OFFICE OF THE DEPUTY PRIME MINISTER
MINISTRY FOR HEALTH

Ref. no: HCS/L/10

LICENCE CERTIFICATE

This is to certify that in terms of Subsidiary Legislation 458.25 Licensing of Private Medical Diagnostic Laboratories and other applicable laws and regulations, the Superintendence of Public Health has granted **Dr Manuele Biazzo** a licence to operate a **Medical Diagnostic Laboratory** at the premises which details appear below.

The Bio Arte Ltd
Malta Life Sciences Park
Triq San Giljan
San Gwann

This licence is issued subject to the above-mentioned provisions as well as to the specific conditions listed overleaf.

This certificate is valid until the 31st December 2022

Prof. Charmaine Gauci
Superintendent of Public Health

On behalf of

Hon Chris Fearne
Deputy Prime Minister
Minister for Health

Health Care Standards Directorate
Superintendence of Public Health
OPD (Level 1), St. Luke's Square Pieta' - Malta PTA 1010
t +356 25953326 e healthstandards.sph@gov.mt

1. The premises shall at all times be kept in conformity with sanitary laws and regulations, in good state of repair, and no structural alterations are to be carried out prior to approval from the responsible Ministry.
2. **Renewal of Licence.** The renewal of the Licence shall be made annually and prior to inspection for renewal the licensee shall present the following information to the licensing officer :
   a. a complete list of tests being performed within the Laboratory/Clinic/Section including tests which are sub-contracted either locally or abroad;
   b. List of SOPs in place – a random number of SOPs will be requested to be submitted prior to inspection;
   c. a full list of laboratory personnel performing duties within each the Laboratory/Clinic/Section (Consultants, Doctors, Medical Laboratory Scientists; etc) complete with their respective State Registration Number – as applicable;
   d. a comprehensive list of all laboratory equipment available within the licensed premises (including unique identification number, model & serial number, etc;)
   e. details of participation in External Proficiency Scheme/s including a copy of the latest participation report including evaluation of performance by participating personnel;
   f. copy of Certificate of Participation in the External Proficiency Scheme/s
   g. details of participation in Internal Proficiency Scheme including a copy of the latest internal evaluation report
   h. a list of personnel authorized (read and write) to issue laboratory results
   i. policy and procedures for quality control, instrument maintenance and laboratory safety

3. **Types of Tests.** The Licence certificate shall specify the tests that may be carried out at the premises, as determined by the Minister to be reasonable in accordance with the facilities available in the laboratory. The licensee shall ensure that no other clinical tests shall be carried out prior to the necessary authorization by the Minister

4. **Facilities.** The licensee shall ensure sufficient spâce, that staff, equipment and facilities are available for the proper performance of the required volume of work to a high standard of accuracy, precision and safety.

5. **Staff.** All medical laboratory tests shall be issued and communicated to clients under the professional direction, supervision and responsibility of a biochemist, microbiologist, pathologist, toxicologist or other person with adequate qualifications. All tests shall be carried out by staff that are suitably qualified and registered as Medical Laboratory Scientist with the Council of Professions Complimentary to Medicine. All persons employed at the laboratory shall be of good conduct. All staff shall register their attendance at the laboratory, indicating date/time of entry and date/time of leaving the laboratory. Such records shall be retained for a period of at least two years from the date of the last entry register.

6. **Laboratory Policies.** There shall be written policies and procedures for:
   a) laboratory quality control, both internal and external
   b) preventive maintenance and/or service agreements on instruments
   c) laboratory safety

   The licensee shall ensure that these policies are strictly adhered to by all persons working in the laboratory. Incidents and corrective actions and results in connection with the above shall be documented. Records for quality control (external and internal) and instrument maintenance shall be kept for at least the last 10 years.

7. **Results Register.** All tests carried out at the laboratory shall be registered together with the following information:
   a) patient's name, ID number, sex, address and date of birth
   b) referring Clinician's name and medical registration number
   c) the date when requested and their results
   d) the test(s) requested and their results
   e) the Professional who carried out the test(s)

   Such records shall be retained for a period of at least two years, except for histological, forensic and toxicological tests, which shall be retained for a period of twenty-five years.

8. **Safety.** The licensee shall:
   a) take all necessary precautions to ensure the safety of all staff on the premises. Moreover, he/she shall provide adequate means of protection against occupational hazards and ensure that all staff are making use of the protection provided.
   b) make arrangements in line with the current policy for the safety and disposal of infected material and sharps by providing amongst other things adequate containers.
   c) maintain all parts of the building in a good structural state of repair and, in particular, provide adequate lighting and ventilation.
   d) maintain a high degree of hygiene in all parts of the building
   e) take precautions against the risk of fire and make arrangements for detecting, containing and extinguishing fires and for the evacuation of staff in the event of fire. The licensee shall comply with such instructions as may be given by the Commissioner of Police in this respect.

9. **Notification of diseases.** The licensee or a representative shall inform forthwith the Superintendence of Public Health through written communication of :
   a) any infectious disease notifiable under the Public Health Act
   b) any malignant disease diagnosed at the laboratory.

   The information submitted shall include the patient's name and ID number, and the referring Clinician's name and medical registration number.

10. **Inspection.** It shall be lawful for any Authorised person to enter without prior notice, at any time of day and night, to inspect any licensed premises. Such authorised person shall be granted access to all records including prices and registers.

11. Premises and practices must be in compliance with the self-assessment sent to the licensee prior to inspection.