

### FREQUENTLY ASKED QUESTIONS

#### **Products**

### 1. How can I find products?

The easiest way to find a product is to type a key word or words into the search box at the top right hand corner of every web page. This is driven by Google and will display **All Results** containing your word(s). If you wish, you can then filter the results by clicking on <u>Products</u> to show product results only. Similarly <u>Instructions for Use</u> will show only IFU results and <u>Search</u> <u>Centre for AIDS Reagents</u> will show results from that product range.

Alternatively you can go to the Biological Materials Product Catalogue

<u>http://www.nibsc.org/products/biological\_reference\_materials/product\_catalogue.aspx</u> and select a sub-category of products to see what is available in a particular field.

### 2. What are biological reference materials?

Biological medicines are more complex than chemically synthesised drugs and therefore cannot be characterized and measured using standard physicochemical means alone. Instead bioassays are performed which require the use of a biological reference material to ensure standardisation of the results.

WHO biological reference materials (WHO International Standards and other materials) provide a common set of standards which are used to ensure the quality of biological medicines worldwide. These International Standards are considered to be the 'gold standard' against which regional, national and international laboratories and manufacturers calibrate their own working standards. They are calibrated in units of biological activity which are assigned following extensive studies involving multiple international laboratories.

# 3. What are working standards?

Users are expected to calibrate their own in-house reference materials from the standards obtained from NIBSC. However, for some frequently used standards, 'working standards' have been prepared at NIBSC and these can be used as direct in-house reference materials.

Working standards are supplied with a handling charge of **GB £100.00 for 5 ampoules or** vials.





### List of Working Standards:

Biotinylated Brad-5 (Bio-Brad-5)	99/774
FEIBA Concentrate 1st NIBSC Working Reference Standard	06/172
Anti-D for assuring operator and test performance	07/304
Blood Coagulation Factors II, IX, and X, concentrate, human (6th British Standard)	07/326
Anti-D immunoglobulin control	99/728
Factor VIII Concentrate (B)	10/188
Anti-D for use with papain preparation 92/658	91/562
Papain preparation for use with Anti-D preparation 91/562	92/658

# **Blood Products & Transfusion Science Reference Materials**

#### **CE Marked**

Negative Control for FCXM	09/112
Positive Control for FCXM	07/214

#### **Viral & Retroviral Reference Materials**

Hepatitis A Virus RNA, Working Reagent for NAT Assays	01/488
Hepatitis B Virus DNA, Working reagent for NAT Assays	10/194
Multiplex Working Reagent (HCV, HAV, HIV, B19) for NAT Assays	99/732

### **CE Marked**

Anti-Hepatitis C Virus (1 in 8 dilution – for use with Abbott PRISM)	10/154
Anti-Hepatitis C Virus, British Working Standard	10/150
Anti-Human Immunodeficiency Virus-1, British Working Standard (1 in 5 dilution)	99/710
Anti-Human Immunodeficiency Virus-1, British Working Standard (for use with 3rd generation assays)	99/750
Anti-Human Immunodeficiency Virus-2, Monitor Sample	99/674





Anti-HTLV1, Monitor Sample	03/104
Hepatitis B Surface Antigen, Revised Concentration British Working Standard 0.2 IU/ml	07/288
Hepatitis B Surface Antigen, Revised Concentration British Working Standard 0.05 IU/ml	07/286
Hepatitis C Virus RNA, Working reagent for NAT Assays	02/264
Human Immunodeficiency Virus-1 RNA, Working reagent (High Copy Number) for NAT Assays (PWS-2)	99/636
Human Immunodeficiency Virus-1 RNA, Working reagent (Medium Copy Number) for NAT Assays (PWS-1)	99/634

# 4. How many International Standards may I order?

International Standards (IS) need to last for many years to avoid frequent changes. Customers are expected to use the IS to calibrate their own in-house working standards. For this reason we do not normally expect to supply more than 10 units of a particular IS to a single laboratory in a year.

Some IS are now in short supply in which case they are restricted to lower numbers per year while replacements are being developed. This number is generally specified on the Product Detail page of the IS on the NIBSC website.

If you require a larger number of an IS, please contact <u>standards@nibsc.org</u> with an explanation of why you require a larger number, or include the explanation with your order. Other products are not usually restricted but where they are, it will be indicated on the Product Detail page.

