

SUPPLEMENT APPROVAL
July 20, 2021

Bio-Rad Medical Diagnostics GmbH
Attention: Marc Gorzellik, PhD
Industriestrasse 1
Dreieich 63303
Germany

Dear Dr. Gorzellik:

We have approved your request dated January 18, 2021, received January 19, 2021, to supplement your Biologics License Applications (BLA) submitted under section 351(a) of the Public Health Service Act to update the package inserts for the following products:

STN	Name of Biological Products
BL 125094/160*	Blood Grouping Reagent, Anti-A (Murine Monoclonal) (Formulated for Automated Testing)
BL 125096/101	Blood Grouping Reagent, Anti-A, B (Murine Monoclonal) (Formulated for Automated Testing)
BL 125097/111	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM) (Formulated for Automated Testing)
BL 125098/133	Anti-Human Globulin (Formulated for Automated Testing)
BL 125202/90	Blood Grouping Reagent, Anti-E, (Monoclonal) (Formulated for Automated Testing)
BL 125203/87	Blood Grouping Reagent, Anti-e (Monoclonal) (Formulated for Automated Testing)
BL 125204/86	Blood Grouping Reagent, Anti-K (Monoclonal) (Formulated for Automated Testing)
BL 125205/85	Blood Grouping Reagent, Anti-c (Monoclonal) (Formulated for Automated Testing)
BL 125206/88	Blood Grouping Reagent, Anti-C (Monoclonal) (Formulated for Automated Testing)
BL 125207/124	Reagent Red Blood Cells
BL 125208/114	Reagent Red Blood Cells for Use in Automated Systems
BL 125212/73	Blood Grouping Reagent, Anti-Fy ^a (Monoclonal)
BL 125213/57	Blood Grouping Reagent, Anti-P1 (Murine Monoclonal)
BL 125214/59	Blood Grouping Reagent, Anti-s (Monoclonal)
BL 125216/59	Blood Grouping Reagent, Anti-S (Monoclonal)

STN	Name of Biological Products
BL 125217/61	Blood Grouping Reagent, Anti-Jk ^b (Monoclonal)
BL 125219/85	Blood Grouping Reagent, Anti-A (Murine Monoclonal)
BL 125220/61	Blood Grouping Reagent, Anti-B (Murine Monoclonal)
BL 125221/57	Blood Grouping Reagent, Anti-A, B (Murine Monoclonal)
BL 125222/54	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125223/61	Blood Grouping Reagent, Anti-D (Monoclonal Blend)
BL 125224/62	Blood Grouping Reagent, Anti-M (Murine Monoclonal)
BL 125225/61	Blood Grouping Reagent, Anti-N (Murine Monoclonal)
BL 125226/55	Blood Grouping Reagent, Anti-C (Monoclonal)
BL 125227/55	Blood Grouping Reagent, Anti-c (Monoclonal)
BL 125228/55	Blood Grouping Reagent, Anti-E (Monoclonal)
BL 125229/58	Blood Grouping Reagent, Anti-e (Monoclonal)
BL 125230/61	Blood Grouping Reagent, Anti-K (Monoclonal)
BL 125231/56	Blood Grouping Reagent, Anti-Jk ^a (Monoclonal)
BL 125233/62	Blood Grouping Reagent, Anti-Le ^a (Murine Monoclonal)
BL 125529/20	Anti-Human Globulin (Rabbit/Murine Monoclonal) (Formulated for Automated Testing)
BL 125532/24	Blood Grouping Reagent, Anti-B (Murine Monoclonal) (IgG) (Formulated for Automated Testing)
BL 125533/19	Blood Grouping Reagent, Anti-D (Monoclonal Blend) (Formulated for Automated Testing)

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

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