RABIES SEROLOGY CERTIFICATE

SAMPLING INSTRUCTIONS:

- Please ensure that all fields are completed fully and accurately
- Complete one rabies serology certificate per animal
- Send a minimum of 1ml serum (preferable) or 2ml clotted blood
- Clearly label sample with animal's name and microchip number

SEND SAMPLE TO:

Biobest Laboratories Ltd
6 Charles Darwin House
The Edinburgh Technopole
Milton Bridge, Nr Penicuik
EH26 0PY
enquiry@biobest.co.uk

SEND RESULTS TO: Owner: ☐ Practice: ☐ Agent: ☐

OWNER'S DETAILS:

Name:

E-Mail:

Address And Postcode (OPTIONAL):

SUBMITTING VETERINARY SURGEON'S DETAILS

Veterinary Practice Name, Address And Postcode:

Telephone:

Signature of submitting veterinary surgeon (blue ink preferred)*:

Name in BLOCK CAPITALS:

Date:

E-Mail:

ANIMAL'S DETAILS

Date of Birth:

Microchip Number:

AVID Microchip Number (if applicable):

Date of Blood Sampling & Microchip Reading:

Cat: ☐ Dog: ☐

Animal Name:

RABIES VACCINATION DETAILS:

Date: (DDMMYY)	Vaccine:	Batch No:

*By signing this form you are confirming that all information on this form is true and correct. You confirm that the animal being sampled appears healthy and is not suspected to be carrying any notifiable disease according to European regulations or the animal health regulations of the country where the animal is based. You are also confirming that the animal is not from a region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animal is susceptible according to European or other national animal health regulations.

BIOBEST USE ONLY:

QC:	I:
Biobest No:	
Date of Receipt:	

RABIES SEROLOGY SAMPLE PAYMENT FORM

PAYMENT OPTIONS

PREFERRED METHOD ☐

Card Payment E-Mail Link

A secure card payment link will be sent to the e-mail address provided below.

Email Address: _____

ALTERNATIVE METHOD ☐

BACS Bank Transfer

An e-mail will be sent to the e-mail address provided above containing our bank account details. Proof of payment will be required before results are released.

RETURN METHOD & ADDRESS

All certificates are returned by standard airmail (no tracking number available) if one of the options below is not selected. Once a certificate has left Biobest we cannot track its location or guarantee delivery.

We can provide the following options:

Standard tracked mail (UPS) - additional cost of £30: ☐

Courier (DHL) - additional cost of £110: ☐

Name: _____

Address: _____
(Please note couriers cannot deliver to a PO Box)

Postal/Area Code: _____

Phone Number: _____

Email Address: _____

If this information is not completed in full the courier company may not be able to deliver.

BIOBEST USE ONLY	Biobest Ref:	Invoice Number:

RABIES SEROLOGY SAMPLE SUBMISSION INSTRUCTIONS

Thank you for requesting details of how to submit a sample for rabies serology to Biobest. Our testing complies with the requirements of all European Pet Travel Schemes. Be aware pet travel rules vary from country to country and that you should check with the relevant authorities in your destination country to ensure you are complying with their testing requirements. Please read and follow these instructions carefully. If you have any questions or problems, please contact any member of our office admin staff - enquiry@biobest.co.uk

1. You will need to send us 1ml of serum or 2ml of clotted blood from your pet. Serum is preferable to clotted blood as it is more stable if the sample is subjected to extremes of temperature. If possible, have your veterinary surgeon centrifuge the blood sample and send only the serum.

2. You will need a rabies serology certificate for each sample, our import licences and a payment form. Your veterinary surgeon must complete the rabies serology certificate in full and the original certificate must accompany the sample. It is possible to send your sample, rabies serology certificate and payment form directly to Biobest.

3. All samples should come in a well-padded, leak proof, rigid container (IATA packing instructions 650).

4. Packages must be clearly labeled with the following information:

- Import Licence numbers: (Scottish airports: TARP(S) 2023/26, English airports: ITIMP23.1011)
- Canine/feline serum samples, no commercial value.
- Animal specimens - not restricted, for diagnostic test and destruction within 30 days.
- Packed in compliance with IATA packing instructions 650.
- Country of origin: (your country)

5. When using a courier to deliver your sample, failure to complete the waybill correctly will result in additional charges. Any additional charges will be billed to the sender, these charges will not be paid by Biobest and this will cause a delay in your samples reaching us or they may be returned to sender. Do not mark the box bill receiver. Please mark the maximum value of the goods as $1, failure to do this will incur additional charges by UK customs and excise.

