

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

PRINTED: 07/13/2015  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>22D0945040</b>		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>02/11/2008</b>	
NAME OF PROVIDER OR SUPPLIER  <b>FOUR WOMEN HEALTH SERVICES LLC</b>				STREET ADDRESS, CITY, STATE, ZIP CODE <b>150 EMORY STREET ATTLEBORO, MA 02703</b>			
(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>493.801(b)(2) TESTING OF PROFICIENCY SAMPLES</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 proficiency testing records for calender years 2006 and 2007 (4 testing events) and confirmed through interview with the laboratory director on 2/11/08, the laboratory did not test proficiency testing samples the same number of times that it routinely tested patient samples. One testing person performs Rh on a particular patient in the laboratory, however, all six testing personnel interpret all 5 proficiency testing samples and report a consensus. Interview with the laboratory director and documented logs for the 4 events confirmed the findings. (Refer to D6016)</p>			D2010			3/20/08
D5435 510M	<p>493.1254(b)(2) MAINTENANCE AND FUNCTION CHECKS</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p>			D5435			4/1/08

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

TITLE

(X6) DATE

03/20/2008

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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D5435	Continued From page 1	D5435			
D6016	<p>This STANDARD is not met as evidenced by: Based on observation of the centrifuge and confirmed through interview with the laboratory director on 2/11/08, the laboratory did not define a function check protocol that ensured that the centrifuge revolutions per minute (RPM) were acceptable in order to assure the appropriate centrifugation of specimens prior to them being sent to the reference laboratory. As a result, the laboratory did not periodically perform and document the RPM's of the centrifuge.</p> <p>493.1407(e)(4)(i) DIRECTOR RESPONSIBILITIES</p> <p>The laboratory director must ensure that proficiency testing samples are tested as required under Subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing records for calender years 2006 and 2007 (4 testing events) and confirmed through interview with the laboratory director on 2/11/08, the laboratory director did not ensure that proficiency testing samples were tested as required under Subpart H of this part (proficiency testing samples are tested in the same manner as patient specimens). One testing person performs Rh on a particular patient in the laboratory, however, all six testing personnel interpret all 5 proficiency testing samples and report a consensus. Interview with the laboratory director and documented logs for the 4 events confirmed the findings. (Refer to D2010)</p>	D6016		4/1/08	
D6054	493.1413(b)(9) TECHNICAL CONSULTANT RESPONSIBILITIES	D6054		4/1/08	

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D6054	<p>Continued From page 2</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on personnel record reviews and confirmed through interview with the laboratory director/technical consultant on 2/11/08, the technical consultant did not evaluate and document the performance of 6 individuals responsible for moderate complexity testing at least annually. Findings revealed that from 2/11/06 through 2/11/08, the technical consultant did not perform any evaluations on laboratory personnel.</p>	D6054			