

**October 21, 2016**  
**SUPPLEMENT APPROVAL**

Our STN: BL 125208/70  
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 application for Reagent Red Blood Cells For Use in Automated Systems to include its use in IH-Red Blood Cell Card products for the detection and identification of ABO serum grouping, and detection and identification of unexpected antibodies, based on the principles of hemagglutination and gel filtration. The IH-Cell products listed below are intended to be used on the IH-1000 Automated Analyzer System.

<b>PROPRIETARAY NAME</b>	<b>INTENDED USE</b>
IH-Cell A1 & B	For detection of antibodies to ABO blood group antigens in human blood
IH-Cell A2	For detection of antibodies to ABO blood group antigens in human blood
IH-Cell I-II	For detection of antibodies to human red blood cell antigens in patient and donor samples
IH-Cell I-II-III	For detection of antibodies to human red blood cell antigens in patient and donor samples
IH-Cell Pool	For detection of antibodies to human red blood cell antigens in donor samples
IH-Panel 11	For identification of antibodies to human red blood cell antigens in patient and donor samples
IH-Panel 11 Papain	For identification of antibodies to human red blood cell antigens in patient and donor samples
IH-Panel Plus 6	For identification of antibodies to human red blood cell antigens in patient and donor samples

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