To whom it may concern,

Applied Biological Materials Inc. (hereon referred as **abm**), is proud to provide the ISO 13485:2016/MDSAP certification for its PCR/qPCR/RT-PCR product lines, including GenomeCoV19 Detection Kits. You will find the ISO 13485:2016/MDSAP certification is attached under the company name of GenomeMe™ Lab Inc. GenomeMe™ Lab Inc. is **abm**'s trusted contract service provider who manufacturers all of **abm**'s proprietary PCR/qPCR/RT-PCR products under strict guidelines and regulations of ISO13485 requirements.

The MDSAP programme was initiated by the IMDRF (International Medical Device Regulators Forum) and the concept involves assessment of the Quality Management System (QMS) by an 'Auditing Organsation' (AO) on behalf of the regulatory bodies from the five participating countries; Australia, Brazil, Canada, Japan and the USA. The MDSAP programme is based around adherence to the QMS for Medical Devices ISO13485:2016 along with additional requirements from the five participating countries aforementioned.

More information regarding MDSAP can be reviewed with the following web link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/international/transition-medical-device-single-audit-program.html

If you have any questions or concerns, please do not hesitate to let me know.

Sincerely,

Heidi Chu
Director of Business Development
Applied Biological Materials Inc.

Date: January 25th, 2021

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Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

GenomeMe Lab Inc.

(F003880) Main site: 1-3691 Viking Way, Richmond, British Columbia (Colombie-Britannique), V6V 2J6, Canada

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The Design, Development and Manufacture of In-vitro Diagnostic Medical Devices, Reagents and Test Kits including Antibodies, HPV Kits, and PCR/qPCR Reagents, used in the Diagnosis, Management and Detection of Cancer.

Certificate Number:
0109792

Initial Certification Date:
24 January 2021

Date of Certification Decision:
24 January 2021

Effective Date:
24 January 2021

Valid Until:
23 January 2024

ISO 13485:2016 CERTIFICATION ™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Intertek

Calin Moldovean
President, Business Assurance

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900 Chelmsford Street
Lowell, MA, USA 01851