6. Attach both import licences (Scottish and English) to the outside of the package with the waybill. The certificate should be packed inside the package to prevent it being removed at customs. We would also advise you to use a reputable courier so that the shipment can be tracked.

7. There is no need to ensure samples remain frozen or refrigerated in transit.

8. An online payment link will be sent to you by email on receipt of your sample, this is the preferred payment method. Payment can also be made by bank transfer. Payment is not required prior to the sample arriving. Current prices are available on our website.

9. Results are usually available in up to 10 working days and we will email a copy prior to posting the certificate back to you by standard untracked airmail. Other options available can be selected on the payment form. We also operate a rabies express service for urgent samples. Further details can be found on the website.

10. For entry into the EU from non-listed countries the blood sample must be taken at least 30 days after rabies vaccination. For travel to other destinations please check with the embassy or animal health department of the relevant country.

11. Should you need to contact us about your sample we will require the animal name and microchip number.

BIOBEST LABORATORIES LIMITED
TERMS & CONDITIONS OF SUPPLY

1. Routine Diagnostic Testing Services

We shall conduct diagnostic testing services ("Routine Diagnostic Testing Services") as follows:

a. We will test a sample following its receipt as per any report or specification provided by us and in accordance with the test schedule and turnaround times publicised in our current marketing materials or on our website (www.biobest.co.uk). The testing schedule is subject to change by us without prior notification. We will use reasonable endeavours to ensure that tests are completed as per this schedule; however we make no guarantees of test times, unless specifically agreed to by us in writing. In this respect time shall not be of the essence. Upon request urgent tests may at our discretion be conducted outside the normal test schedule. In such circumstances additional charges may be applicable, and these shall be notified to you in advance of setting up the test.
b. If a sample is received in a condition such that it is considered to be broken or otherwise unsuitable for testing, we will inform you immediately and request submission of a repeat sample. There will be no additional charge in such circumstances. However, we reserve the right to charge for the original and re-test where the unsuitable condition of the sample does not become apparent until during or after test completion.
c. If we receive a request for test cancellation before we have set up the test, we will provide a full refund. If we receive a request for test cancellation after we have set up the test, we reserve the right to charge an amount to reflect our costs incurred up to the standard test price.
d. If we receive a request from you to add a test to a sample already received, we will conduct this additional test providing there is sufficient material. The additional charge will be as per the standard test price.
e. The diagnostic test service includes as standard faxed or posted report, and where specifically requested or required, telephoned or emailed results; interpretation of results by a veterinary surgeon; advice on sampling and submission; and supply of sampling kits where appropriate. We retain ownership of and retain all copyright and other intellectual property rights in all reports, written advice and other materials prepared by us.

2. Contract Research, Project Studies, Supply of Goods
We shall conduct contract research, project studies, supply of Goods and any other service or product that we supply which is not classified as a Routine Diagnostic Testing Service (together, "the Services"), as per the scope of work and terms and conditions specified and previously agreed to by us in writing in any tender request, proposal documentation and agreed contract. In the absence of any such agreed contract, these Conditions will apply. Unless otherwise agreed in writing payment terms for such research or study work will be 40% of contract value on signature of the contract by us, 30% on completion of testing and 30% on delivery of final report.

3. Samples and Results
a. Unless otherwise agreed with us in writing, all samples received by us for Routine Diagnostic Testing Services shall become our property upon delivery of the sample to us or collection of the sample by us and, on the completion of Routine Diagnostic Testing Services, may be retained and used for research and development and other purposes. Any data or other results (and all intellectual property and other rights in them) arising from such use shall belong to us and you shall not have any rights in any of them.
b. Unless otherwise agreed with us in writing, all data, results, reports and advice produced by us as a result of our carrying out the Routine Diagnostic Testing Services shall be our property and may be used for such purpose(s) as we decide from time to time.
c. . If you provide any data or information with, or relating to, the samples, we may use such data and information for our own purposes and may provide it to third parties in an anonymised manner. All personal data is held in full compliance with the General Data Protection Regulations (GDPR) and will only be passed to third parties where it is a legal requirement for us to do so or where we have your informed consent.

