Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2102329	02/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Accumed Center Sc	2010 S Arlington Heights Rd - Ste 209, Arlington Heights, 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
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 direct observations, record review, and interview, the laboratory failed to follow the manufacturer's instructions for the Emergency Use Authorization (EUA) to document the training of two of two laboratory personnel who performed the Sofia 2 SARS Antigen fluorescence Immunoassay (FIA) test and provide patients with required test information, affecting 24 patients' tests. Findings. 1. The Sofia 2 SARS Antigen FIA Information for Use (IFU), Sofia 2 SARS EUA, and patient reports from 04/30/2021 to 04/18/2022 were reviewed. 2. Direct observation on February 18, 2022 at 11:45 AM, two testing personnel (TP1 and TP2) were observed performing the SARS antigen FIA test using the Sofia 2 analyzer on two patients' samples. 3. Interview on February 18, 2022 at 12:05 PM, TP1 stated that they received training but it was not documented and that they were never instructed to issue the SARS Fact Sheets to patients who were tested.. 4. Review of the IFU and EUA revealed the following: *All operators using the product must be appropriately trained in performing and interpreting the results of your product. *Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. 5. The laboratory has tested and reported 24 patients during the time period reviewed. 6. On February 18, 2022 at 12:05 PM, Staff-A confirmed the above findings.