

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2181537	(X3) Date Survey Completed 01/12/2021
Name of Provider or Supplier White Coat Sciences, Llc	Street Address, City, State 315 Bankhead Highway, Carrollton, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on January 12, 2021. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interviews, the laboratory testing personnel (TP) and lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of American Academy Family Physicians (AAFP) proficiency test (PT) record(s) reveals the TP and LD failed to sign the attestation statement for 2020 Event C. 2. Interview with the Lab Director and the Technical Supervisor on 1/12/2021 at approximately 12: 20 PM in the back office area, confirmed the lack of a signed attestation form.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on observation during the laboratory tour and staff interview, the lab failed to have a shower or drenching hose available for staff to use in case of emergency. Findings include: 1. Observation during the lab tour at approximately 10:10 AM revealed the lack of a shower or drenching hose to use in case of emergency as required by Georgia State requirement found at 111-8-10.08(4)(d). 2. Interview with the Lab Director and the Technical Supervisor on 1/12/2021 at approximately 10:20 AM in the back office area, confirmed the lack of a shower or drench hose.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interviews, the laboratory failed to review and evaluate the results on PT after the results were returned to the lab. Findings include: 1. Review of PT result documents reveals the lack of documentation that the PT results were reviewed and evaluated. 2. Interview with the Technical Consultant and lab director in the back office area on 01/12/2021 at approximately 12:30 PM confirmed the aforementioned lack of documentation.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. Interview with the Technical Consultant in the back office area on 01/12/2021 at approximately 12:30 PM confirmed the SOP did not contain a duties and responsibilities policy and procedure.</p>