# 5. How are International Units defined?

International Units (IU) are assigned to International Standards (IS) or other reference materials to allow the assessment of "biologicals" in a consistent internationally agreed manner. A "biological" can be defined as a material for which the potency cannot be adequately determined by physico-chemical methods alone. In contrast to a fully chemically characterised drug, the assessment of a "biological" requires the measurement of some response in a biological or immunological system, usually by comparison to a reference material with a known or assigned value. Examples of biologicals include blood clotting factors, antibodies and viral or bacterial vaccines.

Biological reference materials, with an assigned value in IU, may be used in situations where physico-chemical determination of SI units, e.g. mass, is not possible or not appropriate. There may be no agreed validated reference methods of determination available, or a simple mass unit may not adequately define a clinically relevant measure of activity e.g.





glycoprotein hormones.

The World Health Organization (WHO) provides biological reference materials which serve as reference sources of defined biological activity expressed in internationally agreed units. Their use should lead to improved agreement between laboratories, and increased patient safety, by helping clinicians, scientists, regulatory authorities and manufacturers to compare data from clinical trials or research publications, and to provide regulatory limits and guidelines for treatment regimes, using a common agreed unit. They are intended for the calibration of secondary reference materials (national or manufacturer) rather than routine inclusion as run controls.

The IS will usually be assigned a value after a multi-centre international collaborative study. The role of the collaborative study is to characterise the performance of the reference material and determine whether it is 'fit for purpose'. The study will be designed to include a wide representation of assay methods, types of laboratory, and countries. This allows an assessment of the candidate standard in different assays and different laboratories, and gives a measure of the between-method or between-laboratory agreement. Other samples may be included in the study, to assess the effectiveness of the candidate reference material to improve between-laboratory agreement. The study should determine whether a single reference material and unit can be used for the available range of assay methods.

The results of the study will determine whether the candidate reference material is suitable for adoption as a WHO IS. This is the formal responsibility of the WHO Expert Committee on Biological Standardization (ECBS). If the reference material is found to be suitable, and there is no pre-existing standard, the reference will be assigned an arbitrary value in International Units. The IU is defined by the contents of the ampoule or vial, and is not usually dependent on the particular assay method used.

Although arbitrary, the number chosen for the first IS is set at a "convenient" level, by choosing a value that will be recognised by clinicians or other users. In some cases, such as blood clotting factors, a link is made to a population value, for example the clotting activity of a fresh normal pool of plasma, which is representative of the population. In some cases, International Units may be assigned to different biological activities within the same physical material. For example, a plasma sample may be assigned units for different clotting factors, or for levels of antibody against different viruses.

As the reference material is a physical entity that is supplied to users, the stocks will eventually be depleted. A replacement standard will then be made. A further multi-centre collaborative study will be carried out, to characterise the candidate replacement standard, and to compare it directly to the existing current standard. The value assigned to the replacement standard, in IU, will be based on a consensus calibration of the candidate replacement to the existing IS. This is to ensure that, as far as possible, the biological activity of an IU remains the same even though there may be a different number of IU per ampoule. In a strict metrological sense, the replacement IU is defined by the contents of the ampoule of the new standard. Every effort is made to maintain the continuity of the IU, but the replacement IU is not formally traceable to the 1<sup>st</sup> IS, only to the physical content of the





replacement IS. For this reason, no uncertainty of measurement is applied to the replacement IS.

Reports of many recent collaborative studies, containing details of the results from all participating laboratories and methods, are available on the WHO website, and summaries are often published in appropriate journals.

# 6. What is the expiry date of WHO and other biological reference materials?

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended. Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Storage instructions are shown on the label of the preparation. Where available, stability information about a particular preparation is detailed on the 'Instructions for Use' supplied with the preparation. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

NIBSC follows the policy of WHO with respect to its reference materials. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

For further information contact the appropriate NIBSC scientist or <u>enquiries@nibsc.org</u>

# 7. Are WHO Reference Materials suitable for ISO 15189 validation?

Yes, WHO Reference Materials are suitable for use in validating medical laboratory equipment to ISO 15189 (Medical Laboratories – Requirements for Quality & Competence).

# 8. Can the online catalogue be made easier to use?

This question was asked in our recent customer survey.

NIBSC has a project underway to improve the online catalogue and search facilities. The first stages were put live in 2010/11. The search box on each page is now powered by Google and customers are advised to use this to search for products by key word. Additional searchable terms have been added to each product to further help customers locate products.

