. The laboratory uses Strep Select Agar (SSA) for

	throat culture testing and Trypticase Soy Agar with 5% Sheep Blood/Eosin Methylene Blue (TSA5 %SB/EMB) Agar for urine culture testing. Review of package inserts for SSA Agar and TSA 5% SB/EMB Agar revealed a required storage temperature of 2-8 degrees Celsius. Review of laboratory procedure entitled "Refrigerator and Incubator Temperature Log" revealed the statement "If a problem arises and the temperature is unsatisfactory, the staff should alert the Medical Director. The following steps should be taken: 1) assess the problem, 2) correct the problem, 3) replace reagent or culture plates after correction if needed, 4) corrective action to be noted in the temperature log, 5) Medical Director must be notified of corrective action, 6) monitor the problem. Review of laboratory refrigerator temperature logs for the refrigerator used to store the SSA and TSA 5% SB/EMB Agar, revealed a 10 day period in which 6 out of 10 days the temperature recorded was below the required storage temperature of 2-8 degrees Celsius. The dates and temperatures recorded are as follows: 6/27/16 - 0.8 C, 6 /29/16 - 0/0.3 C, 7/5/16 - 1.8 C, 7/6/16 - 1.5 C, 7/7/16 - 0.6 C, 7/8/16 - 0.9 C. There was no correction action noted on the laboratory refrigerator temperature log as required per laboratory procedure.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment policy, review of laboratory temperature and humidity records, review of laboratory quality control records and interview with testing personnel (TP) # 9, 01/11/18, the laboratory failed to establish a process for monitoring and assessing the analytic systems within the laboratory. The laboratory conducts moderate complexity testing for Complete Blood Cell count (CBC), Urine Cultures and Throat Cultures. Review of laboratory quality assessment policy, entitled "Quality Assurance Program", revealed the statement, "The program will include the evaluation of patient preparation and specimen collection, preparation, preservation and transportation (pre-analytical), and test result interpretation and reporting (post-analytical)." The quality assessment policy fails to include or establish an ongoing mechanism to monitor, assess and correct problems within the analytical system of the laboratory. For example: There is no periodic review of laboratory refrigerator temperatures. There is no periodic review of laboratory temperature and humidity records. There is no periodic review of laboratory incubator temperatures. There is no periodic review of hematology quality control records. There is no periodic review of Strep Select Agar quality control records. There is no periodic review of Trypticase Soy Agar with 5% Sheep Blood /Eosin Methylene Blue Agar quality control records. There is no periodic review of Strep A Bacitracin Disc quality control records. During interview at approximately 12: 30 pm, TP #9 confirmed there was no periodic review of laboratory quality control records or laboratory temperature and humidity records.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of 2018 proficiency testing enrollment records, review of 2017 proficiency testing records and laboratory personnel meeting minutes 1/11/18, the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for 2017 and 2018. Review of 2018 proficiency testing enrollment records revealed the laboratory was not enrolled in a proficiency testing program for the 2018 calendar year. See deficiency cited at D2000. Review of 2017 proficiency testing records and laboratory personnel meeting minutes revealed the laboratory had previously failed to enroll for 2017 proficiency testing. The failure to enroll was not corrected until June of 2017.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of 2016 and 2017 College of American Pathologists (CAP) proficiency testing (PT) records and interview with TP #9 01/11/18, the laboratory director failed to ensure that CAP proficiency testing results (CAP overall evaluations) were reviewed by testing personnel. Findings: Review of 2016 and 2017 CAP proficiency testing results (CAP overall evaluations) revealed the laboratory director had reviewed proficiency testing results. There was no documentation that the proficiency testing results were also reviewed by the testing personnel. During interview at approximately 12:30 PM, when surveyor asked if the laboratory director reviewed the laboratory's CAP proficiency testing results (CAP overall evaluations) with the testing personnel, TP#9 stated no, she does not discuss or review proficiency testing results with the testing personnel.
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 review of laboratory procedure manual, and review of 2016 and 2017 College of American Pathologists (CAP) proficiency testing (PT) records 01/11/18, the laboratory director failed to ensure that an approved corrective action plan was followed when any proficiency testing scores were found to be unacceptable, unsatisfactory or scored zero. Review of laboratory procedure manual revealed no corrective action plan had been established for unacceptable or unsatisfactory proficiency testing scores. Review of 2016 and 2017 CAP PT records revealed unacceptable or unsatisfactory proficiency testings scores for the CAP PT event MC2-B 2016 and CAP PT event MC2-C 2016. See deficiency cited at D5221. Review of 2016 and 2017 CAP PT records revealed proficiency testing scores of zero for the CAP PT event FH1-A 2016 and CAP PT event FH1-C 2017. See deficiency cited at D5215.
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 review of laboratory "Quality Assurance Program" policy, and review of laboratory quality assessment practices 01/11/18, the laboratory director failed to ensure that pre-analytic and analytic quality assessment programs were established and maintained to assure the quality of laboratory services provided. Review of laboratory's "Quality Assurance Program" policy revealed the the laboratory director had not completed yearly reviews of the policy. See deficiency cited at D5291. Review of laboratory's "Quality Assurance Program" policy revealed the laboratory policy established for pre-analytic quality assessment failed to address ongoing proficiency testing deficiencies. See deficiency cited at D5291. Review of laboratory's "Quality Assurance Program" policy and laboratory quality assessment practices revealed the policy did not include the establishment or monitoring of the laboratory's analytic system. See deficiency cited at D5791.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory personnel report (Form CMS-209), review of 2016 and 2017 competency records, and interview with testing personnel (TP) #9 01/11/18, the technical consultant (laboratory director) failed to evaluate and assure the competency for 4 of 8 testing personnel. Findings: Review of laboratory personnel report (Form

	CMS-209) submitted at time of survey revealed 9 personnel, including the laboratory director, were listed as testing personnel. Review of 2016 and 2017 competency records revealed no documentation of competency evaluations for TP#2, TP#3, TP#4 and TP#5. During interview at approximately 10:30 a.m. with TP#9 when asked by surveyor if TP#2, TP#3, TP#4 and TP#5 were performing laboratory testing, she stated, yes..., the doctors may occasionally run a CBC (complete blood count) or report a urine or strep culture.