



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

mhra.gov.uk

Certificate number: **2021030402194867/1**

Order date: **04/03/2021**

CFS Expiry date: **05/03/2026**

**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, Scotland, United Kingdom, Authorised Representative (Northern Ireland): **EG GENETICS LIMITED**, Moat House, 54 Bloomfield Ave, Belfast, BT5 5AD, Northern Ireland, United Kingdom have been affixed with the CE mark under the 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 the United Kingdom (England, Scotland, Wales, Northern Ireland) and the European Union/EEA.

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,

Ngozi Onyeukwu

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA

Certificate Reference: 2021030402194867/1

Ordered on: 05/03/2021

Directive/Regulation: in vitro diagnostic Medical Devices Directive 98/79/EC

Manufacturer Name: Edinburgh Genetics Limited

CFS Expiry Date: 05/03/2026

#	Medical Device Name	Model
1	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101N
2	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101NA
3	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101NB
4	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101NT
5	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101T
6	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101MT
7	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101
8	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101A
9	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101B
10	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101MB
11	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101M
12	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	EGCV0101MA
13	Edinburgh Genetics ActivXpress+ COVID-19	EGCV0092L

	IgG/IgM Immunoassay Complete Testing Kit	
14	Edinburgh Genetics ActivXpress+ COVID-19 IgG/IgM Immunoassay Complete Testing Kit	EGCV0092

End of Schedule. No additional information past this point.