Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2105193	11/29/2023
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel report (CMS-209), review of competency assessment records, and interview with the laboratory director (LD), the laboratory failed to establish and follow written policies and procedures to assess competency of technical consultants (TCs), technical supervisors (TSs), and general supervisors (GSs). Findings: 1. Form CMS-209 listed three TCs, five TSs, and six GSs. 2. Competency records did not contain assessments for the TCs, TSs, and GSs in their roles and responsibilities as TCs, TSs, and GSs. 3. During the survey on 11/29/2023 at 2:55 PM, the LD confirmed that there were no policies/procedures to assess competency of the TC, TS, and GS roles and responsibilities.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by:

	Based on review of the written procedure and interview, the laboratory written procedures for specimen acceptability did not include specific instructions for identifying unacceptable specimens and the resolutions for such unacceptable specimens. Findings: 1. The written procedure, CTR-Accessioning, for specimen acceptability did not state that the patient specimen container must be labeled with at least the patient name or a unique patient identifier on the container and not just the lid of the container. 2. The written procedure, CTR-Accessioning, for specimen acceptability states that the information on the requisition must match the specimen container, but does not specifically state what must be on the label attached to the specimen container, in addition to the information on the specimen label matching the requisition. 3. The written procedure, CTR-Accessioning, for specimen acceptability did not specifically identify labeling errors that require rejection and those that may be resolved by contacting the user for clarification. 4. The written procedure, CTR-Accessioning, for specimen processing did not state that accessioning staff must affix the laboratory unique specimen identification (accessioning) number to the specimen container and not just the lid of the specimen container.