

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0883917	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Lifenet Health	Street Address, City, State 1864 Concert Drive, Virginia Beach, VA	
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 announced CLIA recertification survey was conducted at LifeNet Health on January 21-22, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The specific deficiency cited is as follows:
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 a tour, a review of manufacturer's user guides, package insert, daily temperature/environment logs, lack of documentation, and interviews, the laboratory failed to monitor the daily relative humidity percent (%) to ensure manufacturer's operating and storage requirements were followed for three (3) of 3 analyzers and McFarland (McF) standard control media utilized in the Serology Nucleic Acid Testing (NAT) and Microbiology test rooms for twenty-three (23) of 23 months reviewed. Findings include: 1. During a tour of the laboratory on 1/21/20 at approximately 1:30 PM, the inspector noted the following analyzers: Roche Cobas TaqScreen analyzer system (pipettor, ampliprep and taq-man components) in use for immunology testing in the Serology NAT lab room; BacTAlert and Vitek 2 systems in use for microbial detection and identification in the Microbiology room. The inspector noted Biomerieux DensiCheck Plus control media in use for measurement performance of McF standard readings in the Microbiology testing area. 2. Review of</p>

the 3 analyzers' user guides revealed the following operating requirements: Roche Cobas manufacturer's technical specifications stated "environmental conditions for running instrument is humidity levels less than 80%"; BacTAlert manufacturer's guide stated "humidity range is to be 10-90% requirement"; Vitek 2 guide stated "environmental requirement range is 20-80%". 3. Review of the McF standard control media package insert revealed Biomerieux manufacturer's instructions: "reagent storage in 20-80% humidity range conditions". 4. Review of the daily temperature /environmental logs from 02/01/18 to 01/22/20, revealed no record of humidity monitoring in the Serology NAT or Microbiology lab rooms. The inspector requested to review documentation of the monitoring. No records were available for review. The laboratory technical supervisor (TS) stated, on 1/22/20 at approximately 2:00 PM: "We have not monitored the humidity since the installation of the analyzers. Our facility's environmental group may have records of the humidity but we will need to reach out to them". 5. In an exit interview with the TS and quality managers, at approximately 3:30 PM on 1/22/20, the above findings were confirmed.