Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2003992	06/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Seashore Pediatrics, Pc	3650 Express Drive, Shallotte, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of 2016, 2017 and 2018 calibration records 06/08/18 and review of Centers for Medicare & Medicaid Services (CMS) Statement of Deficiencies (SOD) and Plans of Correction (POC) dated 07/19/12 and 03/04/16, the laboratory has repeat deficiencies for failure to retain all required documentation for the performance of calibration on the Abbott Cell-Dyn Emerald hematology analyzer. Review of 2016, 2017 and 2018 calibration records revealed the laboratory failed to retain all required documentation for the performance of calibration on the Abbott Cell-Dyn Emerald hematology analyzer (see D3031). Review of CMS SOD and POC's dated 07/09/12 and 03/04/16 revealed the laboratory has repeat deficiencies for failure to retain all required documentation for the performance of calibration on the Abbott Cell-Dyn Emerald hematology analyzer.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including

	instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2016, 2017, and 2018 hematology calibration records 06/08/18, the laboratory failed to retain all required documentation of calibration. The laboratory performs Complete Blood Cell Counts on the Abbott Cell-Dyn Emerald hematology analyzer. Review of 2016, 2017 and 2018 calibration records for Abbott Cell-Dyn Emerald analyzer revealed the laboratory failed to retain all documentation for the performance of calibration. 1. For the calibration performed 3/28/16, the laboratory failed to retain documentation of the pre-calibration factors, post calibration factors, and post calibration quality control records. 2. For the calibration performed 12/20/17, the laboratory failed to retain package insert for the Cell-Dyn 18 Plus Calibrator, Lot #7352C, used in the calibration, and failed to retain documentation of the pre-calibration factors and the calibration verification documentation. This deficiency was previously cited 7/19/12 and 3/04/16.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2016, 2017 and 2018 College of American Pathologists (CAP) proficiency testing record and testing personnel (TP) interview 06/08/18, the laboratory failed to review and evaluate all unacceptable results obtained for proficiency testing. Review of CAP testing event, FH1-C 2016 Hematology Auto Differentials, revealed the laboratory scored 80% for Red Blood Cell Count, specimen FH1-13 was graded as "unacceptable". There was no evidence the unacceptable result was reviewed and evaluated. Interview with TP #2 at approximately 12:30 p.m. confirmed the laboratory did not review or evaluate the unacceptable result. TP #2 stated she thought since the overall score was 80% and passing, that unacceptable results did not need review.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's operating manual, review of 2016, 2017, and 2018 hematology analyzer "Event Logs", maintenance logs, and calibration records, and interview with testing personnel (TP) 06/08/18 and review of Centers for Medicare & Medicaid Services (CMS) Statement of Deficiencies (SOD) and Plan of Corrections

