

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2114140	<b>(X3) Date Survey Completed</b>  04/20/2022
<b>Name of Provider or Supplier</b>  Allen Reproductive Center	<b>Street Address, City, State</b>  8080 State Hwy 121 Suite 240, Mckinney, TX	
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>D0000</b>	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. 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 facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D6127</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, submitted Centers for Medicare and Medicaid (CMS -209) form, personnel records, direct observation and staff interview, the technical supervisor failed to perform testing personnel competency assessments at least semiannually during the first year of patient testing for 1 of 4 testing persons who perform high complexity testing. Findings Included 1. Review of laboratory policy, "Personnel Competency assessment: Andrology Laboratory" revealed the following: "Policy: All new lab staff will undergo initial training and then be</p>

evaluated (utilizing a competency checklist) prior to working actively with patient samples. They will be evaluated semi-annually and then annually thereafter." 2. Review of Centers for Medicare and Medicaid (CMS -209) form submitted at time of survey (04/20/2022) revealed 4 testing persons (TP-1, TP-2, TP-3, TP-4) performing high complexity testing. TP-4's hire date was documented as 4/2021. 3. After review of personnel records, the laboratory was asked to provide documentation of semi-annual competency assessments for TP-4. No documentation was provided. 4. During a tour of the facility on 04/20/2022 at 10:00 a.m. TP-4 was observed performing patient semen processing and analysis. 5. During an interview on 04/20/2022 at 11:45 a.m. with the Technical Supervisor (TS-1), after review of documentation, TS-1 confirmed the above findings.