Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0994693	07/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
White's Pediatrics Of Calhoun	105 Laurel Creek Road Suite 1, Calhoun, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 30, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 the American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory coordinator , the laboratory director failed to attest that PT samples were tested in the same manner as patient specimens by failing to sign attestation forms for Hematology/ coagulation events #2 and #3 of 2017. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed the laboratory director failed to sign the attestation documents for the 2017 testing events #2 and #3. 2. An interview with the laboratory coordinator on 7/30/18 at approximately 01:30 PM in the review room, confirmed the attestations were not signed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: A review of laboratory records and interview with the laboratory coordinator , it was determined that the laboratory failed to provide Competency Assessment for its testing personnel on Hematology testing. Findings include: 1. A review of testing personnel (TP) records revealed there was no annual competency evaluations for testing personnel (#3 - #6 CMS 209) for 2016, 2017 and 2018 on Hematology testing. 2. The laboratory also failed to have semi-annual competencies for testing personnel (#2 - #6 CMS 209). 3. An interview with the laboratory coordinator on July 17, 2018 at 01:36 PM in the review room confirmed that there was no current annual and semi-annual competencies performed for testing personnel.
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 document review and interview with the laboratory coordinator, the laboratory failed to perform corrective action on failed WBC Differential results (Hematology/ Coagulation) for American Proficiency Institute (API) proficiency test (PT) results as required by Clinical Laboratory Improvement Amendments. Findings include: 1. Review of API PT documents revealed the laboratory failed to perform corrective action for the following Hematology/Coagulation PT results: 2017 - 2nd Event (Score of 73 percent WBC Differential); 2018 - 1st event (Score of 93 percent WBC Differential). 2. An interview with the laboratory coordinator on 7/30/2018 in the review room at approximately 01:45 .m. confirmed no corrective action was performed for PT results less than 100 percent correct.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	Based on review of policy and procedure manual, laboratory coordinator's interview, the laboratory failed to include a policy for dealing with panic or alert values in the laboratory that is testing patient samples. Findings include: 1. Policy and procedure manual review revealed there was no policy for panic or alert values in the laboratory testing. 2. An interview with the laboratory coordinator in the review room on 07/30 /18 at approximately 01:50 pm. confirmed there was no policy in their policy and procedure manual for panic or alert values.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP) and interview the laboratory coordinator, the laboratory director (LD) failed to sign, date and approve the new procedure manual and also failed to sign, date and retire the old procedure manual. Findings include: 1. SOP document review revealed the LD failed to approve, sign, and date the current test procedures and did not retire the old procedures. 2. An interview with the laboratory coordinator in the review room on July 30, 2018 at approximately 01:53 p.m. confirmed the LD had not approved, signed, and dated the current SOP while retiring the old SOP.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory documents and interviews with the clinic's laboratory coordinator, the laboratory failed to employ an active and qualified person to fulfill the position of Technical Consultant (TC) from January 2017 to July 2018. Findings include; 1.) Personnel documents review revealed the laboratory's maintenance logs, temperature logs and Quality Control (QC) logs for Hematology were not reviewed by TC from January 2017 to July 2018. 2.) Technical Consultant's personnel file review revealed no proof of at least a year of laboratory supervisor experience or laboratory training during medical school residency rotation. 3.) An interview with the Clinic's laboratory coordinator in the review room on July 30, 2018 at approximately 01:55 PM confirmed that the laboratory did not have proof of a qualified and active Technical Consultant.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on the review of laboratory documents and interviews with the clinic's laboratory coordinator, the laboratory failed to employ an active and qualified person to fulfill the position of Technical Consultant (TC) from January 2017 to July 2018. Findings include; 1.) Personnel documents review revealed the laboratory's maintenance logs, temperature logs and Quality Control (QC) logs for Hematology were not reviewed by TC from January 2017 to July 2018. 2.) Technical Consultant's personnel file review revealed no proof of at least a year of laboratory supervisor experience or laboratory training during medical school residency rotation. 3.) An interview with the Clinic's laboratory coordinator in the review room on July 30, 2018 at approximately 01:55 PM confirmed that the laboratory did not have proof of a qualified and active Technical Consultant. Referrenced from Condition D 6033.
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 personnel competency assessment records and an interview with the laboratory coordinator, the laboratory's Technical Consultant(TC) failed to include

	the six required competency assessment criteria when evaluating annual competency on testing personnel in 2017 and 2018 for Hematology. The findings include: 1. Review of testing personnel (TP #s 3 - 6 on CMS 209) competency assessment records for 2017 and 2018 revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. An interview with the laboratory coordinator in the review room on July 30, 2018 at approximately 02:00 PM confirmed that annual competency assessment for testing personnel (TP# 3-6, CMS 209) did not contain the six required criteria by CLIA.