

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D2213880	<b>(X3) Date Survey Completed</b>  11/15/2022
<b>Name of Provider or Supplier</b>  Shield T3 Llc	<b>Street Address, City, State</b>  800 Florida Ave Ne, Ballard House, Washington, DC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessments and interview with the technical consultant, the laboratory did not have policies to assess general supervisor and technical supervisor competency. Findings: 1. The laboratory competency assessments for general supervisors and technical supervisor did not include assessment of additional supervisory duties assigned to the general supervisors; 2. The technical supervisor did not have competency assessments made by the laboratory director for performance of duties that were assigned; and 3. This was confirmed during interview with the technical supervisor on the afternoon of the survey.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of written procedures and interview, the laboratory written procedures included forms or logs (see appendix B of written procedures) that were</p>

	<p>not used by staff to record reagents in use, tracking of patient testing and maintenance of equipment. Findings: 1. The Master Mix and Positive Control log, Reagent Receipt log, Retest Tracking log and Water Bath Cleaning and Changes log were part of the laboratory's written procedure, but were no longer used by staff to document the tasks described in each of the logs; and 2. This was confirmed during interview with the technical supervisor on the afternoon of the survey.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the calibration verification report and interview with testing personnel (TP), The lab director (LD) failed to ensure that TP were performing test methods as required for accurate and reliable test procedures. Findings: 1. The laboratory performs Virology testing with a saliva sample to detect the presence of SARS-CoV-2. 2. The laboratory mobile trailer moved to a different area on the university campus on August 5, 2022. 3. Calibration verification procedures were performed on August 5, 2022, after the move. To ensure that test methods were functioning properly. 4. The Cal Vera reports were reviewed and signed by the lab director but was not signed and dated by the TP performing verification procedures. 5. The LD and TP confirmed at 2:00 PM on the day of the survey that the Cal Vera reports were not signed and dated by the TP performing the testing.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written quality assurance (QA) procedure and interview with the technical supervisor (TS) The lab director (LD) failed to ensure that QA procedures were performed for accurate and reliable patient testing. Findings: 1. The written QA procedure did not show how often the LD would meet with the TS, the documentation of lab huddles with staff performed by the TS, nor the inclusion of all lab staff in QA procedures. 2. The LD stated on the day of survey at 1:00 PM that he meets with the TS monthly to discuss lab concerns. The meeting minutes were not kept on file with the TS to ensure that all lab staff was informed of the minutes 3. The TS stated on the day of the survey at 1:30 PM that she has meetings with lab staff about lab errors and concerns. The TS stated that meeting minutes were not documented for review by the LD nor the lab staff. 4. The TP stated on the day of the survey at 1:30 PM that quality metric data is done monthly. This data is not included in the QA reporting by the TS for review with the LD and lab staff.</p>