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):	10/05/2020
	Survey Event ID Number:	G1J111

ID Prefix Tag (X4)	Provider's Plan of Correction (Each corrective action must be cross-referenced to the appropriate deficiency.)	Completion Date (X5)
D5217	Microscope wet preparations and use of microscope has been discontinued as of 10/06/2020 due to lack of patient testing.	10/05/2020
D5401	 Procedure manual has been updated to include proper laboratory procedure/technique for performing all currently used laboratory tests including Rh testing slide method with light box. Updates include written procedures for using Quotient Anti-D blend reagent and Rh testing slide method. 	10/15/2020
	 All laboratory personnel reviewed manufacturer's insert for Quotient Anti-D blend reagent, and written procedure for Rh testing slide technique using the Quotient Anti-D blend reagent. 	10/23/2020
	 On-site training for laboratory personnel was performed by mixing staffs' blood samples (positive/negative) and Quotient Anti-D blend reagent (incubated 5 minutes before use) while reading results with light box and were directly observed by the Laboratory Director for accuracy and competency. 	10/27/2020
· ·	 New audit to monitor laboratory personnel's accuracy for patient results and proper use for Quotient Anti-D reagent. 	
D5401	 Manufacturer's instructions for the Quotient Anti-D blend reagent have been placed into the procedure manual. All laboratory personnel reviewed manufacturer's insert for Quotient 	10/06/2020
85400	Anti-D blend reagent.	
D5409	 Discontinued Rh view box method for Rh testing as of 10/27/2020. Discontinuation notice in manual as required. Light box is being utilized to help read results for mixing Quotient Anti-D blend reagent with blood sample. 	10/27/2020
	 Discontinued Eldon Cards in 2019 and resumed Rh view box slide method. Discontinuation notice for Eldon cards and written 	10/15/2020
	 procedure for Rh view box in manual as required. Discontinuation notice for Ortho Anti-D reagent will be placed into manual. 	10/15/2020
D6013	 Specific performance characteristics of the Quotient Anti-D reagent: the reagent was tested using FDA-recommended methods against a 	10/06/2020

DEPARTMENT OF HEALTH SERVICES STATE OF WISCONSIN Division of Quality Assurance F-00344 (07/17)

PLAN OF CORRECTION

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Name - Provi	ider/Supplier.	
Milwaukee V	Vomens Medical Services	
Street Addres	ss/City/Zip Code:	
1428 N Farw	ell Ave, Milwaukee, WI 53202-2904	
	License/Certification/ID Number (X1):	52D0888142
	Survey Date (X3):	10/05/2020
	Survey Event ID Number:	G1J111
	comparator reagent (data on file with Alba Bioscience Limited). Positive percent agreement and negative percent agreement were both 100. One-sided 95% exact lower confidence limit was 99.15 for positive percent agreement and 94.79% for negative percent agreement. • Test characteristics are judged appropriate for patient testing.	
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