

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304393	(X3) Date Survey Completed 03/06/2019
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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS Laboratory Personnel Report for CLIA (Clinical Laboratory Improvement Amendments), a lack of documentation, and an interview with the laboratory owner/manager, the surveyor determined the laboratory director failed to ensure the position of technical consultant was filled, to ensure technical oversight in accordance with 493.1413 of the CLIA requirements. The former laboratory director, who previously qualified as the technical consultant, discontinued employment in August of 2018. Additionally, the laboratory (and Laboratory Director) failed to ensure the competency of two of five testing personnel was assessed at least annually, following the first year of employment. This affected Testing Personnel (TP) #5 and #4. The competency assessments are included in the responsibilities of a qualified technical consultant (493.1413). The findings include: 1. Refer to D6033, 493.1409, Laboratories Performing Moderate Complexity Testing; Technical Consultant.</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 the CMS Laboratory Personnel Report for CLIA (Clinical Laboratory Improvement Amendments), a review of the personnel records, a lack of documentation, and an interview with the laboratory owner/manager, the surveyor determined the laboratory failed to ensure the position of technical consultant was filled, to ensure technical oversight in accordance with 493.1413 of the CLIA requirements. The former laboratory director, who previously qualified as the technical consultant, discontinued employment in August of 2018. Additionally, the laboratory failed to ensure the competency of two of five testing personnel was assessed at least annually, following the first year of employment. This affected Testing Personnel (TP) #5 and #4. The competency assessments are included in the responsibilities of a qualified technical consultant (493.1413). The findings include: 1. On 3/06/2019, the laboratory manager provided the CLIA Laboratory Personnel Report (form #209) to the surveyor for review. The report failed to include a named technical consultant. 2. At 10:50 AM on 3/06/2019, the surveyor inquired of the manager who was the laboratory's technical consultant; and explained the requirements for CLIA positions of laboratories who perform moderate complexity testing. The surveyor also discussed the qualifications of one who might fill the position of a technical consultant. 3. During the survey, no qualified person was named to fulfil the CLIA position of technical consultant. 4. On 3/08/2019, the laboratory faxed transcripts and other personnel documentation for the laboratory director and a nurse for possible consideration of fulfilling the requirements of technical consultant. Based on the documentation provided, the surveyor determined these individuals do not meet the qualifications. 5. A review of the personnel records revealed TP #4 was initially trained in April of 2017. The testing personnel's competency in the laboratory was assessed in July, 2017 (semiannual assessment), but not since that date. 6. TP #5 was initially trained in August of 2017. A semiannual competency assessment was performed on 11/03/2017; but no annual competency assessment was done (2018). 7. In an interview on 3/06/19 at 10:50 AM, the laboratory manager stated TP #5 did not work in the laboratory in 2018; however was considered a back-up testing personnel, if needed. The laboratory manager stated all staff, listed on the form 209, had been trained in the laboratory to perform Rh testing. Additionally, the laboratory manager stated TP #5 could have performed Rh testing, if it became necessary. The laboratory manager confirmed TP #4's competency had not been assessed in 2018 (annually); although her OSHA training had been updated.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of the CMS Laboratory Personnel Report for CLIA (Clinical Laboratory Improvement Amendments), a lack of documentation, and an interview with the laboratory owner/manager, the surveyor determined the laboratory failed to ensure the position of technical consultant was filled, to ensure technical oversight in accordance with 493.1413 of the CLIA requirements. The former laboratory director, who previously qualified as the technical consultant, discontinued employment in August of 2018. Additionally, the laboratory failed to ensure the competency of two of five testing personnel was assessed at least annually, following the first year of employment. This affected Testing Personnel (TP) #5 and #4. The competency assessments are included in the responsibilities of a qualified technical consultant (493.1413). The findings include: 1. Refer to D6033, 493.1409, Laboratories Performing Moderate Complexity Testing; Technical Consultant.