

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2016	<p>493.803(a)(b)(c) SUCCESSFUL PARTICIPATION</p> <p>Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.</p> <p>Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.</p> <p>If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:</p> <p>(1) There is immediate jeopardy to patient health and safety.</p> <p>(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.</p> <p>(3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing review for calendar years 2014 and 2015 (three testing events), the laboratory failed to successfully participate (achieve a score of 100 percent or more) in a</p>	D2016			

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

TITLE

(X6) DATE

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.

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2016	Continued From page 1 proficiency testing program for the D(RhO) typing analyte as evidenced by the following: First Unsuccessful Occurrence: D(RhO) typing analyte: The laboratory achieved a score for D(RhO) typing of zero (0) percent for the second testing event of 2014 (failure to participate - refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in unsuccessful performance for the analyte and the specialty area of immunohematology. Second Unsuccessful Occurrence: D(RhO) typing analyte: The laboratory achieved a score of 60 percent for the third testing event of 2014 and a score of 80 percent for the first testing event of 2015 resulting in the second unsuccessful performance for the analyte and the specialty area of immunohematology. (Refer to D2162 and D2163). Based on this evidence the laboratory failed to undertake the appropriate training and/or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the D(RhO) typing analyte.	D2016			
D2153	483.857(a) ABO GROUP AND D(RHO) TYPING Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review of calendar years 2014	D2153			

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2153	Continued From page 2 and 2015 proficiency testing results (three testing events), the laboratory failed to attain a score of at least 100 percent for each analyte leading to unsatisfactory performance and two unsuccessful performances for the same analyte (refer to D2016). The laboratory received a testing score for the D(RhO) typing analyte of sixty (60) percent for the third testing event of 2014 resulting in unsatisfactory performance for the testing event. The laboratory subsequently received a testing score for the D(RhO) typing analyte of eighty (80) percent for the first testing event of 2015 resulting in unsatisfactory performance for the testing event	D2153			
D2154	493.859(b) ABO GROUP AND D(RHO) TYPING Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review of calendar year 2014 proficiency testing results (three testing events), the laboratory failed to attain an overall testing event score of at least 100 percent for specialty area of immunohematology leading to unsatisfactory performance resulting in a second unsuccessful performance for the specialty area of Immunohematology. The laboratory received a testing score for immunohematology of sixty (60) percent for the third testing event of 2014 resulting in unsatisfactory performance for the testing event.	D2154			

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2154	Continued From page 3 The laboratory achieved a testing score for immunohematology of eighty (80) percent for the first testing event of 2015 resulting in unsatisfactory performance for the testing event.	D2154			
D2155	493.859(c) ABO GROUP AND D(RHO) TYPING Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on proficiency testing review for calendar years 2014 and 2015 (three testing events), the laboratory failed to participate in one testing event resulting in unsatisfactory performance and a score of zero (0) percent for the testing events as evidenced by the following: The laboratory failed to participate in the second testing event of 2014 resulting in scores of zero (0) percent for the testing event for the Rh D typing analyte and the specialty area of immunohematology.	D2155			
D2160	493.859(e) ABO GROUP AND D(RHO) TYPING	D2160			

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2160	Continued From page 4 For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on calendar years 2014 and 2015 proficiency testing review (three testing events), the laboratory failed to undertake remedial action in response to unsatisfactory proficiency testing events as evidenced by the following: The laboratory achieved a score for D(RhO) typing of zero (0) percent for the second testing event of 2014 (failure to participate - refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in the first unsuccessful performance for the analyte and the specialty area of immunohematology. The laboratory achieved a score for D(RhO) typing of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second occurrence of unsuccessful performance for the analyte and the specialty area of immunohematology (refer to D2016).	D2160			
D2162	493.859(f) ABO GROUP AND D(RHO) TYPING Failure to achieve satisfactory performance for	D2162			

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2162	Continued From page 5 the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of calendar years 2014 and 2015 proficiency testing results (three testing events), the laboratory failed to attain a testing event score of at least 100 percent for all immunohematology analytes leading to unsuccessful performance. The laboratory received an overall testing score for the D(RhO) typing analyte of zero (0) percent for the second testing event of 2014 (failure to participate- refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in the first unsuccessful performance for the analyte and the specialty of Immunohematology. The laboratory subsequently obtained a testing event score for the D(RhO) typing analyte of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second unsuccessful performance for the analyte and the specialty of Immunohematology.	D2162			
D2163	493.859(g) ABO GROUP AND D(RHO) TYPING Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of calendar years 2014 and 2015 proficiency testing results (three testing	D2163			

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
D2163	Continued From page 6 events), the laboratory failed to attain a testing event score of at least 100 percent for the specialty of immunohematology leading to unsuccessful performance. The laboratory received an overall testing event score for immunohematology of zero (0) percent for the second testing event of 2014 (failure to participate- refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in the first unsuccessful performance for the specialty of immunohematology.	D2163			
D6076	The laboratory subsequently obtained a testing event score for immunohematology of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second unsuccessful performance for the specialty of immunohematology. 493.1441 LABORATORY DIRECTOR The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency testing results resulting in the second unsuccessful performance for the D(RhO) typing analyte and the specialty of immunohematology (refer to D2016).	D6076			
{D9999}	CLOSING COMMENTS	{D9999}			

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: 22D0945040	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 05/21/2015
NAME OF PROVIDER OR SUPPLIER FOUR WOMEN HEALTH SERVICES LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 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	
{D9999}	<p>Continued From page 7</p> <p>§493.857 Condition: Immunohematology. The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification. This CONDITION is not met as evidenced by: Based on review of proficiency testing records for calendar years 2014 and 2015, the laboratory achieved a score for D(RhO) typing of zero (0) percent for the second testing event of 2014 (failure to participate- refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in unsuccessful performance for the analyte and the specialty of immunohematology.</p> <p>The laboratory subsequently obtained a testing event score for immunohematology of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second unsuccessful performance for the specialty of immunohematology.</p>	{D9999}			