4. Prices and Payment
a. Prices are publicised on our website and in our current marketing materials. We reserve the right to change prices.
b. All prices for eligible transactions are subject to VAT at the current rate.
c. For non-account holders and new customers we require payment upon submission of the sample before an order will be accepted. We accept payment in pounds Sterling in the form of a cheque, bankers draft, by an electronic transfer of funds to a bank account of our choosing (with you being responsible for any costs associated with such transfer) or by debit or credit card.
d. For repeat customers and account holders we will invoice on a monthly basis. You shall pay the full amount of any invoice within 30 days from date of invoice. We will exercise our statutory right to charge interest and compensation for debt recovery costs under late payment legislation if we are not paid according to agreed credit terms.
e. We will request two trade and one banker's reference in order to set up a new account.

5. Delivery
a. If any Goods are to be delivered by us as part of this Contract then such Goods shall be delivered to a delivery address agreed to by the parties during our normal business hours. If any Goods are to be delivered outside the United Kingdom, such delivery shall be Exworks Incoterms 2000.
b. We shall make reasonable endeavours to deliver any Goods within timescales notified to you. If no dates are specified, delivery shall be within a reasonable time, however time shall not be of the essence.
c. The Goods shall remain our property and title in the Goods shall not pass to you until all sums due by you to us have been paid.
d. Until the transfer of title in terms of Condition 5c above:-
(i) you shall store the Goods in a manner which distinguishes them from any other goods and which indicates that the Goods are owned by us;
(ii) the Goods shall be kept at your premises and you shall take good care of the Goods and use and maintain them in accordance with good industry practice;
(iii) you shall be responsible for loss of, or damage to the Goods; and
(iv) you shall not permit any form of security or charge to be created over the Goods.
e. Until the property in the Goods passes to you in accordance with the provisions of Condition 5c above, you shall keep the Goods insured to their full replacement value with full comprehensive insurance to be approved by us and with our interest noted on the policy. Evidence of such insurance shall be made available to us at any time on request.

6. Warranty of Performance
a. We shall exercise all reasonable skill, care and professional due diligence in the performance of the Services, however we do not guarantee or warrant that any particular result is correct or otherwise.
b. All conditions, representations and warranties relating to the Goods and/or the Services and their use and receipt and all remedies otherwise available to you are excluded to the fullest extent permitted by law.

7. Limitation of Liability
a. Under no circumstances shall our liability for any loss or damage suffered by you or any other person as a result of our performance or nonperformance of our obligations under this Contract be greater than £10,000 or the total sums received by us under the provisions of the Contract, whichever is the greater. You shall indemnify us in respect of any loss sustained and any expenses incurred by us arising directly out of or in connection with your breach of this Contract.
b. We shall not be liable in any circumstances for any indirect or consequential loss or loss of anticipated profits, loss of anticipated savings or any other economic loss of yours.
c. Notwithstanding the provisions of Condition 7a and 7b above, neither party excludes or limits liability to the other party for death or personal injury arising from the breach of duty of such party.
d. Our liability to you under this Contract is excluded to the fullest extent permitted by law.
e. Should any limitation or provision contained in this Condition be held to be invalid under any applicable statute or rule of law it shall to that extent be deemed omitted but if either party thereby becomes liable for loss or damage which would otherwise have been excluded such liability shall be subject to the other limitations and provisions set out herein.

8. Force Majeure
a. Any delay or failure by either party in performance hereunder, other than your obligation to pay us any monies due to us, shall be excused if and to the extent that such delay or failure is caused by occurrences beyond such party's reasonable control including but not limited to, acts of God, decrees or restraints of government, strikes, war, fire, riot, sabotage, terrorism and any other cause or causes whether similar or dissimilar to those already specified which cannot reasonably be controlled by either party. Such performance shall be so excused for the period during which such inability of the party to perform is so caused but for no longer period and shall be remedied as far as possible with all reasonable despatch. Any time period for performance shall be extended by a period equal in duration to any period during which such performance is excused by this Condition.
b. If any of the events detailed in Condition 8a above prevents either party from performing all of its obligations under the Contract for a period in excess of one month, the party affected by such non-performance may terminate the Contract.

