



Our STN: BL 125308/56

SUPPLEMENT APPROVAL

May 11, 2020

Alba Bioscience Limited
Attention: Mr. Jeremy Stackawitz
Quotient Biodiagnostics Inc.
301 South State Street, Suite S-204
Newtown, PA 18940

Dear Mr. Stackawitz:

We have approved your request submitted February 17, 2020, received February 19, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Blood Grouping Reagent Anti-M (Murine Monoclonal) (IgG) to increase the concentration of the preservative, sodium azide, to 0.5% (w/v).

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

Sincerely,

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