	(POC) dated 07/19/12, 02/18/14 and 03/04/16, the laboratory has repeat deficiencies for failure to document and/or perform required maintenance and has repeat deficiencies for failure to perform required calibration of the Abbott Cell-Dyn Emerald hematology analyzer. Review of manufacturer's operating manual, review of 2016, 2017, and 2018 hematology analyzer "Event Logs" and maintenance logs, and interview with TP #2 revealed the laboratory failed to document and/or perform required maintenance of the Abbott Cell-Dyn Emerald hematology analyzer (see D5429). Review of manufacturer's operating manual, review of 2016, 2017 and 2018 hematology analyzer calibration records, and interview with TP #2 revealed the laboratory failed to perform required calibration of the Abbott Cell-Dyn Emerald hematology analyzer (see D5437). Review of SOD and POC's dated 07/09/12, 02/18 /14, 03/04/16 revealed the laboratory has repeat deficiencies for failure to document and/or perform required maintenance of the Abbott Cell-Dyn Emerald hematology analyzer, and has repeat deficiencies for failure to perform required calibration of the Abbott Cell-Dyn Emerald hematology analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's operating manual, review of 2016, 2017 and 2018 hematology analyzer "Event Logs" and maintenance logs and interview with testing personnel (TP) 6/08/18, the laboratory failed to document and/or perform required maintenance of the Abbott Cell-Dyn Emerald hematology analyzer. Review of manufacturer's operating manual for the Abbott Cell-Dyn Emerald hematology analyzer revealed, "Section 9..Service and Maintenance...Preventive Maintenance Schedule....Monthly Maintenance...Bleach Cleaning....Cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected.....Semi-Annual Maintenance...Lubricating the Pistons...For optimal operation, the Syringe Pistons should be lubricated every six months as described below:". Review of 2016, 2017 and 2018 hematology analyzer "Event Logs", and maintenance logs revealed the following: 1. The laboratory failed to document the "Monthly Maintenance....Bleach Cleaning" as required. From 3/16 until time of survey on 6/08/18, the laboratory documented "Monthly Maintenance.....Bleach Cleaning" only four times: 3/16, 10/16, 2/17 and 4/17. 2. There was no documentation that the "Semi-Annual Maintenance...Lubricating the Pistons.." had been performed every 6 months as required from 2016 until time of survey 2018. 3. The maintenance log used by the laboratory includes columns titled: "Monthly -Bleach Cleaning" and "Semi-Annually - Lubricate the Pistons". Interview with TP #2 at approximately 12: 30 p.m. confirmed the laboratory failed to document or perform all required maintenance of the Abbott Cell-Dyn Emerald hematology analyzer. TP #2 stated she knew monthly bleaching was performed but she had forgot to print the "Event Logs" sometimes. She stated she did not realize that the analyzer required semi-annual maintenance of lubricating the pistons, and was unaware it was listed on the laboratory maintenance log. She also stated she had no idea how to perform that maintenance. This deficiency was previously cited 7/19/12, 2/18/14, and 3/04/16.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's operating manual, review of 2016, 2017 and 2018 hematology calibration records, and interview with testing personnel (TP) 06/08/18, the laboratory failed to calibrate the Abbott Cell-Dyn Emerald hematology analyzer every 6 months as required. Review of Abbott Cell-Dyn Emerald hematology analyzer operating manual revealed "Section 6...Calibration...Calibration verification criteria include:...When indicated by Quality Control data...After major maintenance and service procedures....At least every six months....". Review of 2016, 2017, and 2018 calibration records for the Abbott Cell-Dyn Emerald hematology analyzer revealed calibration was performed 03/28/2016 and 12/20/2017, a gap of 21 months in which calibration was not performed. Interview with TP #2 at approximately 12:30 p. m. confirmed the laboratory was aware the calibration had not been performed on the Abbott Cell-Dyn Emerald hematology analyzer every 6 months as required. This deficiency was previously cited 07/19/12, 02/18/14, and 03/04/16.
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: Based on review of 2016, 2017 and 2018 laboratory records and testing personnel (TP) interviews 06/08/18, the laboratory director failed to provide overall management and direction for the laboratory. 1. The laboratory director failed to ensure testing personnel met the minimum education requirements for performing moderate complexity testing (see D6063). 2. The laboratory director failed to to ensure the laboratory's quality assurance program was able to identify and correct problems as they occurred (see D6021). 3. The laboratory director failed to ensure acceptable levels of analytic performance were maintained for the Abbott Cell-Dyn Emerald hematology analyzer (see D6023). D6063 was previously cited 07/19/12 and 02/18/14. D6021 and D6023 were previously cited 07/19/12, 02/18/14, and 03/14/16.
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 2016, 2017 and 2018 hematology calibration records, hematology analyzer maintenance records, and laboratory quality assurance (QA) records 06/08 /18, the laboratory director failed to ensure the laboratory's QA program was effective at identifying and correcting problems, and preventing their recurrence. 1. The laboratory failed to retain all calibration records for the Abbott Cell-Dyn Emerald hematology analyzer (see D3031). 2. The laboratory failed to document and/or perform required maintenance of the Abbott Cell-Dyn Emerald hematology analyzer (see D5429). 3. The laboratory failed to calibrate the Abbott Cell-Dyn Emerald hematology analyzer every 6 months as required (see D5437). This deficiency was previously cited 07/19/12, 02/18/14, and 03/04/16.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of 2016, 2017 and 2018 hematology records 06/08/18, the laboratory director failed to ensure acceptable levels of analytic performance were maintained for the Abbott Cell-Dyn Emerald hematology analyzer. Review of Abbott Cell-Dyn Emerald hematology analyzer records revealed the laboratory director had not performed and documented a periodic review of calibration records and maintenance records between March 2016 and June 2018. This deficiency was previously cited 07 /19/12, 02/18/14, and 03/14/16.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on deficiency cited at D6065 and review of personnel records 06/08/18, the laboratory failed to verify that 2 of 5 testing personnel met the minimum education requirements for performing moderate complexity testing. This deficiency was previously cited 07/19/12, and 02/18/14.

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with TP #2 06/08/18, the laboratory failed to verify that 2 of 5 testing personnel met the minimum education requirements for performing moderate complexity testing. To be qualified to perform moderate complexity testing, personnel must have a minimum of a high school diploma or a high school graduation equivalency diploma (GED). Review of personnel records revealed no education credentials on file for TP #4. The records for TP #5 included a "North Carolina Nurse Aide I Registry" verification, but did not include documentation of education. Interview with TP #2 at approximately 12:30 p. m. confirmed the laboratory failed to verify the TP #4 and TP #5 met the minimum education requirement for performing moderate complexity testing. This deficiency was previously was previously cited 7/19/12 and 2/18/14.