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Q&A

International Shipping FAQ's

Q1. Are there any special procedures, regulations, and/or permits required for shipping samples from outside the United States?

A. Yes.

Please download and print the [CDC Import Permit](#) located on the [Forms Page](#) of our [website](#). Attach the CDC permit to the outside of the shipping container.

Foreign clients are responsible for ensuring that samples are shipped in accordance with mandated shipping regulations. Foreign clients are also responsible to ensure that samples are shipped in accordance with regulations that are mandated by the Centers for Disease Control (CDC), United States Customs, the United States Fish & Wildlife Service (US F&WS), the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Proper permits must be obtained before shipping samples that are collected from any non-human primate. More information is located on the website. It is the policy of the B Virus Resource Laboratory that these requirements MUST be met in all cases.

A CITES export permit will be necessary if you are shipping non-human primate samples. Please visit the CITES website <http://www.cites.org/eng/app/appendices.shtml> where you will see that all non-human primates are listed under Appendix II of the Convention. As a

result, you will be required to obtain a CITES Export permit from the Management Authority responsible for implementation of CITES in your country before shipment of any samples to the U.S.. Under CITES, blanket permits for such exports are authorized and in some countries they are available. If they are not available, it will be necessary to obtain an individual export permit before shipment to the U.S. Failure to obtain the appropriate permit can cause serious problems in the U.S. Unless you are already familiar with the requirements, you should check with your local Management Authority to determine the appropriate requirements. If this CITES permit is not properly completed and attached to the exterior of the shipping container, it is possible that your shipment may be detained when it enters the U.S.

If the species is listed on Appendix I of CITES (i.e. *Macaca silenus*, A.k.A. lion tailed macaque), then please contact our laboratory. You will still be required to obtain a CITES Export permit, but in addition, we will be required to supply you with a copy of a CITES Import permit, which we are currently attempting to obtain. Both the Export permit and a copy of the Import permit must be affixed to the exterior of the shipping container.

Please contact our laboratory with any inquiries you may have regarding procedures, regulations, and/or permits.

Q2. When shipping non-human primate samples from outside the United States, are there any special documentation requirements?

A. Yes. The term "CITES" must be the first item listed in the airway bill description. Please include two sets of all documentation (CITES permits, CDC permits, etc). Include one set inside the package, stored dry and separate from the sample (in a "zip-lock" type bag). And include one set attached to the exterior of the package in a document pouch.

Domestic Shipping FAQ's

Q3. Should we ship on Friday, or store the specimens and ship them on Monday?

A. Human and non-human primate (NHP) baseline virus cultures should be shipped on Friday for Saturday delivery. It is clinically important for the patient to have these samples tested as soon as possible. We have technicians available on Saturday to accept packages. Culture samples received will be plated on Saturday. Serum samples received will be tested on Monday. There are no courier services available for Sunday delivery.

We have had some difficulties with Saturday deliveries. To help alleviate these problems, please be sure to ship for "Saturday Delivery" only with Federal Express. Be sure to mark the package and the shipping form for "Saturday Delivery". Do not mark the form for "Next Day Delivery", Federal Express considers this as the next business day and the package will not be delivered until Monday. Federal Express offers "Saturday Delivery" stickers for these packages to make them easier to identify. Also be sure to notify our offices on Friday by phone, fax or email to alert us of the delivery and to provide us with the Federal Express tracking number. This information is required for our staff in attempting to trace a package that may not arrive as expected.

Q4. We collected the samples, but then they did not get shipped as scheduled. Are they still acceptable?

A. Virus cultures can be stable in a refrigerator for up to one week. If they are stored at $\leq -60^{\circ}\text{C}$, they may be stable for a month or longer.

Serum samples can be stable in a refrigerator for up to one week. If they are stored at $\leq -20^{\circ}\text{C}$, they may be stable for several months.

Sample Collection FAQ's

Q5. Why do I need to take 2 serum samples from an individual who has been potentially exposed to B virus as a result of an injury?

A. Two samples are recommended because the first one represents antibodies you have at the time of an injury. In most sera there will be no evidence of B virus antibodies present at this time. The second sample is evaluated along with the first sample so that a comparison can be made between the two. The first sample is the baseline and the second is called a convalescent serum. If there is no difference between the two, your physician will tell you that you are not showing any signs of being infected. If there is a difference, but you are having no symptoms, your physician may discuss with you whether you wish to be treated, because the presence of antibodies in the second sample suggests that you were infected, probably at the time of the injury for which a baseline sample was collected.

Some infected individuals already have antibodies, but the second sample will determine if there has been recent activity by the virus. A 2-4 fold increase alerts you to recent, acute virus replication and antiviral therapy then becomes important.

Complete information on patient management for B virus exposure is located on the [Forms Page](#) of our [website](#). Please download and review the [2002 B Virus Guidelines](#).

Q6. Why can't I take swabs from the monkey associated with an injury 1-2 days or more after the incident?

A. Swabs taken immediately after an incident inform you of whether the macaque was shedding virus at that time. Taken several days later, or even several hours later can result in misinformation, because animals may shed intermittently. Rarely, there are animals that have prolonged bouts of shedding, but in general, what you wish to determine is whether there is virus being shed at the time you were around the macaque. It is recommended that NHP swabs be collected within 4 hours of an exposure.

Q7. If an injury occurs on late Friday, a weekend or a holiday, how do we store the samples until they are shipped?

A. Virus culture samples can be stored in one of two methods for optimum virus recovery. Either store the samples in a refrigerator (2 to 4°C) or store them at $\leq -60^{\circ}\text{C}$. Please do not store them at -20°C .