9. Termination
a. We may terminate this Contract by providing written notice to that effect to you.
b. In addition to, but without prejudice to our other rights and remedies under and in terms of this Contract, we may terminate this Contract forthwith if:-
(i) you fail to pay any part of the price payable to us by the date specified in Condition 4 above;
(ii) you become insolvent or enter into any arrangement with your creditors;
(iii) a petition is presented, or a resolution proposed, for the winding-up of your business;
(iv) any procedure is commenced with a view to the appointment of an administrator, receiver or administrative receiver in relation to you or any other party gives notice of its intention to appoint an administrator to you;
(v) you are unable to pay your debts as they fall due;
(vi) you cease trading or threaten to cease trading; or
(vii) any equivalent event as outlined in Conditions 9b(i) – 9b(vi) occurs in any jurisdiction other than Scotland.
c. In the event of termination of this Contract you shall pay to us all amounts which remain outstanding for Services performed or Goods delivered by us under this Contract within 10 Business Days of this Contract terminating.

10. Assignation
We shall be entitled to assign, transfer or sub-contract any of our rights or obligations under this Contract. You shall not assign, transfer or sub-contract any of your rights or obligations under this Contract or purport to do so unless you have obtained our prior written consent.

11. Dispute Resolution
Should any dispute arise between us and you, the parties will attempt to resolve the dispute in good faith. If the parties are unable to resolve any such dispute between them, either party may request that the parties seek to resolve the dispute through mediation using the services of the Centre for Dispute Resolution to facilitate the mediation process but this shall not prejudice a party's right to raise court or other proceedings.

12. Entire Agreement
This Contract and any other document referred to herein as being applicable contains the entire agreement of the parties with respect to the subject matter of this Contract and supersedes all prior agreements and arrangements whether written or oral between the parties with respect to the subject matter of this Contract. Nothing in this Condition 12 shall have effect to exclude the liability of either party for fraud or fraudulent misrepresentation.

13. Severability
If any provision of this Contract is held by the appropriate court or other competent authority to be void or unenforceable in whole or in part this Contract shall continue to be valid as to the other provisions of it and the remainder of the affected provision.

14. Governing Law
This Contract shall be governed by and construed in accordance with the law of Scotland and the parties hereby submit to the non-exclusive jurisdiction of the Scottish courts.

15. Definitions, Interpretation and Basis of Contract
a. In these Conditions, unless the context requires otherwise, the following words and phrases shall have the meanings set opposite them:
"Business Day" means any day from Monday to Friday inclusive on which we are open for business;
"Conditions" mean the terms and conditions of supply as set out in this document;
"Contract" means the agreement incorporating the Conditions concluded between us and you pursuant to Condition 15c for the supply of Goods and/or Services incorporating the Conditions;
"Goods" means the goods, if any, to be supplied under the Contract;
"Purchaser" shall mean the individual or company to whom we are supplying Goods and/or Services under the Contract;
"Services" means the services, if any, to be supplied under the Contract, as more particularly described in Conditions 1 and 2 above; and
"VAT" means value added tax.
b. All references to "us", "our" and "we" shall mean Biobest Laboratories Limited and references to "you" and "your" shall mean the Purchaser.
c. All purchase transactions between us and you are, unless otherwise agreed to in writing by us, subject to these Conditions which are deemed to be incorporated into any Contract. These Conditions shall apply to the Contract to the exclusion of any other terms and conditions including without limitation, any terms and conditions of yours. No variation to the Contract or these Conditions shall be binding unless accepted in writing by us.

Scottish Government
Riaghaltas na h-Alba

Agriculture and Rural Economy Directorate
Animal Health and Welfare Division

Commission Regulation (EU) No 142/2011[1] implementing **Regulation (EC) No 1069/2009** of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing **Council Directive 97/78/EC** as regards certain samples and items exempt from veterinary checks at the border under that Directive **("Regulation 142/2011")**
Commission Delegated Regulation (EU) No 2019/2122 supplementing **Regulation (EU) 2017/625** of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers' personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending **Commission Regulation (EU) No 142/2011 ("Commission Delegated Regulation 2019/2122")**
The Trade in Animals and Related Products (Scotland) Regulations 2012[2]
The Animal By-Products (Enforcement) (Scotland) Regulations 2013[3]

AUTHORISATION FOR THE IMPORTATION FROM THIRD COUNTRIES OF RESEARCH AND DIAGNOSTIC SAMPLES

The Scottish Ministers, under Article 27 of Regulation (EU) 142/2011, Article 4 of Commission Delegated Regulation 2019/2122, and paragraph 3 of schedule 3 of the Trade in Animals and Related Products (Scotland) Regulations 2012 authorise

