Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1060433	10/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Brentwood Pediatrics Pllc	5111 Maryland Way Suite 301, Brentwood, TN	

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
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 the complete blood count (CBC) instrument quality control records and interview with Testing Person #3 determined that the laboratory failed to maintain the CBC instrument QC printouts when the results were not in range, for at least two years. The findings include: 1) Review of the CBC instrument quality control for Oct. 2017, Feb, 2018, June 2018, Aug. 2018, and Sept. 2018 did not reveal any quality control results that requested a repeat or were not in range. 2) Interview with Testing Person #3 on 10/4/18 at 10:00am confirmed that the laboratory staff were discarding all unacceptable quality control results for the CBC instrument.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the hematology complete blood count (CBC) proficiency testing (PT) records and interview with Testing person #3 determined the laboratory failed to retain all PT records for at least two years in 2017 and 2018. The findings include: 1. Review of the hematology CBC PT records for 2017 and 2018 revealed the laboratory

	failed to retain the attestation sheets for 2017 events two and three and 2018 event one and two. 2. Interview with Testing Person #3 on 10/4/18 at 10:30am confirmed that the laboratory failed to retain all CBC PT records for 2017 and 2018.
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 record review and interview it was determined that the laboratory did not laboratory failed to verify the performance specifications of reportable range and reference(normal) range on the CBC instrument (See D5421), failed to perform a successful calibration verification every six months when the lab's quality control did not meet the lab's criteria for acceptability (See D5439), failed to follow quality control instructions by not performing three levels of controls each day of testing (See D5441), laboratory used expired calibrators to perform calibration verification on their CBC instrument twice in 2018(See D5417), and the laboratory failed to document the refrigerator temperature on the temperature log in June 2018 (See D5413).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the refrigerator temperature log, chart review and interview with Testing Person #3, it was determined that the laboratory failed to document the refrigerator temperature on the temperature log in June 2018. The findings include: 1. A review of the refrigerator temperature log indicated blank boxes for the dates of 6.16.18 and 6.23.18. 2. Review of 5 patient charts indicated that Patient #5 had a CBC reported on 6.16.18 without refrigerator temperatures being documented. 3. An interview with Testing person #3 verified that CBC results are reported on Saturdays and temper are required to be documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the observation of CBC calibrators, review of calibration records and interview with Laboratory Director, determined the laboratory used expired calibrators to perform calibration verification on their CBC instrument twice in 2018. The findings include: 1. An observation of the CBC calibrators in the laboratory refrigerator on 10/4/18 at 9:00am verified a May 2018 expiration date. 2. Review of the calibration records for 2018(May 5, 2018 & Oct. 4, 2018) verified that both calibration verification reports had flagged some parameters as needing calibration. 3. An interview with the Laboratory Director on 10/4/18 at 2:00pm verified that both calibration verification records had flagged parameters.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification studies on the complete blood count (CBC) instrument and interview with Office Manager, determined the laboratory failed to verify the performance specifications of reportable range and reference (normal) range before using the instrument to report patient results. The findings include: 1. A review of the laboratory's verification study verified that the reportable range and reference(normal) range data was missing. 2. An interview with Office Manager on 10/4/18 at 2:30pm verified that the staff were unable to locate the documents that verified the CBC instrument reportable range and normal range.
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 calibration records for the complete blood count (CBC) instrument, review of manufacturer's Operator's Guide, review of quality control (QC) records, chart review, and interview with the Laboratory Director, determined the laboratory failed to perform a successful calibration verification every six months when the lab's quality control did not meet the lab's criteria for acceptability in 2017 and 2018. Findings included: 1. A review of calibration records for the CBC instrument indicated that the calibration performed on Jan. 10, 2017 indicated a status of "Needed" for RBC(red blood cell). There were no records to verify that calibration verification was performed in June 2017 or January 2018. The June 5, 2018 calibration record indicated a status of "Needed" for WBC(white blood cell), RBC & HGB(hemoglobin). 2. Manufacturer's Operator's Guide indicates, "If needed appears for any of the parameters, calibration adjustments are required. Print the new calibration factors and place them in your log book." The print-out of the new calibration factors were not available. 3. A review of quality control records for Oct. 2107, Feb. 2018, June 2018, Aug. 2018 and Sept. 2018 verified that on 6.6.18 the high control level was missing and on 6.16.18 all three levels of QC were out of range. 4. Review of 5 patient charts indicated that Patient #4 had a CBC reported with the high level QC missing. Patient #5 had a CBC reported on 6.16.18 with all three levels of control unacceptable. 5. Interview with the Laboratory Director on 10/4/18 at 1:00pm verified that the calibration verification on the CBC instrument had not been performed on June 2017 and Jan. 2018 and the other verification results indicated needed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the hematology instrument quality control data, chart review, and interview with Testing Person #3, it was determined that the laboratory failed to follow quality control instructions by not performing three levels of controls each day of testing for 2018. Findings include: 1. A review of quality control records for Oct. 2107, Feb. 2018, June 2018, Aug. 2018 and Sept. 2018 verified that on 6.6.18 the high

