Our STN: BL 125445/47

SUPPLEMENT APPROVAL
September 29, 2021

Diagnostic Grifols, S.A.
Attention: Mr. Joaquín Alberto Tamparillas
Avda. De la Generalitat, 152
Sant Cugat del Valles
08174 Barcelona
Spain

Dear Mr. Alberto Tamparillas:

We have approved your request submitted April 19, 2021, received April 21, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Anti-Human Globulin to add a new limitation in the Instructions for Use to address the sensitivity of the standard technique in the screening and identification of unexpected antibodies on the DG Gel 8 Anti-IgG (Rabbit) card.

LABELING

We hereby approve the draft package insert labeling dated April 19, 2021. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at http://www.fda.gov/udi.

Please submit all final printed labeling as PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address **(*See Note)**:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112

NOTE: In response to the COVID-19 public health emergency, CBER's Document Control Center (DCC) does not have staff on site to accept packages. Device submissions for CBER regulated devices may still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions found at https://www.fda.gov/media/83522/download. CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG account can be found at https://www.fda.gov/industry/electronic-submissions-gateway.

Submissions may also be submitted electronically via email (under 150MB) at CBERDCC_eMailSub@fda.hhs.gov. For larger files, you may submit multiple emails with the subject line of each noting 'New [Submission Type] / Supplement to STN ### - Email 1 of # (total number)'; New [Submission Type] / Supplement to STN ### - Email 2 of # (total number)'; etc. We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID - 19 CBER Regulated Biologics page found at https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics.

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

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