Mr Stuart Marshall Biobest Laboratories Ltd, 6 Charles Darwin House, The Edinburgh Technopole, Milton Bridge, Midlothian, EH26 0PY	*Name and full address of importer responsible for consignment*
	Full address of destination premises (if different from importer) – This address must be in Scotland

to import, in accordance with the conditions set out below,

Whole blood, serum or plasma from companion animals (pet dogs and cats) Samples are from healthy animals that are not known to be (or suspected to be) infected with a pathogen which causes a notifiable disease according to EU regulations intended for particular studies or analyses only. (Not for resale).	*Product*

from

All Countries	*Countries of origin*

at

[1] Commission Regulation (EU) No 142/2011 (legislation.gov.uk)
[2] The Trade in Animals and Related Products (Scotland) Regulations 2012 (legislation.gov.uk)
[3] The Animal By-Products (Enforcement) (Scotland) Regulations 2013 (legislation.gov.uk)

All ports and airports in Scotland	*Ports of entry*

This authorisation expires on 31 March 2030

Signed:  Dated: 31 March 2025

Name: Jacqueline Quigley

A member of staff of the Scottish Minister

CONDITIONS ATTACHED TO THIS AUTHORISATION

1. The authorisation is valid for multiple consignments and the net weight per consignment must not exceed **5kg**

2. Any breach of these conditions must be reported to the Scottish Government (at the contact address below).

Packaging

3. The material must be packed in leak-proof sealed containers.

4. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.

5. The packaging must be clearly labelled to indicate the nature of the product, that it is intended for *in vitro* use in research or diagnostics and that it is **not** for human or animal consumption.

6. Irrespective of the mode of transport, all specimens must be packaged so that they fully comply with the requirements of relevant Post Office or International Air Transport Association (IATA) regulations.

7. The products must always remain in their original packaging and wrapping until their arrival at the destination.

Storage, use and handling

8. The samples and material derived from the samples shall be for *in vitro* use only.

9. None of the material this authorisation relates to shall be used for human or animal consumption under any circumstances.

10. Any subsequent use of these products for purposes other than those referred to in point 38 of Annex 1 of Regulation (EU) No 142/2011, is prohibited.

11. Samples must be handled and stored under containment level conditions which are appropriate to the risks presented by the product. This should be determined by the operator, following a suitable risk assessment, in accordance with The Control of Substances Hazardous to Health Regulations 2002. In doubt, contact the Health and Safety Executive.

12. Users shall take all necessary measures to avoid spreading diseases communicable to humans or animals during the handling of the materials under their control, particularly by applying good laboratory practice.

13. Unless they are kept for reference purposes or re-dispatched to the third country of origin, the research and diagnostic samples, products derived from their use and waste shall be disposed of appropriately. This must be done in accordance with Section 1 of Chapter III of Annex XIV to Regulation 142/2011.

14. Any transfer of the imported research and diagnostic samples and any products derived from the samples from the authorised user to any other user must be pre-authorised by the Scottish Government.

Transportation

15. The consignment must be sent directly from the point of entry into Scotland to the authorised user at the destination address listed on the commercial document.

16. The material must be transported, handled and labelled in accordance with the Animal By-products Regulations.

17. Before starting operations, the transporter and destination address must be registered or approved (see note D) in accordance with the Animal By-Products (Enforcement) (Scotland) Regulations 2013.

Import Documentation

18. Each consignment must be accompanied by a:

- copy of this authorisation
- commercial documentation (see point 18)

19. Each consignment must be accompanied by a commercial document signed by a person with knowledge of, and responsibility for, the relevant parts of the production process. It must be on company letter-headed paper and dated within 2 months of the importation date of each consignment. The document must include the:

- description of the product and animal species of origin
- category of the product (1, 2 or 3) as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009
- quantity of the product
- place and country of origin
- place of dispatch of the product
- name and address of consignor
- name and address of the consignee or user, or both

The document should also confirm that the product:

- is derived from animals which did not show any signs of disease communicable to humans or animals.
- does not originate from animals located in, and has not been dispatched from holdings, establishments or zones which are subject to restrictions due to the presence of a serious transmissible disease, to which species the products are obtained from are susceptible:
  - listed in Annex I to Directive 92/119/EEC; or
  - listed by the WOAH in Chapter 1.3 of the Terrestrial Animal Health Code, [2024] edition, and in Chapter 1.3 of the Aquatic Animal Health Code, [2024] edition

NOTES

A. Please note that while this authorisation was current at the time of its issue, conditions can be subject to frequent change and importers are advised to check the latest position with the Scottish Government, at the address below.

