Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2105193	04/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Chesapeake Toxicology Resources, Llc	8415 Progress Drive, Suite V, Frederick, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the toxicology and COVID-19 proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to ensure that the PT attestation statements were being printed, signed and dated by the laboratory director and testing person. Findings: 1. The PT records for toxicology (5 events) and COVID-19 (3 events) testing were reviewed. 2. The PT records did not include the attestation worksheet that is required to be printed and signed by the laboratory director or designee and testing person. 3. During the survey on 04/11/2022 at 4:30 PM, the TP confirmed that the attestation statements were not being printed, signed and dated as required.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in

	paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the quality assurance manager (QAM), the laboratory failed to provide clients with instructions for how to collect, store and transport specimens referred for COVID-19 reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The laboratory's procedure manual did not include approved instructions for clients referring specimens for COVID-19 RT-PCR testing including, from CFR 493.1242(a)(1) through (a)(7), patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, and specimen acceptability and rejection. 2. During the survey on 04/11/2022 at 4:30 PM, the QAM confirmed that the laboratory did not provide clients with instructions for how to collect, store and transport specimens referred for COVID-19 RT-PCR testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the quality assurance manager (QAM), the laboratory failed to record which reagent lot numbers were in use for each batch of patient specimens for COVID-19 reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The laboratory maintained a list of reagents and lot numbers used for the extraction and amplification of patient specimens for COVID-19 RT-PCR testing. The laboratory also created a worksheet for each batch of patient specimens to record each step performed in the testing procedure. 2. Neither the list of reagents nor the batch worksheets indicated which lot numbers of reagents were used for each batch of patient specimens tested. 3. During the survey on 04/11/2022 at 4:30 PM, the QAM confirmed that the laboratory did not have documentation of which reagent lot number was used for each batch of patient specimens for COVID-19 RT-PCR testing.