

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304393	(X3) Date Survey Completed 12/13/2021
Name of Provider or Supplier Reproductive Health Services	Street Address, City, State 811 South Perry Street, Montgomery, 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
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 a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure reviews were documented on returned proficiency testing evaluations for seven of seven 2019-2021 PT surveys. The findings include: 1. A review of the returned API survey results (for D (Rho) Typing) revealed no documentation of review (as indicated by a signature and date) for the following seven surveys: 2019 Events #1, #2, and #3; 2020 Event #1, #2, #3, and 2021 Event #2. 2. During an interview with the Technical Consultant on 12/13/2021 at 10:00 AM, the above noted findings were reviewed and confirmed. .</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Rh typing procedures, a lack of "Instructions for Use" for the current Anti-D reagent, and an interview with the Technical Consultant, the laboratory failed to ensure the Anti-D typing procedures corresponded with the manufacturer's</p>

instructions. The findings include: 1. During the initial tour of the laboratory on 12/13 /2021 at approximately 8:50 AM, the surveyor requested the Rh typing procedure. The Technical Consultant provided the procedure "Rh Typing" with the Reference "Applied Group Serology, Second Edition..., 1975". The surveyor noted the age of the procedure (1975) and asked if instructions in the manufacturer's assay sheet for the current reagent (Ortho Diagnostics Anti-D) corresponded with the laboratory procedure. 2. A review of the assay sheet obtained from the box of Ortho Anti-D reagent only provided instructions on "How to Obtain the Instructions for Use". During the survey, the Technical Consultant was unable to obtain the manufacturer's instructions and was unable to determine if the laboratory Rh Typing was performed as per manufacturer's instructions. .

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Technical Consultant, the Laboratory Director failed to ensure results were submitted before the cutoff date, or ensure the PT provider was notified in writing of the problem. This affected one of three 2021 PT surveys. The findings include: 1. A review of the API PT records revealed no documentation for the 2021 Event #1 survey for D (Rho) Typing. A review of the CMS (Center for Medicare and Medicaid Services) CASPER Report 0096D revealed the laboratory received a 0% score for the first survey event in 2021. 2. During an interview on 12/13/2021 at 10:00 AM, the surveyor requested the 2021 Event #1 records. The Technical Consultant explained the laboratory had not performed this survey because the clinic was closed from 3/19/2021 thru 5/10/2021. No patients were being tested at the time the survey was due, however no one informed API. The surveyor explained the laboratory can receive a waiver, however notification concerning the problem must be submitted in writing, otherwise the PT provider assigns a score of 0%, due to "Failure to Participate". .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on observations during the initial laboratory tour, reviews of personnel files and laboratory procedures, and an interview with the Technical Consultant, the Technical Consultant failed to ensure two of three testing personnel had documentation of

training on Rh (Anti-D) typing before performing patient testing. The findings include: 1. During the initial tour of the laboratory on 12/13/2021 at 8:45 AM, the surveyor observed Testing Personnel (TP) #1 perform Rh typing on a patient specimen. As TP #1 rocked and warmed the slide on the Thermolyte Rh View Box, the surveyor asked how long the slide should be warmed before interpretation of the results; TP #1 stated she was not sure and did not know. The surveyor further noted TP #1 failed to perform an Rh patient control slide with the test slide. The surveyor then requested the procedure. 2. A review of the procedure "Rh Typing" with the Reference "Applied Group Serology, Second Edition..., 1975", revealed "...Label two slides and add reagents as follow: Slide labeled with patients name = Anti D Sera Slide labeled "C" Control = Rh-hr Control Sera Add two drops of anticoagulated blood to both slides ...mix...Place on lighted typing box, rock gently, and read results within two minutes. ..." 3. A review of personnel files revealed the following: A) TP #1 was hired 5/1/2020 and the file included training for waived tests, however there was no documentation for the moderate complexity (Rh typing) testing. B) TP #3 was hired in 2014, however she was not listed on the previous Form CMS-209 (Laboratory Personnel Report), and her file did not include documentation of training for moderate complexity (Rh typing) testing. 4. In an interview with the Technical Consultant on 12/13/2021 at 9:05 AM, the surveyor discussed and confirmed the lack of documentation of training for two testing personnel, and the surveyor's observation of the TP #1 failing to perform the Rh typing test correctly. .

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 reviews of personnel files and an interview with the Technical Consultant, the Technical Consultant failed to ensure annual competencies were performed and documented for three of three testing personnel, and included the six minimal regulatory requirements for assessment of competency on moderate-complexity testing. The findings include: 1. A review of personnel files revealed the following: A) Testing Personnel (TP) #1 was hired 5/1/2020. The file included no documentation of training for moderate-complexity (Rh typing) testing; of further note during the initial laboratory tour, the surveyor observed TP#1 did not perform the Rh test as per procedure. (Refer to D6045.) The file contained only one annual competency assessment performed by the new Technical Consultant on 10/4/2021, however only pre-analytical and waived procedures were assessed. The Technical Consultant failed to ensure an evaluation included the six minimal regulatory requirements for assessment of competency when testing personnel performed Rh typing. B) TP #2 was hired in 2017; the surveyor reviewed an annual competency assessment performed on 12/12/2019. There was no assessment of competency in 2020. The new Technical Consultant performed an annual evaluation on 10/4/2021, however only pre-analytical and waived procedures were assessed. C) TP #3 was hired in 2014 had no documentation of competency assessment in 2019 or 2020 (the review period for this survey). The new Technical Consultant performed an annual evaluation on 10/4/2021, however only pre-analytical and waived procedures were assessed. 2. In an interview with the Technical Consultant on 12/13/2021 at 9:05 AM, the surveyor discussed and confirmed the missed assessments in 2019 and 2020, and the Technical Consultant's

failure to ensure the 2021 evaluations included the six minimal regulatory requirements for assessment of competency when testing personnel performed Rh typing. SURVEYOR ID #32558 Licensure and Certification Surveyor