

**SUPPLEMENT APPROVAL
March 10, 2021**

Micro Typing Systems, Inc.
Attention: Ms. Leah Van De Water
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

Dear Ms. Van De Water:

We have approved your request submitted December 18, 2020, received December 22, 2020, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to update the Instructions for Use (IFU) to include the addition of the new ORTHO Optix™ Reader and performance data for MTS Gel Cards.

STN	Name of Biological Products
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BL 103461/5114*	Anti-Human Globulin
BL 103756/5095	Blood Grouping Reagent Combination Kit
BL 103787/5087	Blood Grouping Reagent Anti-A (Murine Monoclonal)
BL 103789/5087	Blood Grouping Reagent, Anti-B (Murine Monoclonal)
BL 103790/5088	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal)
BL 103791/5088	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125001/84	Blood Grouping Reagent, Anti-C (Monoclonal)
BL 125002/82	Blood Grouping Reagent, Anti-E (Monoclonal)
BL 125004/87	Blood Grouping Reagent, Anti-e (Monoclonal)
BL 125017/85	Blood Grouping Reagent, Ant-c (Monoclonal)

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