Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0667228	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Consolidated Nuclear Security, Llc	Jack Case Center 301 Bear Creek Road, Oak Ridge, TN	

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 onsite survey was conducted 05/10/2022. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The laboratory was found to be in COMPLIANCE with 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed and recertification is recommended.
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 a review of instrument operators manuals and interview of the laboratory director the laboratory failed to document the room humidity of the laboratory. Findings: 1. A review of the Alfa Wassermann ACE Alera Operator's Manual, Revision 12/04, page 31, 2.8 Specifications, revealed an operating humidity requirement of 20-80%. 2. A review of the TOSOH AIA-360 Operator's Manual, Revision 11, page 2-1, Table 2-1 Operating Environment Conditions, revealed an operating humidity requirement of 40-80%. 3. An interview of the laboratory director on 05/10/2022 at 2:30 PM confirmed that the laboratory was not documenting the humidity of the laboratory.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, laboratory verification studies for the Alfa Wassermann ACE Alera Chemistry analyzer, and confirmed in interview, the laboratory failed to ensure the reportable ranges (linearity) utilized by the laboratory corresponded to the verified reportable ranges for the analytes tested. Findings Included: 1. During a tour of the laboratory two (2) Alfa Wasserman ACE Alere chemistry analyzers (ACE Alera #1 Serial number 04110055 and ACE Alera #2 Serial number 10050874) were observed. The chemistry analyzers tested for the following analytes: Alkaline Phosphate (ALP) Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Cholesterol (Chol) Creatinine (Creat) Gamma-glutamyl transpeptidase (GGT) Glucose (Glu) High Density Lipoprotein (HDL) Total Bilirubin (TBil) Triglycerides (Trig) Uric Acid (UA) 2. Review of the laboratory policy titled, "ACE Alera Clinical Chemistry System" revealed the following "ACE Alera Linear Ranges" defined for the analytes tested on the ACE Alera chemistry analyzers: ALP; 2 - 1400 ALT; 5 - 480 AST; 7 - 450 BUN; 0 - 100 Chol; 4 - 600 Creat; 0.0 - 25.0 GGT; 5 - 950 Glu; 0 -750 HDL; 3 - 125 Trig; 8 -1000 UA; 1.3 - 16.0 3. The verification studies for the Alfa Wasserman ACE Alera chemistry analyzer #2 (Serial Number 10050874) conducted 10/20/2021 stated, "When a new laboratory analyzer is brought into the lab, several steps must be taken before the analyzer can be used for patient testing ...Linearity: For immunoassay and chemistry analyzers that give a quantitative value, linearity studies must be done for each assay to define the range of the method ...Linearity studies performed with commercially available linearity sets will verify the accuracy of the assay across the reportable range." Further review of the verification studies for the Alfa Wasserman ACE Alera chemistry analyzer #2 (Serial Number 10050874) conducted 10/20/2021 revealed the following verified linear ranges: ALP; 9 - 1205 The laboratory failed to verify the defined linear range of 2 -1400 for ALP. ALT; 14 - 989 The laboratory failed to verify the defined lower linear range value of 5 for ALT. AST; 11 - 787 The laboratory failed to verify the defined lower linear range value of 7 for AST. BUN; 3 - 136 The laboratory failed to verify the defined lower linear range value of 0 for BUN. Chol; 19 - 524 The laboratory failed to verify the defined linear range of 4 - 600 for Chol. Creat; 0.44 - 23.42 The laboratory failed to verify the defined linear range of 0.0 - 25.0 for Creat. GGT; 11 - 940 The laboratory failed to verify the defined linear range of 5 - 950 for GGT. Glu; 7 - 842 The laboratory failed to verify the defined lower linear range value of 0 for Glu. HDL; 10 -125 The laboratory failed to verify the defined lower linear range value of 3 for HDL. Trig; 24 - 898 The laboratory failed to verify the defined linear range of 8 -1000 for Trig. UA; 1.9 - 20.6 The laboratory failed to verify the defined lower linear range value of 1.3 for UA. 4. In an interview on 05/10/2022 at 3:30 pm, the Laboratory Director, after review of the documentation, confirmed the above findings.