# 9. Can I see if products are in short supply?

This question was asked in our recent customer survey.

Most International Standards are restricted to 10 per year to ensure that they last for many years and are not used as working standards. Where products are only available to customers in more limited numbers, we now include this information on the web site on the relevant product page.





# **10.** Can contact details for appropriate individuals be included in the details for each product?

This question was asked in our recent customer survey.

Further information about products is included on the NIBSC web site under the Science Tab. In many cases, scientist contact details are included there. General order enquiries should still be routed to <u>standards@nibsc.org</u>

### 11. Can you supply glass knives for opening ampoules?

This question was asked in our recent customer survey.

Modern ampoules do not require a glass knife as they are easy to open using the plastic breaker supplied. The neck is scored around the constriction and should snap open easily and safely.

As we have products dating back to the 1950's, some are supplied in old style ampoules with no scoring or constriction. For these products we provide instructions on opening and a metal ampoule opener. BEFORE using the opener it is necessary to score the neck with a glass knife.

For many years we were able to supply a small glass knife free of charge with each ampoule but these are no longer manufactured and replacements are too expensive for us to supply free of charge with each ampoule. Suitable glass knives are available cheaply from most laboratory suppliers.

#### Instructions For Use (IFU's)

12. Where can I find Instructions for Use - Data Sheets

Instructions for use / data sheets can be found on our website. Navigate to the relevant Product Detail page via the Product Catalogue or Search box. Then click on the link under the product description. Or use the search box and then filter for <u>Instructions For Use</u>.

# 13. Can more information on unitage and dilution of the material and the origin of materials be included in IFU's?

This question was asked in our recent customer survey.

NIBSC recognises that the information provided in IFU's varies, particularly for old products. We have revised our guidelines for information to be provided in an IFU which should improve new and revised IFU's. Unfortunately with over 2000 products available,



we cannot update them all.



# 14. Can I receive a Certificate of Analysis for the Lot Number of the product supplied?

This question was asked in our recent customer survey.

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards (revised 2004)

http://www.who.int/bloodproducts/publications/TRS932Annex2\_Inter\_biolefstandardsrev2004.pdf

They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.

Certificates of Analysis are available for CE-marked products, but only if indicated as such in the Customer Notes section of the product information.

Most products do not have lot numbers as each product code is unique.

#### **Ordering**

### 15. How can I place an order? What information is required?

#### **New Customer**

New customers will need to complete a 'New account Form' before placing an order and email/fax it to our Sales office.

- New Account form (Word)
- New Account Form(PDF)

# You can place an order on-line on this web site, by email, by Fax or by mail. Orders placed on-line will be processed more quickly. See FAQ <u>Can I place orders</u> <u>electronically or on-line?</u>

- Order Forms for Biological Standards And Reference Materials
- Order Form for Quality Control Reagents (QCR's)

Typically, NIBSC supplies Biological Reference Materials to National Control Authorities/Laboratories, Pharmaceutical and In Vitro Diagnostic Manufacturers, Transfusion Services, Hospitals, Universities and Research Organisations. NIBSC reserves the right not to supply Biological Reference Materials to organisations who cannot adequately satisfy NIBSC





of their scientific remit and/or of the appropriate intended use of the requested materials.

# To process your order, we need the following information, preferably on-line or using one of our order forms:

- Your contact name, organisation name, NIBSC account number, telephone number, email address, fax number, Purchase Order Number, VAT Number if applicable, delivery address and contact details, invoice address and contact details, the product codes for the products you want, the full names of the materials, the quantities required, if you are a National Control Laboratory, and any special instructions for shipping.
- We will acknowledge receipt of your order when it is authorised, within 3-4 days. We would prefer to contact you by email.
- An import licence, if required by your authorities, must be attached to your order.
- In addition, orders for infectious materials must include the following statement:

"I understand that these reagents contain infectious materials. These will be handled only in appropriate containment facilities by fully trained and competent staff in accordance with my national safety guidelines. I accept full responsibility for the use and disposal of the material. (For non-UK recipients) I confirm that these materials may be legally imported without delay in their delivery."

This statement is included on our order forms for infectious materials.

#### 16. Can I place orders electronically or on-line?

This question was asked in our recent customer survey.

A new on-line ordering system was introduced in 2011. This allows you to add products to your basket, view your account, and re-order products you or your colleagues have previously ordered.

