

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2096022	(X3) Date Survey Completed 11/16/2021
Name of Provider or Supplier Liberty Doctors, Llc	Street Address, City, State 418 Folly Road, Suite B, Charleston, SC	
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: During an onsite recertification survey on 11/16/2021, based on the Tosoh G8 operator's manual review, laboratory humidity record review, and testing personnel interview, it was determined that the laboratory failed to maintain acceptable humidity readings for 22 out of 1,050 days from January 2019 through November 2021. Findings include: 1. Review of the Tosoh G8 operator's manual revealed that he instrument had a required room humidity of 40 to 80 percent. 2. Review of the laboratory's humidity readings revealed the following days that humidity was documented as less than 40% from January 2019 through November 2021. a. 2019:11/13/2019, 11/21/2019 b. 2020: 01/20/2021, 01/21/2021, 01/22/2021, 01/23/2021, 01/24/2021, 02/20/2021, 02/21/2021, 02/27/2021, 02/28/2021, 04/02/2021, 04/03/2021, 04/10/2021, 11/18/2021, 11/19/2021 c. 2021: 02/02/2021, 02/03/2021, 03/08/2021, 03/09/2021, 04/02/2021, 04/22/2021. 3. Testing personnel confirmed during an onsite interview on 11/16/2021 at 3:15pm that the laboratory failed to maintain acceptable humidity readings for 22 out of 1,050 days from January 2019 through November 2021.</p>