

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 01D0304393	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/12/2015
NAME OF PROVIDER OR SUPPLIER REPRODUCTIVE HEALTH SERVICES			STREET ADDRESS, CITY, STATE, ZIP CODE 811 SOUTH PERRY STREET MONTGOMERY, AL 36104		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
D2010	<p>TESTING OF PROFICIENCY SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the facility owner (laboratory manager), it was determined the laboratory failed to ensure proficiency testing specimens were tested only the same number of times patient specimens are routinely tested. The findings include:</p> <ol style="list-style-type: none"> 1. A review of the proficiency testing records revealed the attestation statements for all three events in 2013 and 2014 were signed by multiple testing personnel (three to five testing personnel), indicating all specimens were tested by all personnel. 2. In an interview on 2/12/2015 at 10:00 AM, the (b)(6)(b)(7)(c) stated all testing personnel test all the proficiency testing samples, prior to submission of the results. The (b)(6)(b)(7)(c) (b)(6)(b)(7)(c) further stated patient samples are not routinely tested this number of times and by multiple testing personnel. <p>(b)(6)(b)(7)(c) Licensure and Certification Surveyor</p>	D2010		3/18/15	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

03/18/2015

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The (b)(6)(b)(7)(c) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the (b)(6)(b)(7)(c) it was determined the (b)(6)(b)(7)(c) failed to ensure one of three testing personnel presented with the appropriate educational credentials, prior to allowing the personnel to perform moderate complexity testing.</p> <p>The findings include:</p> <ol style="list-style-type: none"> During an interview on 2/14/17 at 9:05 AM, the (b)(6)(b)(7)(c) stated she had trained an employee, who had not yet provided evidence of education. Testing Personnel #3 (TP #3), who performs (b)(6)(b)(7)(c) at the laboratory. According to the (b)(6)(b)(7)(c), the testing privileges of TP #3 was recently suspended, due to the educational credentials not being provided. The (b)(6)(b)(7)(c) also stated she understands 	D6029		3/2/17	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

03/02/2017

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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D6029	Continued From page 1 the regulation that the educational credentials must be verified, prior to allowing an employee to test patient samples. 2. A review of TP #3's personnel file confirmed no educational credentials were filed for this personnel. TP #3's date of hire was listed as (b)(6)(b)(7)(c) with orientation dated (b)(6)(b)(7)(c) and initial laboratory training completed (b)(6)(b)(7)(c) (b)(6)(b)(7)(c) Licensure and Certification Supervisor	D6029			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

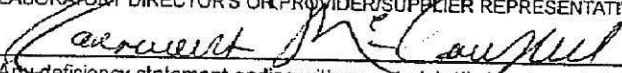
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D6029	<p>493.1407(e)(11) LABORATORY DIRECTOR RESPONSIBILITIES</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.</p> <p>(e) The laboratory director must—</p> <p>(e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the (b)(6)(b)(7)(c) it was determined the (b)(6)(b)(7)(c) failed to ensure one of three testing personnel presented with the appropriate educational credentials, prior to allowing the personnel to perform moderate complexity testing.</p> <p>The findings include:</p> <p>1. During an interview on 2/14/17 at 9:05 AM, the (b)(6)(b)(7)(c) stated she had trained an employee, who had not yet provided evidence of education. Testing Personnel #3 (TP #3), who performs (b)(6)(b)(7)(c) works (b)(6)(b)(7)(c) at the laboratory. According to the (b)(6)(b)(7)(c), the testing privileges of TP #3 was recently suspended, due to the educational credentials not being provided. The (b)(6)(b)(7)(c) also stated she understands</p>	D6029	<p>493.1407(e)(11) This was immediately corrected and Testing Personnel #3 has not performed any further testing. Testing Personnel will not be performing any further testing at all. Testing Personnel #3 failed to provide the necessary education documentation.</p> <p>No Testing Personnel will be trained without the necessary education documentation required by CLIA in place and reviewed by the Director and no testing will be done prior to said documentation.</p> <p>An additional check of this credentialing will be added to the initial training and annual certification evaluation of lab personnel.</p>	3/2/17
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE Assistant Director	(X9) DATE 3/2/17
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D6029	<p>Continued From page 1</p> <p>the regulation that the educational credentials must be verified, prior to allowing an employee to test patient samples.</p> <p>2. A review of TP #3's personnel file confirmed no educational credentials were filed for this personnel. TP #3's date of hire was listed as 7/15/15 with orientation dated 7/15/15 and initial laboratory training completed 10/25/15 (b)(6)(b)(7)(c)</p> <p>(b)(6)(b)(7)(c) Licensure and Certification Super (b)(6)(b)(7)(c)</p>	D6029		