

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2242637	(X3) Date Survey Completed 12/14/2023
Name of Provider or Supplier Access Health Group, Ltd	Street Address, City, State 1700 75th St, Downers Grove, IL	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to monitor and document the daily room temperatures for Rhesus factor (Rh factor) immunohematology testing for four of five dates, and the daily refrigerator temperatures for two of five dates in 2021, 2022, and 2023. Findings Include: 1. Review of the laboratory's "RH FACTOR Principle of Test" sheet revealed the following: "REAGENTS 1. Blood Grouping Reagent Anti-D. Do not use beyond expiration date. Store at 1 - 8 C when not in use." 2. Review of the laboratory's "Equipment Preventive Maintenance" manual revealed the following: "II. Refrigerators and Incubator 1. Will be monitored with thermometers. 2. Any fluctuation beyond posted temperature limits are noted and adjustments made." 3. Review of the daily refrigerator temperature log, and lack of documentation revealed the laboratory failed to record the daily refrigerator temperatures for the Rh factor test for two of five dates in 2021 and 2023. a) Date: 12/31/2021 Refrigerator Temperature: Not Indicated b) Date: 07/06/2023 Refrigerator Temperature: Not Indicated 4. Review of daily room temperature log and lack of documentation revealed the laboratory failed to record the daily room temperatures for the Rh factor test for four of five dates in 2021, 2022, and 2023. a) Date: 12/31/2021 Room Temperature: Not Indicated b) Date: 04/16/2022 Room Temperature:</p>

Not Indicated c) Date: 09/17/2022 Room Temperature: Not Indicated d) Date: 07/06/2023 Room Temperature: Not Indicated 5. On 12/14/2023 at 10:10 a.m., an interview with the LD confirmed the above findings.