Online orders are processed automatically so you will normally receive a Sales Order Number within an hour. They will be checked and processed first on each working day so you should receive your products more quickly, subject to authorisation and destination.

#### On-line ordering is now our preferred route to receive your orders.

Locate the product page from the catalogue or using the Google search box on each page. Login with your account number/username and password(e-mail). Add the product to your basket. You easily can change the quantity and add more products. Then submit your order following on-line instructions.

If you wish to place an order electronically via your local purchasing system, e.g. ARIBA,





please contact standards@nibsc.org and we will do our best to set up a suitable system

### 17. Order Forms for Biological Standards And Reference Materials

We have four different types of order forms to help you provide all of the information we require:

- For general biological reference materials PDF / Word .
- For infectious materials used in NAT assays PDF / Word .
- For infectious materials used in blood virology PDF / Word .
- For infectious influenza preparations PDF / Word .

18. What is the contact point for placing an order?

#### National Institute for Biological Standards and Control

Standards Processing Division Blanche Lane, South Mimms, Potters Bar, Hertfordshire. EN6 3QG UNITED KINGDOM Phone: +44 (0) 1707 641467 Fax: +44 (0) 1707 641064 Email: <u>standards@nibsc.org</u>

# Please do not send orders to personal or any other e-mail addresses as this may delay your order.

#### Please note: We do not accept telephone orders.

For other general enquiries to the Institute please use the following contact points;

Fax: +44 (0) 1707 641050 Telephone +44 (0) 1707 641000 Email: enquiries@nibsc.org

19. What is an account number?







An account number (Ac No) is a unique five digit alpha numeric code allocated to each customer on receipt of their first order. By definition our web site ordering procedure cannot be used by new customers who must place their first order in the traditional manner either by fax or e mail. The unique code will appear on all our documents, usually an X followed by four digits.

It is used as your Username for on-line ordering

# 20. What is my NIBSC Account Number and password?

The NIBSC Account Number is your customer account number which is a single alpha followed by four numerics, you will find this quoted on all ordering documentation issued by NIBSC. It is used as your Username for on-line ordering

Your password is your e mail address (which you have previously supplied to NIBSC).

# 21. How long will it take before my order is dispatched?

Usually, orders with complete information are dispatched within 6 working days. (See FAQ - 'How can I place an order? What information is required?') On-line orders are processed more quickly and should despatch within 2-3 working days Dry Ice and Infectious materials may be deliberately held back by a few days prior to shipment to avoid arrival at the delivery address on a weekend.

# 22. Can I receive a prompt order confirmation?

This question was asked in our recent customer survey.

If you order via our online system or e-mail you will receive an immediate confirmation of order receipt. Users of the on-line ordering system should receive a Sales Order Number within one hour.

Our procedure then requires that each order is verified, permits and licences are obtained, and the responsible scientist authorises that your order may be fulfilled. Once this is completed we will send you an order acknowledgement that we intend sending the products you ordered. This can take 3-4 days. On-line orders are processed first and so receive the order acknowledgement more quickly.

Once the order is picked for despatch, you will receive a pick confirmation e-mail.

If your order is despatched using our normal courier then you will receive tracking details





by e-mail shortly after collection.

If you place your order by fax, you will not receive an immediate confirmation of order receipt but will have to wait until the order is authorised.

Some customers do make repeated enquiries about their order status by e-mail and by telephone. This is very disruptive and slows the processing significantly for all our customers. Please allow a week before checking if your order is being processed as we will normally contact you within this period. We aim to ship all orders within 6 working days of order unless there are delays such as permits, in which case we will inform you.

# 23. Does NIBSC supply to organisations other than the end user?

It is WHO policy to supply biological standards directly to the end-user.

NIBSC supports this policy and, in general, does not supply distributors. However, if you prefer to order through a distributor or an importer, please ensure the order includes a letter or traceable e-mail from the end-user stating they are aware that material can be obtained direct from NIBSC and of the NIBSC handling charge, but prefer to obtain the material via the distributor.

# **Shipping**

24. Do I need an import permit?

Please see the following documents for further information:

Importing NIBSC Reagents .

Importing NIBSC Influenza Reagents .

25. How are the materials dispatched and how much does this cost?

Most of the preparations available from NIBSC are dispatched by standard (air) mail. The cost of this is covered by the handling charge. (See 'How much do the reference materials cost? Does this charge include shipping costs?')

