



Our STN: BL 103898/5089

SUPPLEMENT APPROVAL

December 3, 2019

Medion Grifols Diagnostics AG
Attention: Mr. Joaquin Alberto Tamparillas
Avda. de la Generalitat, 152
Sant Cugat del Valles
Barcelona 08174
Spain

Dear Mr. Alberto Tamparillas:

We have approved your request submitted and received on September 30, 2019 to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Reagent Red Blood Cells. This approval is to add the following Reagent Red Blood Cell Kits: Data-Cyte® Plus 2 and Data-Cyte® Extend Reagent. These products will be manufactured at your facility at Dudinggen, Switzerland.

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