



**October 21, 2016  
SUPPLEMENT APPROVAL**

Our STN: BL 125098/88  
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 Anti-Human Globulin (Formulated for Automated Testing) to include its use in the IH-AHG Card Anti-IgG for the detection and identification of clinically relevant antibodies, cross matching and Direct Antiglobulin Tests (DAT), based on the principles of hemagglutination and gel filtration at your location in Dreieich, Germany. The IH-AHG Card Anti-IgG product is intended to be used on the IH-1000 Automated Analyzer System.

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