All preparations sent to India, China, Israel, South America and Japan and all orders with a value in excess of £200.00 are sent by courier. The current charge per order for this to UK customers is GB £26 and for overseas customers is GB £58 in addition to the handling charges for the products. Also, when a postal shipment is reported as not delivered, we will then use courier for future shipments.





Infectious materials, and all materials shipped on dry-ice, are classified as 'Dangerous Goods'. Within Europe these can be despatched by courier at a higher fee of approximately £85 per shipment. For other destinations these MUST be dispatched by airfreight at a cost of approximately £250 per shipment.

### Infectious preparations

It is our policy that every order is accompanied by the following statement:

I understand that these reagents contain infectious materials. These will be handled only in appropriate containment facilities by fully trained and competent staff in accordance with my national safety guidelines. I accept full responsibility for the use and disposal of the material. (For non-UK recipients) I confirm that these materials may be legally imported without delay in their delivery.

It is the responsibility of the originator to obtain all necessary import permits/licences needed to accompany the dispatch and to keep NIBSC appraised of any changes in legislation. These permits should be sent to NIBSC at the time of ordering. In addition, any special instructions, such as using a particular broker to clear your customs, should be included. This should avoid infectious or temperature-sensitive materials becoming delayed in your customs.

If you choose to use your own broker then NIBSC liability will cease when the goods are handed over to that broker. You will be responsible for all charges and ensuring that correct storage conditions are maintained if there are any delays.

In addition to the handling charge, there are two additional charges for infectious materials: GB £26 for the certified packaging that must be used with these materials and the shipping charge, which is charged at cost and will depend on destination. If necessary, please ask for a quotation.

#### Dry Ice dispatches (Infectious or non-infectious materials)

In addition to the handling charge, there is a shipping charge for dry-ice dispatches which is charged at cost and is dependent on the destination - please ask for a quotation.

**26.** The standards that I have received are labelled 'store at -20°C. Why are they not dispatched at this temperature?

The majority of standards are freeze-dried so that the biological material is locked into a stable matrix, which enables these preparations to be shipped at ambient temperatures





without a detrimental effect on activity.

For long term preservation of the biological properties of these materials, the majority of preparations are stored at NIBSC at -20°C. If you intend storing the reagents for any time then we recommend that you store them at the storage temperature specified in the IFU.

**27.** Can you supply a tracking number?

If a delivery contact email address is provided with your order, we will let you know when your order is shipped and the tracking number for all shipments sent by courier or freight agent will be sent automatically to you.

28. Can I use my own courier and courier account number?

NIBSC prefers not to book couriers using customers' own account numbers as this requires special arrangements to be made for each shipment.

If you wish to use your own courier account, you need to arrange for the collection of your order from NIBSC by your courier. We will provide you or your courier with a date for collection. Please ensure that your account is authorised for dangerous goods shipments if you are ordering any infectious products or require shipment over dry ice.

In the event that you are utilizing your own carrier, then **all liability will pass from NIBSC to you on collection of the shipment.** 

Please Note:

In view of heightened air security, some carriers will not collect packages from NIBSC if the collection has not been arranged by NIBSC staff.

29. Can I use my own customs broker to clear the shipment?

You may use your own agent or broker to clear a shipment provided you make this clear at the time of order.

If you request the package to be handed over to your local clearing agent or customs broker then we will deliver to that organisation. All NIBSC liability then ends. Onward shipment to your address is then your responsibility to arrange.

If you ask for the shipment to be handed over to your local agent at the port of entry, then it is the local agent's responsibility to re-ice.





It is NIBSC experience that local agents can cause extra charges, delays, or failure to reice. If we deliver door to door then NIBSC takes full responsibility for delays, re-icing, and makes no extra charges, though you will remain responsible for payment of any local taxes. (see **Why do I have to pay taxes or duty on my shipment?)** 

### 30. Can shipments be sent door to door?

This question was asked in our recent customer survey.

NIBSC ships door to door to the delivery address and contact person specified with your order.

If you require delivery to a specific room or person and not to reception/stores in your building, please highlight this in your order instructions. Couriers will tend to leave goods in the specified building and rely on local staff to deliver to the recipient.

If you request the package to be handed over to your local clearing agent or customs broker then we will deliver to that organisation. All NIBSC liability then ends. Onward shipment to your address is then your responsibility to arrange.

