

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0895220	(X3) Date Survey Completed 04/08/2025
Name of Provider or Supplier Texas Medical Specialty Inc	Street Address, City, State 7777 Forest Lane Suite C-768, Dallas, TX	
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	Validation Survey A validation survey was performed on 4/8/2025 with standard level deficiencies cited.
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's requisition form, laboratory's instructions, and interview with General Supervisor #1 and Laboratory Director, the laboratory failed to provide written instructions to the laboratory's clients concerning conditions for specimen transport (HLA Typing [Panel Review Antibody, sequence-specific oligonucleotide, Next-generation sequencing, Real time Polymerase Chain Reaction]) in 2025 as evidenced by: 1. In review of the laboratory's requisition form, HLA TMSI LABORATORY REQUEST-THFW, there were no conditions for specimen transport listed in their instructions. 2. In review of laboratory's "Step to Perform Before Sending Sample", there were no condition for specimen transport listed on their instructions. 3. In review of the laboratory's, "G-048: Shipment Of Specimens To Texas Medical Specialty." there were no conditions of transport listed in their instructions. 4. In an interview with the General Supervisor #1 at 0943 on 4/8/2025 stated that she could not find conditions for transport in any of the the documents provided to labs. In confirmation with laboratory director at 0945 confirmed that they didn't have the condition of transport on any of the documents.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p>

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure, interviews testing person (TP) #2 and TP #3 , and confirmed by General Supervisor #2, the laboratory failed to follow their established maintenance protocol for cleaning all their centrifuges in 2025 as evidenced by: 1. In a review of the laboratory's procedure "G-740: Centrifuge Cleaning Procedure" states, " All centrifuges must be cleaned daily and immediately after any spill. Use a damp sponge, warm water, and a mild liquid detergent suitable for washing dishes by hand. After cleaning, dry each part with a clean absorbent towel. Mark the log sheet with the date and your initials." 2. In an interview on how they clean all centrifuges at 1235, TP #2 and TP#3 stated they use isopropanol for cleaning their centrifuges, then they use bleach afterwards with a paper towel. 3. In an interview with GS #1 at 1240 she confirmed the findings and didn't know they were using isopropanol and bleach for cleaning centrifuges.