

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0665664	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Associated Medical Specialists, Pa DbA	Street Address, City, State 8121 Rourke Street, Myrtle Beach, 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 06/07/2023 and concluded on 06/07/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of the policy/procedure manual and interview, the laboratory failed to establish a written policy/procedure to specify how employee competency would be assessed. Findings included: A review of the laboratory policy/procedure manual, reviewed and approved by the Laboratory Director on 09/26/2022, revealed there was not a written policy/procedure to indicate how employee competency would be evaluated. In an interview on 06/07/2023 at 1:30 PM, the Technical Consultant /Testing Personnel #1 said the laboratory did not have a policy to indicate how employee competency would be evaluated.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p>

This STANDARD is not met as evidenced by:
Based on observation, laboratory policy review, and interview, the laboratory failed to evaluate the relationship between test results gathered from 2 of 2 hematology analyzers operated at the laboratory to ensure each analyzer produced consistent results. Findings included: A review of a laboratory policy titled, "Hematology Analyzer Procedure," reviewed and signed by the Laboratory Director (LD) on 09/26/2022, revealed there was not a written procedure for the required twice-yearly evaluation of test results between the two hematology analyzers. During a tour of the laboratory on 06/07/2023 at 12:15 PM, the surveyor observed two complete blood count (CBC) analyzers in use. In an interview on 06/07/2023 at 1:20 PM, the Technical Consultant/Testing Personnel #1 stated the two hematology (CBC) analyzers were not evaluated to ensure consistent results.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on document review, policy review, and interviews, the Laboratory Director failed to establish policies and procedures to indicate how testing personnel competency assessments would be monitored. Findings included: A review of laboratory policy/procedure manual, reviewed and approved by the Laboratory Director on 09/26/2022, revealed there was not a policy/procedure to indicate how the competency of testing personnel would be monitored. A review of the Technical Consultant/Testing Personnel #1's personnel file, revealed there was no competency assessment. In an interview on 06/07/2023 at 1:30 PM, the Technical Consultant /Testing Personnel #1 stated the laboratory did not have a policy that addressed the competency assessment of testing personnel. In a follow-up interview on 06/07/2023 at 2:30 PM, the Technical Consultant/Testing Personnel #1 stated they had not had a competency assessment since hire.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on interview and document reviews, the Technical Consultant failed to evaluate

the performance of testing personnel (TP) semiannually during their first year of employment for 5 of 18 TPs reviewed. Findings included: A review of the "Laboratory Personnel Report (CLIA) [Clinical Laboratory Improvement Amendments]," signed by the Laboratory Director and dated 06/07/2023, indicated the laboratory had a total of 18 testing personnel qualified to perform moderate complexity testing. A review of TP #5's "New Employee Criteria," revealed TP #5's hire date as 10/18/2021. Per the document, TP #5 had one competency evaluation during their first year of employment on 12/04/2021. A review of TP #6's "New Employee Criteria," revealed TP #6's hire date as 10/27/2021. Per the document, TP #6 had one competency evaluation during their first year of employment on 12/08/2021. A review of TP #7's "New Employee Criteria," revealed TP #7's hire date as 04/26/2021. Per the document, TP #7 had one competency evaluation during their first year of employment on 06/15/2021. A review of TP #8's "New Employee Criteria," revealed TP #8's hire date as 02/02/2022. Per the document, TP #8 had one competency evaluation during their first year of employment on 03/14/2022. A review of TP #13's "New Employee Criteria," revealed TP #13's hire date as 08/10/2021. Per the document, TP #13 had one competency evaluation during their first year of employment on 10/05/2021. In an interview on 06/07/2023 at 2:30 PM, the Technical Consultant/TP #1 stated there were multiple TPs who missed one or both of their semiannual competency assessments. Per the TC, staff were provided a training worksheet when first hired, but competency was not evaluated twice during their first year of employment.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on interview and document reviews, the Technical Consultant failed to annually evaluate the performance of 2 of 18 testing personnel (TP) qualified to perform moderate complexity testing. Findings included: A review of the "Laboratory Personnel Report (CLIA) [Clinical Laboratory Improvement Amendments]," signed by the Laboratory Director and dated 06/07/2023, indicated the laboratory had a total of 18 testing personnel qualified to perform moderate complexity testing. A review of TP #3's "Annual Employee Competency Assessment," revealed their last competency assessment was completed on 03/19/2021. A review of TP #4's "Annual Employee Competency Assessment," revealed their last competency assessment was completed on 04/01/2021. In an interview on 06/07/2023 at 2:30 PM, the Technical Consultant /TP #1 stated there were multiple TPs who missed their annual competency assessment.