STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22D0945040	A. BUILDING _____ B. WING _____	01/29/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN HEALTH SERVICES LLC	150 EMORY STREET ATTLEBORO, MA 02703

(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
D 000	INITIAL COMMENTS A CLIA recertification survey was conducted for Four Women Health Services , LLC pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.	D 000		
D5411 510M	493.1252(a) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant on 1/29/14, the laboratory failed to follow the manufacturer's instructions for Rh blood testing. Findings revealed: On 1/29/14, the surveyor reviewed the manufacturer's package insert instructions for the use of anti Rh reagent. The manufacturer instructed the user to add one drop of anti Rh reagent to a glass slide and then add two drops of whole blood. The surveyor also reviewed the laboratory procedure for using anti Rh reagent. The procedure instructed the user to add two drops of whole blood to the glass slide and then add one drop of reagent. This protocol is contrary to the manufacturer's instructions and creates the potential for contaminating the reagent with a patient specimen.	D5411		1/31/14

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 02/19/2014

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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5411	Continued From page 1 The technical consultant confirmed that laboratory testing personnel followed the instructions outlined in the laboratory procedure and not the manufacturer's instructions. The laboratory performs 2200 Rh tests annually.	D5411		