# 31. Are dry ice shipments re-iced if delayed?

This question was asked in our recent customer survey.

NIBSC endeavours to ensure plenty of dry ice is included with shipments. We also include a simple freeze/thaw indicator with instructions to show if the shipment has thawed in transit. If a shipment is delayed our shippers are instructed to re-ice as necessary. However, where a customer has asked for the shipment to be handed over to their local agent at the port of entry, then it is the local agent's responsibility to re-ice.

Packages are clearly marked with the international label for dry ice or store at 2-8°C when shipped over ice packs.

# 32. Can dry ice shipments be shipped on a Monday to allow time for customs clearance by Friday?

This question was asked in our recent customer survey.

NIBSC ships dry ice packages on a Monday for short flights, i.e. Europe. For longer flights, they are shipped on a Friday so that they arrive on a Monday and can be cleared during the week.

# 33. Can the financial invoice be included in the package?





This question was asked in our recent customer survey.

For most of our customers the payment address is different from the delivery address so it is not appropriate to include the financial invoice with the shipment. Invoices cannot be printed until despatch is confirmed and are sent out by our finance department on a different site, up to several days after shipment.

### 34. Are documents placed on the outside of the package?

This question was asked in our recent customer survey.

NIBSC routinely attaches a despatch note, commercial (shipping) invoice, and any permits to the outside of the package in a clear plastic adhesive envelope. These are used by the shipping agent and customs to progress the shipment. On rare occasions some or all of the documents do not get replaced correctly, which causes delays.

It is not possible to put a second set of documents on the outside of the package as these too would have to be inspected by the shipper and customs.

Until recently we did not attach these documents to the outside of packages sent by post. In response to customer comments we now do so.

# **35.** Can NIBSC provide more guidance on goods clearance, customs, and shipping requirements for each country?

This question was asked in our recent customer survey.

Unfortunately NIBSC ships to over 80 countries whose regulations are very different and change frequently. We have to rely on customers to contact their local customs department to find out what is required for their own country. We will advise where we can because we regularly ship into a particular country but we cannot publish detailed advice on the web site.

# 36. Can NIBSC documentation be improved to speed up customs clearance?

This question was asked in our recent customer survey.

NIBSC are constantly improving our documentation as issues arise. However we are not familiar with regulations in every country so we rely on customers to tell us what is required. Where we are informed of delays due to documentation, we try to update our documents to avoid future delays. If you have a particular requirement please contact <a href="mailto:standards@nibsc.org">standards@nibsc.org</a>







#### 37. Can my package be clearly labelled "For laboratory use" in my local language?

This question was asked in our recent customer survey.

NIBSC are required to follow IATA guidelines for marks on packages. This prevents us putting on extra labels. We are also not familiar with all languages used by our customers. However we do include this statement in English in the shipping documents on the outside of the package.

### 38. Can my package be marked with the lot number/catalogue number?

This question was asked in our recent customer survey.

NIBSC are required to follow IATA guidelines for marks on packages. This prevents us putting on extra labels. However we do include this information in the shipping documents on the outside of the package.

#### 39. Can my package have the contact person details on the outside of the package?

This question was asked in our recent customer survey.

NIBSC endeavours to include the correct contact person's details and the Purchase Order number on the address label.

Problems can arise where the order is not raised by the end user but by the purchasing department. If your orders are placed by purchasing, please ask the person placing the order to clearly indicate the name of the person who should receive the products. We will then include this on the address label.

#### 40. Why do I have to pay taxes or duty on my shipment?

This question was asked in our recent customer survey.

In general, the tariff code used for NIBSC products is duty free so you should not pay duty.

Many countries will charge local taxes such as VAT on the value of the goods. This is the customer's responsibility to pay promptly to avoid delays.

Even when a shipment is being sent free of charge, local taxes may still be charged on the value of the shipment. It is a legal requirement that NIBSC declare a value for customs based on the normal selling price of the product. This value may then be used for assessing local taxes.

In many cases you can reclaim the tax from your government after delivery.

In some cases taxes are waived if the documentation includes a letter from NIBSC confirming that the goods are a donation for medical research and of no commercial





value. This information is usually included in the shipping invoice but if a separate letter or special wording is required, please contact <a href="mailto:standards@nibsc.org">standards@nibsc.org</a>

# Payment

**41.** How much do the reference materials cost? What are the shipping costs?

The handling charge for reference materials is reviewed annually and any increase applied in April of each year.

