Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0694079	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sas Health Care Center	700 Research Drive, Cary, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, interview and email (3/19/24) with technical consultant (TC#1) 3/12/24, the laboratory failed to ensure the storage temperature of 6 waived test kits were monitored, approximately 1,902 tests are performed on patients in a twelve month period. Findings: During facility tour at approximately 10:00 a.m. the surveyor observed the following 6 waived test kits in a storage room apart from the laboratory. a. Quidel Sofia RSV, FIA b. Quidel Sofia Influenza A & B c. Cepheid Genexpert - Covid/Flu/RSV d. Cepheid Genexpert - Covid e. Sekisui Osom Mono f. Sekisui Osom Ultra Strep A Review of manufacture's instructions for the 6 waived test kits revealed the following storage requirements. a. Quidel Sofia RSV, FIA - "...Kit Storage and Stability...Store the kit at room temperature, 59 to 86 degrees Fahrenheit (F) (15 to 30 degrees Celsius (C))...". b. Quidel Sofia Influenza A & B - "...Kit Storage and Stability...Store the kit at room temperature, 59 to 86 degrees F (15 to 30 degrees C)...". c. Cepheid Genexpert - Covid /Flu/RSV - "...Storage and Handling...Store the Xpert Xpress cartridges at 2-28 degrees C. ". d. Cepheid Genexpert - Covid - "...Storage and Handling...Store the Xpert Xpress cartridges at 2-28 degrees C. ". e. Sekisui Osom Mono - "...Kit Contents and Storage...Store Test Sticks and reagents tightly at 15-30 degrees C (59-86 degrees F)." f. Sekisui Osom Ultra Strep A - "...Kit Contents and Storage...Store Test Sticks and reagents tightly at 15-30 degrees C (59-86 degrees F).". Interview with TC #1 at 12:20 p.m. confirmed the facility failed to ensure the storage temperature of 6 waived test kits was monitored. She stated the storage room was monitored by the nursing staff and was unaware the storage room temperature was not monitored. Receipt and

	review of TC #1 email sent 3/19/24 revealed 1,902 tests were performed on patients in a twelve month period. a. Quidel Sofia RSV, FIA - 8. b. Quidel Sofia Influenza A & B - 142. c. Cephid Genexpert - Covid/Flu/RSV - 403. d. Cepheid Genexpert - Covid - 607. e. Sekisui Osom Mono - 33. f. Sekisui Osom Ultra Strep A - 709.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2022 and 2023 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with technical consultant (TC#1) 3/12/24, the laboratory failed to evaluate unacceptable PT results to ensure corrective action was taken and documented if required. Findings: Review of laboratory procedure, "Quality Assurance Plan", revealed "...Proficiency Testing...If any component of the testing is less than 100% successful, the lab manager will work to identify and correct the problem and provide educational feedback to the team.". Review of 2022 and 2023 MLE PT records revealed the following unacceptable results. a. 2022 MLE-M1 - unacceptable results samples K-2 and US-1. b. 2022 MLE-M2 - unacceptable results sample DIF-9, for Neutrophils, Lymphocytes and Monocytes. c. 2023 MLE-M1 - unacceptable results sample 3, for Monocyte % and Basophil %. All unacceptable results were highlighted with a marker but there was no documentation of an evaluation to determine if corrective action was required. Interview with TC#1 at approximately 2:30 p.m. confirmed the unacceptable results were not evaluated to determine if corrective action was required. She stated she was under the impression that no corrective action was necessary if the MLE summary report for each speciality was at least 80% correct.