

October 21, 2016
SUPPLEMENT APPROVAL

Bio-Rad Medical Diagnostics GmbH
 Attention: Dr. Rolf Vornhagen
 Industriestrasse 1
 D-63303 Dreieich
 Germany

Dear Dr. Vornhagen:

We have approved your request to supplement your biologics license applications to include a new indication for your Blood Grouping Reagents (BGRs) listed below as reactive components of a buffered (b) (4) gel suspension filled into the IH-Cards. The BGRs will be used for the detection and identification of blood grouping antigens based on the principles of hemagglutination and gel filtration. The IH-Cards are intended to be used on the IH-1000 Automated Analyzer System for ABO/Rh D grouping and Rh/Kell Phenotyping.

STN	Name of Biological Products	Proprietary Names
*125094/113	Blood Grouping Reagent, Anti-A (Murine Monoclonal)(Formulated for Automated Testing)	IH-Card ABO/D(DVI-)+Rev A1,B IH-Card ABO/D(DVI+)+Rev A1,B IH-Card ABO/RhD(DVI+) IH-Card Group ABO IH-Card ABD(DVI-)-Conf IH-Card ABD(DVI+)-Conf
125096/58	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal)(Formulated for Automated Testing)	IH-Card ABO/RhD(DVI+) IH-Card Group AB
125097/67	Blood Grouping Reagent, Anti-D (Monoclonal)(IgM)(Formulated for Automated Testing)	Anti-D-: IH-Card ABO/D(DVI-)+Rev A1,B IH-Card ABD(DVI-)-Conf IH-Card Anti-D (DVI-) IH-Card RhD(DVI-)+Phenotype Anti-D+: IH-Card ABO/D(DVI+)+Rev A1,B IH-Card ABO/RhD(DVI+) IH-Card ABD(DVI+)-Conf IH-Card Anti-D(DVI+)

STN	Name of Biological Products	Proprietary Names
125202/50	Blood Grouping Reagent, Anti-E (Monoclonal)(Formulated for Automated Testing)	IH-Card Rh-Phenotype+K IH-Card Anti-E IH-Card Anti C-E-K IH-Card RhD(DVI-)+Phenotype
125203/48	Blood Grouping Reagent, Anti-e (Monoclonal)(Formulated for Automated Testing)	IH-Card Rh-Phenotype+K IH-Card Anti-e IH-Card RhD(DVI-)+Phenotype
125204/46	Blood Grouping Reagent, Anti-K (Monoclonal)(Formulated for Automated Testing)	IH-Card Rh-Phenotype+K IH-Card Anti C-E-K IH-Card Anti-K
125205/46	Blood Grouping Reagent, Anti-c (Monoclonal)(Formulated for Automated Testing)	IH-Card Rh-Phenotype+K IH-Card Anti-c IH-Card RhD(DVI-)+Phenotype
125206/48	Blood Grouping Reagent, Anti-C (Monoclonal)(Formulated for Automated Testing)	IH-Card Rh-Phenotype+K IH-Card Anti-C IH-Card Anti C-E-K IH-Card RhD(DVI-)+Phenotype

Please submit all final printed labeling at the time of use and include implementation information on Form FDA 356h and Form FDA 2567 as appropriate. Please provide a PDF electronic copy as well as three original paper copies for circulars and other labels.

Two draft copies of the proposed introductory promotional labeling may be voluntarily submitted for advisory comment with a Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Orieji Illoh, MD
Acting Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research