

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1054277	(X3) Date Survey Completed 04/02/2024
Name of Provider or Supplier American Health S, Llc	Street Address, City, State 7175 66th St N, Pinellas Park, FL	
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	<p>An announced CLIA recertification survey was conducted at American Health S, LLC on 3/27/24 to 4/02/24. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the Laboratory Personnel Report, laboratory procedure manual and staff interview, the Laboratory Director failed to specify, in writing, the responsibilities and duties for one of one Clinical Consultant and one of one Technical Consultant. Findings included: Review of the Laboratory Personnel Report (Form CMS-209), signed by the Laboratory Director on 3/19/2024, revealed there was one Clinical Consultant and one Technical Consultant for the laboratory. Review of the laboratory's procedure manual, signed by the Laboratory Director on 4/29/2021, showed there was no written job descriptions for the the Clinical Consultant and the Technical Consultant. On 3/27/2024 at 11:00 AM, the Technical Consultant confirmed the lack of written job descriptions for these consultants.</p>