PLAN OF CORRECTION

The individual signing the first page of the CMS-2567, *Statement of Deficiencies (SOD),* is indicating their approval of the plan of correction being submitted on this form.

Name - Provider/Supplier:	
Milwaukee Womens Medical Services	
Street Address/City/Zip Code:	
1428 N Farwell Ave, Milwaukee, WI 53202-2904	
License/Certification/ID Number (X1):	**52D0888142**
Survey Date (X3):	**11/27/2020**
Survey Event ID Number:	**G1J112**

ID Prefix Tag (X4)	Provider's Plan of Correction (Each corrective action must be cross-referenced to the appropriate deficiency.)	Completion Date (X5)
D5217 493.1236(c)(1)	Microscopy was only performed by the laboratory director, and only when indicated according to the director's clinical judgment. The director also judges that microscopy was not performed and was not felt to be indicated for greater than one year prior to the review, and that patients were not harmed by the discontinuation of this test, or by the lag time between when microscopy was stopped and when it was removed from the procedures manual. The laboratory director also commits to ensuring that verification of accuracy of microscopy is performed at least twice annually if microscopy should be resumed.	
D5401 **493.1251(a)**	The laboratory director observed testing personnel performing the testing using the Quotient Anti-D reagent. It was judged that the protocol described in the reagent package insert and the procedure manual was being followed. The tests were performed using known controls (Rh+ and Rh negative staff members), and the results were found to be congruent. Testing personnel ran positive and negative controls using the Quotient Anti-D reagent daily from the time of initiation of use of the reagent. It is the laboratory director's judgment that there was no detectable impact on patient testing as a result of this deficiency. The Technical Consultant will be responsible for maintaining the laboratory manual, including ensuring that it contains current descriptions of the Quotient procedure and other testing protocols.	
D5409 493.1251(e)	The laboratory director evaluated the impact on patient testing that could have been caused by the inclusion of discontinued procedures (microscopy) in the manual. The director concluded that since no one besides the director herself was performing such procedures, no harm came to patient testing from the inclusion of this procedure in the manual. Going forward, the Technical Consultant will maintain the procedure manual, including ensuring that discontinued procedures are documented as such, including the date of discontinuation.	
D6013 493.1407(e)(3)(ii)D6013	Multiple testing personnel performed testing using the Quotient Anti-D reagent using known controls, and found that the results matched. This was performed initially at the time that use of the Quotient Anti-D reagent was begun, and has	

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493.1407(e)(3)(ii)	continued to be performed regularly. No discrepancies have been observed. Consequently, the laboratory director finds no discernible impact on patient testing from not verifying the manufacturer's performance specifications, since verification occurred beginning the day the protocol was initiated.	