



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

mhra.gov.uk

Certificate number: **2020060502181653/1**

Order date: **09/06/2020**

CFS Expiry date: **09/06/2025**

**Medicines and Healthcare products
Regulatory Agency**
On behalf of the Secretary of State for Health and Social Care

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by: Legal Manufacturer: **Edinburgh Genetics Limited**, 64a Cumberland Street, Edinburgh, EH3 6RE, United Kingdom, have been affixed with the CE mark under In-Vitro Diagnostic Medical Devices Directive 98/79/EC as transposed into UK legislation (UK Medical Devices Regulations 2002 S.I. No. 618, as amended) and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

Please see attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

Deanna Brownlie

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA

Certificate Reference: 2020060502181653/1

Ordered on: 09/06/2020

Directive/Regulation: In-Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer Name: Edinburgh Genetics Limited

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#	Medical Device Name	Model	CE certificate number
1	Edinburgh Genetics ActivXpress+ COVID- 19 IgG/IgM Immunoassay Complete Testing Kit	ActivXpress+	NA
2	Edinburgh Genetics Complete Whole Blood Collection Kit	Whole Blood Collection Kit	NA
3	Edinburgh Genetics COVID-19 Colloidal Gold Immunoassay Testing Kit, IgG/IgM Combined	COVID-19 Colloidal Gold Immunoassay Testing Kit	NA
4	Edinburgh Genetics Viral Transport Media	Viral Transport Media	NA
5	Edinburgh Genetics Virus Swab Sampling Kit	Virus Swab Sampling Kit	NA

End of Schedule. No additional information past this point.