The normal handling charge per ampoule or vial is GB £74.00 or £77.00 Working standards (see 'What are working standards') are charged at GB £20.00 each in multiples of 5 ampoules or vials total £100.00. Panels are charged at GB £147.00\* \*there are exceptions which will cost more.

All orders outside the UK with a value in excess of  $\pounds$ 200.00 will be shipped by courier at a minimum charge of GB  $\pounds$ 55.00.

Please note, from 1st April 2004 NIBSC will issue invoices for biological standards only in sterling pounds (GBP), the national currency of the UK where NIBSC is located.

The alternative prices in Euros and US Dollars will no longer be offered.

Customers who use other currencies for international transactions should consult their banks about the best way to pay sterling invoices at the current exchange rate. Customers are responsible for paying all bank charges associated with paying our invoice in full in GBP.

# **IMPORTANT:**

- There are additional costs associated with the dispatch of infectious materials, those sent on dry-ice and those requested to be sent by courier - See FAQ ' How are the materials dispatched and how much does this cost?'
- For UK customers. VAT is charged on the total charges unless you have a certificate of exemption from the VAT authority.
- For non-UK EU customers. If your VAT number is not supplied, NIBSC has to charge UK VAT on the total charge unless you have a certificate of exemption from your VAT authority. You can reclaim UK VAT from your VAT authority.





42. How can I pay for my order?

Following the dispatch of your order, we will send you an invoice. Payment can be made by cheque or telegraphic transfer:

- By Cheque or Bank Draft for invoices issued in GB Sterling. •
- GB Sterling cheque or GB Sterling bank draft drawn on a UK bank
- Please make sure that the Financial Invoice Number is clearly included with your payment. This will have the format SI12345.
- Make payments payable to GBS re MHRA NIBSC and send to:

NIBSC Accounts Receivable Team, Public Health England, Manor Farm Road, Porton Down, Salisbury, Wiltshire SP4 0JG E-mail remittancesnibsc@phe.gov.uk

# Payment by credit card

NIBSC can accept payment of FINANCIAL invoices by credit card.

Telephone +44 (0) 1980 619918 to pay by credit card.

# **Payment by Telegraphic Transfer**

Instruct your bank to transfer funds to:

Payee:	GBS re MHRA NIBSC
Bank:	Citibank N.A.
Sort Code:	08-33-00
Account Code:	12939959
BIC/SWIFT:	CITIGB2L
IBAN:	GB70CITI08330012939959
Bank Instructions:	<b>Give details of the NIBSC Invoice number.</b> All bank charges incurred when paying are paid

by the originator.

Medicines and Healthcare Products Regulatory Agency





### 43. Can I pay for my order by credit card?

This question was asked in our recent customer survey.

Payment by credit card at the time of placing an order is not possible. Not all orders are authorised. For example the quantity may be reduced or there may be a replacement product. In addition the cost of shipping varies depending on the location and nature of the products.

NIBSC can accept payment of issued financial invoices by credit card. Telephone +44 (0) 1980 619918 to pay by credit card

### 44. Do National Control Authorities (Laboratories) pay charges?

The handling charge is not applied to International Standards or to any Influenza standards ordered by National Control Authorities (Laboratories). There is a limit of 10 units of each IS per year. NIBSC reserves the right to charge the full handling fee for units ordered above 10 per International Standard.

However, National Control Authorities (Laboratories) do pay the handling charge for all non-International Standards (except Influenza standards, as stated above), and all shipping charges for items that cannot be dispatched by (air) mail.

# Complaints

#### 45. What do I do if there is a problem with my shipment?

Please contact <a href="mailto:standards@nibsc.org">standards@nibsc.org</a> as soon as you discover the problem.

You will be informed when the goods are dispatched so please contact us immediately if they do not arrive as expected.

Please check your order carefully on receipt as we cannot take responsibility for missing, incorrect, or broken items if we are not informed in writing within 14 days of receipt.

Please check the package carefully for missing items as there may be several smaller packages within the shipping container.

#### 46. How do I make a complaint / give feedback?

All complaints are investigated by NIBSC and should be sent in writing (email, fax or letter) to the contact point for placing orders (What is the contact point for placing an order?).





Please send any feedback on our products / services to the contact point for placing orders (What is the contact point for placing an order?).

