

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0879460	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier West Alabama Women's Center	Street Address, City, State 535 Jack Warner Parkway, Suite 1, Tuscaloosa, AL	
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
D2155	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the American Proficiency Institute (API) Proficiency Testing (PT) records, corrective action documentation from the Laboratory Director, and an interview with the Clinic Administrator, the laboratory failed to participate in the 3rd Event 2019 Immunohematology survey. This was noted on one out of eight 2018 - 2020 Immunohematology Proficiency Testing Events. The findings include: 1. A review of API PT records revealed the postmark due date for the 3rd Event 2019 Immunohematology survey was Friday 12/13/2019; however, the results submitted by the laboratory were postmarked 12/14/2019. 2. A review of corrective action documentation from the Laboratory Director revealed "Director missed mailing deadline by one day resulting in API (American Proficiency Institute) returning the entire packet...." 3. During an interview on 03/16/2021 at 12:35 PM, the Clinic Administrator confirmed the above findings. .</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p>

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of CMS-209 Laboratory Personnel Report and an interview with the Clinic Administrator, the laboratory failed to have a technical consultant who met the qualification requirements. This was noted after the new Laboratory Director started the position on 03/03/2021. The findings include: 1. A review of CMS-209 Laboratory Personnel Report revealed that the laboratory failed to fill the technical consultant position. 2. During an interview on 03/16/2021 at 12:35 PM, the Clinic Administrator confirmed the current Laboratory Director does not have laboratory experience to qualify as the Technical Consultant and failed to fill the position with a qualified individual. .

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on a review of CMS-209 Laboratory Personnel Report and an interview with the Clinic Administrator, the laboratory failed to have a technical consultant who meets the qualification requirements. This was noted after the new Laboratory Director started the position on 03/03/2021. The findings include: Refer to D6033. .

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 a review of personnel evaluation records and an interview with the Clinic Administrator, the Technical Consultant failed to evaluate and document the performance of individuals at least semiannually during the first year of performing Rh Typing. This was noted on three out of three new employees since the previous survey. The findings include: 1. A review of personnel evaluation records revealed the semiannual performance was not evaluated or documented for Testing Personnel #1, #2, and #4. Testing Personnel #1's initial training was performed on 08/03/2018, Testing Personnel #2's initial training was performed on 09/16/2019, and Testing Personnel #4's initial training was performed on 10/23/2019. 2. During an interview on 03/16/2021 at 12:35 PM, the Clinic Administrator confirmed the semiannual evaluations were not performed on the above testing personnel. .

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 a review of personnel evaluation records and an interview with the Clinic Administrator, the Technical Consultant failed to evaluate and document the performance of individuals at least annually after the first year of performing Rh Typing. This was noted on four out of four employees since the previous survey. The findings include: 1. A review of personnel evaluation records revealed the annual performance was not evaluated or documented for Testing Personnel #1, #2, #3, and #4. Testing Personnel #1's initial training was performed on 08/03/2018, Testing Personnel #2's initial training was performed on 09/16/2019, Testing Personnel #3's annual training was performed on 12/29/2018, and Testing Personnel #4's initial training was performed on 10/23/2019. For Testing Personnel #1, #2, and #4 after initial training was performed no annual performance was evaluated and documented. For Testing Personnel #3 no annual performance was evaluated and documented for 2019 and 2020. 2. During an interview on 03/16/2021 at 12:35 PM, the Clinic Administrator confirmed the above findings.