B. It is the responsibility of the importer to follow good laboratory practice standards and to prevent the sample entering the environment in any manner.

C. In accordance with Annex VIII, Chapter III, point 5 of Regulation (EU) No 142/2011, all records and related documentation associated with material imported under this authorisation must be kept for a minimum of 2 years for presentation to the competent authority.

D. For information on registration/approval, please see the website: https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered

E. References to European Union (EU) legislation within this document are references to direct EU legislation which has been assimilated in Great Britain (assimilated direct legislation), as defined in the Retained EU Law (Revocation and Reform) Act 2023), and can be viewed on the UK legislation website (legislation.gov.uk)

Further information regarding changes to the import controls from an EU country from 31 January 2024 can be found on GOV.UK at:

https://www.gov.uk/government/publications/risk-categories-for-animal-and-animal-product-imports-to-great-britain

CAUTION

It is the importer's responsibility to ensure that any import covered by this authorisation complies with the terms and conditions as set out. If you cannot comply with any of the conditions above, please contact the Scottish Government.

Any breach of any conditions attached to this Authorisation may constitute an offence against regulation 33 of the Trade in Animals and Related Products (Scotland) Regulations 2012 or regulation 18 of the Animal By-Products (Enforcement) (Scotland) Regulations 2013.

CONTACT FOR FURTHER INFORMATION

Scottish Government
Agriculture and Rural Economy Directorate
Animal Health and Welfare Division
P Spur
Saughton House
Broomhouse Drive
EDINBURGH
EH11 3XD
United Kingdom

Email: animal.health@gov.scot

Animal & Plant Health Agency

Commission Regulation (EU) 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive **("Regulation 142/2011")**
The Trade in Animals and Related Products Regulations 2011
Animal By-products (Enforcement) (England) Regulations 2013

AUTHORISATION FOR THE IMPORTATION FROM THIRD COUNTRIES OF RESEARCH AND DIAGNOSTIC SAMPLES

The Secretary of State for Environment, Food and Rural Affairs, by this authorisation issued under Article 27 of Regulation (EU) 142/2011, authorises:

Mr Stuart Marshall Biobest Laboratories Ltd 6 Charles Darwin House The Edinburgh Technopole Milton Bridge, Nr Penicuik, EH26 0PY	*Name and full address of importer responsible for consignment*

Dr Paul Burr Biobest Laboratories Ltd 6 Charles Darwin House The Edinburgh Technopole Milton Bridge, Nr Penicuik, EH26 0PY	*Full address of destination premises (if different from importer)*

to land in England, in accordance with the conditions set out below,

Whole blood, serum and plasma samples from pet cats and dogs, intended for particular studies or analyses only. (Not for resale).	*Product*

from

All countries outside the EU	*Countries of origin*

at

All ports and airports in England	*Ports of entry*

This licence expires on 2 years less one day from the date of signature. After this date the licence should have either been renewed if required and deleted or cancelled and archived.

Signed: Dated: 09 May 2024

Name: Andrew Lee
Officer of the Animal and Plant Health Agency
authorised by the Secretary of State.

CONDITIONS ATTACHED TO THIS AUTHORISATION

1. This authorisation is valid for multiple consignments and the net weight per consignment must not exceed 1 Kg.

2. Any breach of these conditions must be reported to the Animal and Plant Health Agency (APHA) Centre for International Trade, Carlisle.

Packaging

3. The material must be packed in leak-proof sealed containers.

4. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.

5. Irrespective of the mode of transport, all specimens must be packaged so that they fully comply with the requirements of relevant Post Office or International Air Transport Association (IATA) regulations.

6. The packaging must be clearly labelled to indicate the nature of the product, that this is intended for *in vitro* use for research and that it is **not** for human or animal consumption.

