Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0238676	07/30/2021
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of operator's manual for the Cell-Dyn Emerald hematology analyzer, review of calibration records, and interview with testing personnel (TP #6) 7/30/21, the laboratory failed to perform calibration of the Cell-Dyn Emerald hematology analyzer at least every 6 months from 7/20/19 until 7/22/21, a period of approximately 24 months in which calibrations were not performed. Findings: Review of operator's manual for the Cell-Dyn Emerald hematology analyzer revealed under Section 6, page

	6-3 "When to Calibrate...At least every 6 months." Review of calibration records for Cell-Dyn Emerald hematology analyzer revealed the laboratory performed a calibration on 7/20/19, the next calibration was performed on 7/22/21. A period of approximately 24 months in which calibrations were not performed. Interview with TP #6 at approximately 1:45 p.m. confirmed the laboratory failed to perform calibrations of the Cell-Dyn Emerald hematology analyzer as required. She stated the laboratory ended their service contract and failed to realize it included shipment of calibration reagents so they didn't realize it needed to be performed.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for Hardy Diagnostics Strep Select Agar (SSA), review of laboratory records, review of quality assurance (QA) records, review of monthly laboratory meeting notes and interview with TP #6 7/30/21, the laboratory failed to perform QC of the SSA media as required from 8/2/19 until 4/6/21, approximately 19 months. 488 patients were tested. Findings: Review of QC records for SSA media revealed on 8/2/19 the statement that the laboratory was unable to continue QC of the throat culture plates (SSA media) due to manufacturer back order of control organisms from their supplier HealthLink. There was no documentation QC was performed again until 4/6/21, approximately 19 months in which QC for the SSA media was not performed. Review of laboratory records revealed a statement entitled "Temporary suspension of IQCP". "August 02, 2019... Unable to continue ..QC..Plan at this time. Strep plate...controls are on manufacturer back order. Health Link products no longer available, awaiting alternate controls.... December 16, 2019...Strep...controls continues to be unavailable for order...March 20, 2020...continue to be unable to order Strep plate controls due to COVID-19 pandemic....March 22, 2021...Order Strep plate controls placed through McKesson... April 6, 2021...Received Strep A & B controls...from Microbiologics...". The records failed to show documentation from manufacturer's that controls were unavailable. The records also failed to document if alternative manufacturer's were contacted for availability of controls. Review of QA records from 8/2/19 through 4/6/21 for "Strep Select Agar Quality Control" revealed the laboratory directors' initials under the column indicated for review but no documentation of "Any issues or Corrective Actions" from 8/2/19 through 4/6/21 for the SSA QC reviewed by the laboratory director (LD). Review of "monthly laboratory meeting notes" revealed no documentation that the laboratory was unable to obtain QC organisms for SSA media to indicate if providers were notified of the lack of QC and how the laboratory should proceed with performing throat cultures due to lack of QC being performed. Interview with TP #6 at approximately 10:00 a.m. confirmed the laboratory did not perform QC for the SSA media from 8/2/19 until 4/6/21. She also confirmed 488 patients were

	tested during this time period. She stated they tried to sub-plate at one point but the organisms did not survive. She also confirmed she had no documentation that she contacted alternate manufacturer's to obtain QC organisms for the SSA media.
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 deficiency cited at D5439, review of laboratory "Quality Assurance" policy and review of laboratory QA records 7/30/21, the LD failed to ensure the QA program established was maintained to ensure calibrations were performed as required on the Cell-Dyn Emerald hematology analyzer. Findings: The laboratory failed to perform calibration of the Cell-Dyn Emerald hematology analyzer as required. See D5439. Review of laboratory "Quality Assurance" policy revealed "The following indicators will ensure quality....5. Routine maintenance and calibration of instrumentation as recommended by manufacturer.". Review of QA records revealed no documentation of QA practices to ensure calibrations of the Cell-Dyn Emerald hematology analyzer were performed as required.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, review of TP training records, review of laboratory QA policy and interview with TP #6 7/30/21, the LD failed to ensure training was documented for TP #4 and TP #5 for the performance of throat and urine culture testing and reporting. Findings: Review of laboratory personnel records revealed 2 new providers (TP #4 and TP #5) began performance of throat and urine culture testing since time of last survey 1/11/18. Review of TP training records revealed no documentation of training for the performance of throat and urine culture testing and reporting for TP #4 and TP #5. Review of laboratory QA policy revealed "2. On-going Laboratory Training:...New hires will be trained within 30 days of hire...". Interview with TP #6 at approximately 11:45 a.m. confirmed there was no

	documentation of training for TP #4 and TP #5. She stated the laboratory was not aware that new providers should have documented training for the performance of throat and urine culture testing and reporting.