	control level was missing and on 6.16.18 all three levels of QC were out of range. 2. Review of 5 patient charts indicated that Patient #4 had a CBC reported with the high level QC missing. Patient #5 had a CBC reported on 6.16.18 with all three levels of control unacceptable. 2. An interview with the lead testing person at 12 PM on December 16, 2009 confirmed the laboratory was alternating two levels of controls each day of testing and not doing three levels each day.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of 5 final test reports, review CBC instrument print-out, and interview with Testing Person #3 , determined the final MCH(mean corpuscular hemoglobin) result was entered incorrectly into the chart of Patient #4. The findings include: 1. Review of the CBC result for Patient #4 revealed a MCH of 32.8/pg. 2. the instrument print-out for the MCH of Patient 4 revealed a MCH of 23.8/pg. 2. An interview with Testing Person #3 on 10/4/18 at 11:01am verified that the MCH did not match between the two reports
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 record review and interview it was determined that the laboratory director failed to ensure that laboratory personnel have appropriate education (See D6028), ensure all personnel had documented initial competency (See D6029), and ensure duties and responsibilities of each person is specified in writing (See D6032).
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in

	accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a lack of education records and interview with the Office Manager, determined the Laboratory Director failed to ensure that the proof of highest level of education was available for all testing personnel in 2018. The findings include: 1. Education records, verifying highest degree of education, were not able to be located for testing person #2 and #7. 2. An interview with the Office Manager on 10/4/18 at 2: 00pm confirmed there was no proof of highest level of education for testing person #2 or #7.
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 lack of initial training records, review of some initial training records for the laboratory testing personnel and interview with Office Manager determined the Laboratory Director failed to document initial training for 10 out of 11 testing personnel performing Hematology CBC testing in 2017 and 2018 when they were newly hired. The findings include: 1. Initial training records were not available for review for testing personnel # nine, ten and eleven that included documented review by the Technical Consultant for 2017 and 2018. 2. Review of the initial training records for testing personnel # 1, #2, #3, #4, #5, #6, and #7 dated 10.3.18 did not have the signature of the Technical Consultant to verify the testing person's training. 3. Interview with the Office Manager on October 4, 2018 at 2:30pm confirmed the initial training records dated 10.3.18 were not signed by the Technical Consultant.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on a review of job responsibilities and duties and interview with Testing Person #3, it was determined the Laboratory Director did not ensure that the duties and responsibilities of all staff were documented in 2017 and 2018. Findings include: 1. A review of the job responsibilities and duties verified that the duties for the technical consultant and clinical consultant were missing. 2. An interview with Testing Person #3 at 10:00am on 10/4/18 confirmed the duties for the technical consultant and clinical consultant were not available.
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 lack of competency records, review of some competency assessment records for the laboratory testing personnel and interview with Office Manager determined the Technical Consultant failed to document annual competency, which contained all six required components, for all three of the testing personnel performing Hematology CBC testing in 2017 and 2018 that were not newly hired. The findings include: 1. Competency records were not available for review for testing personnel # nine, ten and eleven that included the required six components (direct observation of patient testing, monitoring the recording and reporting of test results, review of intermediate results or worksheets, observation of performance of maintenance and function checks, assessment of test performance, and assessment of problem solving skills) with documented annual review by the Technical Consultant for 2017 and 2018. 2. Review of the competency records for testing person # 8 dated 1.27.17 and 10.3.18 did not include the required six components (direct observation of patient testing, monitoring the recording and reporting of test results, review of intermediate results or worksheets, observation of performance of maintenance and function checks, assessment of test performance, and assessment of problem solving skills) and the Technical Consultant did not verify the testing person's competency per her signature in 2017 or 2018. 3. Interview with the Office Manager on October 4, 2018 at 2:00pm confirmed the annual competencies could not be located on testing personnel #9, 10 & 11. She also confirmed that the annual competency for testing person #8 was not signed by the Technical Consultant and all of the annual competencies were lacking the required six components for 2017 and 2018.