



Our STN: BL 103461/5128

**SUPPLEMENT APPROVAL**

October 10, 2025

Micro Typing Systems, Inc.  
Attention: Darlene J. Phillips  
100 Indigo Creek Drive  
Rochester, NY 14626

Dear Darlene Phillips:

We have approved your request received June 12, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Anti-Human Globulin to manufacture a new ID MTS™ Gel Card configuration of Anti-Human Globulin Anti-IgG (Rabbit)/Anti-C3b, -C3d (Murine Monoclonal)/DAT Control, MTS™ DAT Card containing microtubes with in vitro substances currently used in manual tube immunohematology testing to distinguish between IgG and/or C3 coating on red blood cells at the Pompano Beach, Florida facility.

### **Labeling**

We hereby approve the draft package insert submitted under amendment # 5005, dated September 4, 2025. 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:

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 BLA file.

Sincerely,

Wendy Paul, MD  
Acting Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research