

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0250964	(X3) Date Survey Completed 10/09/2023
Name of Provider or Supplier Palmetto Adult And Children's Urology, Pa	Street Address, City, State 2890 Tricom Street, North Charleston, SC	
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	A Recertification Survey was initiated on 10/09/2023 and concluded on 10/09/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document review, policy review, and interview, the laboratory failed to review and sign graded proficiency testing (PT) results for 1 (2023 Microbiology - 2nd Event) of 5 PT events reviewed. Findings included: Review of the policy titled, "PCR [polymerase chain reaction] Proficiency testing and ordering," with a revision date of 09/06/2023, revealed "Completed Results 1. Check the report when returned and correct any errors. 2. Ensure signatures are on the form." Review of the "American Proficiency Institute Performance Summary" for the "2023 Microbiology - 2nd Event," revealed the report was not signed and dated by the Laboratory Director (LD) or designee to indicate the report was reviewed. During an interview on 10/09 /2023 at 10:30 AM, the Testing Personnel stated she forgot to mark the document for the LD's review and signature during the LD's recent onsite visit.</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p>

This STANDARD is not met as evidenced by:

Based on document reviews, policy review, and interview, the laboratory failed to ensure the semiannual and annual competency evaluation for 1 of 1 testing personnel (TP) reviewed indicated the results of the competency evaluation. Findings included: Review of the "Laboratory Personnel Report," signed by the Laboratory Director (LD) and dated 10/09/2023, indicated the LD held the position of director, clinical consultant, and technical supervisor. The Laboratory Personnel Report further indicated the laboratory had one employee that held the position of Testing Personnel. Review of the laboratory policy titled, "Technical Supervisor Responsibilities," with a revision date of 09/06/2023, revealed "(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually." A review of the "[laboratory name] PCR [polymerase chain reaction] Competency," for the TP's "6-Month [semiannually]" competency with an evaluation date of 02/28/2023, revealed the LD signed the semiannual competency on 03/01/2023; however, the competency did not specify whether the TP was competent to perform the required skills. A review of the "[laboratory name] PCR Competency," for the TP's "Annual" competency with an evaluation date of 09/16/2023, revealed the LD signed the annual competency on 10/08/2023; however, the competency did not specify whether the TP was competent to perform the required skills. During an interview on 10/09/2023 at 12:25 PM, the TP stated the LD assessed their competency by direct observation as they performed laboratory testing but did document the results of their performance on the form.