Date: February 2, 2018
BLA APPROVAL

Diagast
Attention: Ms. Marcia Palma
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Dear Ms. Palma:

Please refer to your Biologics License Applications (BLAs) dated August 17, 2016, received August 19, 2016, submitted under section 351(a) of the Public Health Service Act (PHS Act) for the following biological products:

STN	Name of Biological Products
125618/0	Blood Grouping Reagent, Anti-s (Human/Murine Monoclonal) (IgG)
125627/0	Blood Grouping Reagent, Anti-P1 (Murine Monoclonal)
125628/0	Blood Grouping Reagent, Anti-Fy^a (Human/Murine Monoclonal)(IgG)

LICENSING

We have approved your BLAs for the Blood Grouping Reagents listed above effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, the biological products listed above under your existing Department of Health and Human Services U.S. License No. 1744. The Blood Grouping Reagents listed above are indicated to determine the presence of blood group antigens s, P1, and Fy^a on the surface of human red blood cells by manual method.

These products will be supplied to (b) (4) under a contract manufacturing arrangement for distribution in the USA by Grifols Diagnostic Solutions Inc., Emeryville, CA 94608, USA.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture the products listed above at your facility located at Loos, Cedex, France. You may label your products as Blood Grouping Reagent Anti-s, Anti-P1, and Anti- Fy^a and market them as approved in your license applications.

ADVISORY COMMITTEE

We did not refer your applications to the ADVISORY COMMITTEE because our review of information submitted in your BLAs, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for the products listed above shall be 24 months from the date of manufacture when stored at 2 °C to 8 °C. The date of manufacture (DOM) from (b) (4) is the date of (b) (4) . The DOM of the BGR produced from 2 °C to 8 °C (b) (4) is the date of (b) (4) .

Following the final sterile filtration, no reprocessing/reworking is allowed without prior approval from the Agency.

FDA LOT RELEASE

Please submit protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, 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

MANUFACTURING CHANGES

You must submit information to your BLAs for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of the Blood Grouping Reagents listed above, or in the manufacturing facility.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 12, dated January 9, 2018, and the draft carton and container labeling submitted under amendment 12, dated January 9, 2018. 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, http://www.fda.gov/udi.

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:

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

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the Medical Device Reporting (MDR) requirements for medical devices (21 CFR 803) as required by 21 CFR 600.80(k)(2). Since your products are characterized as a devices as well as a biologics, submit these reports to the MedWatch System using MedWatch Reporting Form 3500A or an electronic equivalent. Please refer to the February 2014 document *Questions and Answers about eMDR – Electronic Medical Device Reporting – Guidance for Industry, User Facilities and FDA Staff* at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/UCM2019327.htm.

Required reports are to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Sincerely,

Jay S. Epstein, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research