Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2097170	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Numale North Carolina, Sc	330 Billingsley Road, Suite 211, Charlotte, NC	

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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the TOSOH operator's manual, review of the laboratory's 2020, 2021, 2022, and 2023 humidity logs and interview with TP (testing personnel) #1 on 5/17/23, the laboratory failed to establish a humidity range that adhered to the operational humidity range required by the manufacturer. The TOSOH operator's manual requires operation of the instrument within an environment of 40-80% humidity. A review of the laboratory's 2020, 2021, 2022, and 2023 humidity logs revealed the laboratory's acceptable range was listed as 20-80%. During an interview at approximately 12:05 p.m., TP #1 confirmed that the laboratory utilized a humidity range of 20-80%.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the TOSOH operator's manual, review of the laboratory's 2020, 2021, 2022, and 2023 humidity logs, and interview with TP (testing personnel) #1 on 5/17/23, the laboratory failed to take and document corrective action for humidity readings outside the acceptable range specified by the TOSOH manufacturer for 66 of 105 days from 12/1/22 - 4/28/23. The TOSOH operator's manual requires operation of the instrument within an environment of 40-80% humidity. A review of the laboratory's humidity logs during the months December 2022, January 2023, February 2023, March 2023 and April 2023 revealed the humidity was below the acceptable range with no corrective action documented on the following dates: a. December 1, 2, 5, 6, 7, 13, 14, 15, 16, 19, 20, 21, 22, 23, 27, 28, 29, 30, 2022; b. January 10, 11, 12, 13, 16, 17, 18, 23, 24, 25, 26, 27, 30, 2023; c. February 6, 7, 8, 9, 14, 15, 16, 20, 2023; d. March 1, 10, 13, 14, 15, 16, 17, 20, 21, 22, 23, 29, 30, 31, 2023; e. April 3, 10, 11, 12, 13, 17, 18, 19, 20, 21, 24, 25, 26, 2023. During an interview at approximately 12:05 p.m., TP #1 stated that no corrective actions were performed when the laboratory's humidity fell below 40% because they were unaware of this requirement.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with staff 5/17/23, the laboratory director failed to perform TP (testing personnel) competency evaluations on-site in the laboratory utilizing direct observation. Findings: Review of personnel records revealed TP #1 had competency evaluations performed in November 2022 and May 2023, and TP #2 had a competency evaluation performed in November 2022. During interview at approximately 10:15 a.m., TP #1 stated that the laboratory director does not come to the laboratory. She stated he performed competency evaluations using FaceTime. During a telephone interview at approximately 10:30 a.m., the off-site consultant stated that the laboratory director is based in another state and she confirmed he does not routinely visit the laboratory.