Import Documentation

7. Each consignment must be accompanied by a copy of this import authorisation and a commercial document which must confirm:

    i. The description of the material and the animal species of origin;

    ii. The category, 1, 2 or 3, of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009[1];

    iii. The quantity of the material;

    iv. The place of origin and the place of despatch of the material;

    v. The name and the address of the consignor;

    vi. The name and address of the consignee and/or user;

8. Each consignment must be accompanied by a signed and dated declaration completed by a veterinarian, on official paper, confirming that:

    i. the products are **not** derived from animals known or suspected to be infected with a pathogen which causes a notifiable disease to which the animals from which the products are derived are susceptible according to retained European Regulations[2] or the Animal Health Regulations of the exporting country; and

    ii. the products **do not** originate from animals in a premises or region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals are susceptible according to European or other National Animal Health Regulations.

[1] https://www.legislation.gov.uk/eur/2009/1069/title/I/chapter/I/section/4
[2] https://www.legislation.gov.uk/eudr/1982/894

iii. the animals from which samples were collected did not show any sign of infectious disease at the time of collection

Transportation

9. The consignment must be sent directly from the point of entry into Great Britain to the authorised user at the destination address on page 1.

10. The material must be transported, handled and labelled in accordance with the Animal By-products Regulations.

11. The transporter and destination address must be registered or approved (see note E) in accordance with the relevant Animal By-Products (Enforcement) Regulations, (ABPE) before commencing operations.

12. The products must remain in their original wrapping at all times until their arrival at the destination address on page 1.

Storage, Use and Handling

13. Users shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.

14. The samples and material derived from the samples shall be for in vitro use only.

15. Samples must be handled and stored under containment level conditions which are appropriate to the risks presented by the product. This should be determined by the operator, following a suitable risk assessment, in accordance with The Control of Substances Hazardous to Health Regulations 2002.

16. None of the material to which this authorisation relates shall be used for human consumption under any circumstances.

17. Any subsequent use of these products for purposes other than those referred to in point 38 of annex 1 of Regulation (EU) No 142/2011, is prohibited.

18. Importers shall keep a register of consignments of samples imported under this authorisation, which should contain the information referred to in condition 7 above as well as the date and method of disposal.

19. Unless they are kept for reference purposes, transferred or re-dispatched to the third country of origin, research and diagnostic material, products derived from their use and waste shall be disposed of appropriately, in accordance with The Waste (England and Wales) Regulations 2011/The Waste (Scotland) Regulations 2012 or Animal By-Product Regulations (Regulation (EC) 1069/2009 and Regulation (EU) 142/2011).

Transfer of Material

20. Any transfer of material from the authorised user to any other user must be pre-authorised by APHA.

NOTES

A. When expired or exhausted this authorisation is to be deleted or cancelled and archived.

B. Please note that while this authorisation was current at the time of its issue, conditions can be subject to frequent change and importers are advised to check the latest position with Animal and Plant Health Agency, Imports Team, Carlisle, at the address below.

C. It is the responsibility of the importer to follow good laboratory practice standards and to prevent the sample entering the environment in any manner.

D. In accordance with Annex VIII, Chapter III, point 5 of Regulation (EU) No 142/2011, all records and related documentation associated with material imported under this authorisation must be kept for a minimum of 24 months for presentation to the competent authority.

E. For information on registration/approval, please see the website: https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered

F. References to European Union (EU) legislation within this document are references to direct EU legislation which has been assimilated in Great Britain (assimilated direct legislation), as defined in the Retained EU Law (Revocation and Reform) Act 2023), and can be viewed on the UK legislation website (legislation.gov.uk)

Further information regarding changes to the import controls from an EU country from 31 January 2024 can be found on GOV.UK at:

https://www.gov.uk/government/publications/risk-categories-for-animal-and-animal-product-imports-to-great-britain

CAUTION

It is the importer's responsibility to ensure that any import covered by this authorisation complies with the terms and conditions as set out. If you cannot comply with any of the conditions above, please contact the APHA Imports Team.

Any breach of any conditions attached to this Authorisation will constitute an offence against regulation 39 of the Trade in Animals and Related Products Regulations 2011 or regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2013.

CONTACT FOR FURTHER INFORMATION

Animal and Plant Health Agency, Imports Team
Centre for International Trade – Carlisle
Eden Bridge House,
Lowther Street,
Carlisle, CA3 8DX Tel: 03000 200 301 Email: imports@apha.gov.uk