Serum should be separated from the blood clot into a non-glass tube and can be stored in a refrigerator or frozen at $\leq -20^{\circ}\text{C}$.

Q8. We do not have any Viral Transport Media (VTM) or the media that we do have is expired. What do we do?

A. For optimum virus recovery, we recommend the use of commercially prepared VTM, such as the options that are listed on the web page (Instruction Sheet). There are also a few “home made” options available when this is not possible.

Q9. The policy at our institution is to immediately place exposed employees on prophylaxis treatment. Does this affect the recommendations for sample collection?

A. Yes. It is recommended that a second convalescent serum sample be collected 14 to 21 days post medication. This means a total of three serum samples for patients prescribed anti-viral treatment. 1- baseline serum; 2- first convalescent serum collected 14 to 21 days post injury; 3- second convalescent serum collected 14 to 21 days post medication.

B Virus FAQ's

Q10. Will antibodies against B virus protect me from future infections?

A. Antibodies against B virus are generally not protective in the sense that they will prevent another infection or even a reactivation of a latent infection. This situation is similar to what is seen for herpes simplex infections. High levels of antibodies to HSV do not prevent the development of fever blisters periodically.

Q11. Where can we get Medical Alert cards to carry to alert medical personnel to the fact that we work with macaques?

A. We provide Medical Alert cards to any interested individuals or groups. These cards were designed by Dr. Terry Blasdel and provide information in the event of need. The [Medical Alert card](#) can be downloaded from the [Forms Page](#) of our [website](#).

Q12. Why should I consider carrying a Medical Alert card indicating that I have been around macaques?

A. In the past, individuals who have been infected by B virus, but not treated early enough to prevent fatality, have shown up in emergency rooms disoriented, distressed, and unable to provide useful information to medical personnel. These cards will alert health care workers to the fact that you work or have worked with macaques. As a result they can order tests that can quickly rule out whether your symptoms are due to B virus.

Q13. Are there any drugs that effectively eliminate B virus from an infected individual?

A. There are no drugs that will eliminate B virus from an infected individual. Drugs such as acyclovir, famvir, ganciclovir can, however, be used to control infection and prevent the development of severe infection and death. We are working to identify new drugs that will be effective at later stages of infection, but it is not likely that any drug will ever completely eliminate virus from the body because it hides out effectively in a state of latency.

National B Virus Resource Center FAQ's

Q14. What kinds of educational programs does the National B Virus Resource Center offer?

A. The staff of this Comparative Medicine Resource Center can provide in-service workshops on site for employees, access to all published literature about B virus for historical perspective, collaborations on interesting research topics, guidance for retrospective analyses, and resources for evaluating macaques to determine whether they are infected with B virus. The Resource also provides resources for studying other nonhuman primate herpesviruses. The [website](#) offers comprehensive information for injury response and answers to general questions posed to the resource staff.

Q15. Why does the laboratory charge for samples they test?

A. Test charges pay for testing materials and personnel who perform analyses on serum and swab samples. This laboratory is provided to you through NIH's National Center for Research Resources Comparative Medicine Program. NIH funds some of the staff, but your payment makes up the difference, insuring that trained staff are present at all times and supplies are available to analyze incoming samples and that all necessary tests can be run on your samples. The B Virus Resource Center is a nonprofit activity. The staffs are committed to not only test your samples, but to use the resultant data to learn to prevent B virus infections or control them in the event prevention fails, store your samples in the event you need a future analysis, and assist medical staff in the event that you develop symptoms later.

Q16. What are the current testing charges?

A. \$60.00 per sample for antibody analysis; \$40.00 per sample for virus isolation analysis; \$200.00 per sample for PCR analysis.

Q17. Why can't I get you to give me results over the phone when I call?

A. When you send samples for evaluation you fill out a submission form that lists the name of the person you wish the results to be given. No one else is authorized to receive your results, and CLIA regulations are followed to insure confidentiality. If we were to give someone other than the listed individual results we would lose our CLIA license to test. If you wish for some additional party to receive your results, you may fax a signed request to Dr. Julia Hilliard, (404) 463-9951 or email the request to bvirus@gsu.edu.

Q18. Why don't other labs test humans for B virus antibodies?

A. B virus testing requires a BL-4, or Maximum Containment Laboratory, because large amounts of B virus are used to run ELISA and western blot assays. B virus is also classified as a Select Agent by CDC/USDA, as a result of precautions taken following 911. Thus, an FBI security clearance is required for all members of the lab. A false positive result or a false negative result can be very damaging and result in significant distress for a patient. With all the regulations and the need for precision, other labs are not investing in testing humans. B virus is an orphan disease in that it happens rarely, and as such a specialty lab is often the most prudent way to handle potential exposures, active cases, and monitoring for recurrent infections.

Q19. When can we get recombinant B virus antigens to use in our own labs?

A. Recombinant B virus glycoproteins are presently being studied to determine the best combination of these proteins for detection of a broad range and level of antibodies. Once we es-

establish the ideal approach for use of recombinant proteins in diagnostic tests, we will prepare large lots of these antigens. The average time for preparation of each lot is 3–5 months for each protein. Meeting the laboratory’s need will be first priority, and subsequently we will be able to make these available to laboratories that wish to perform tests onsite.

Q20. If I’m injured on a Sunday morning, can I wait until Monday when I can get someone at the lab to answer my questions?

A. You can reach Dr. Hilliard at any time 24/7/365 by calling (404) 358–8168. In the event you are asked to leave a message, your call will be promptly returned.

Q21. What should I do if it is a holiday and I need to find out my results?

A. Call our 24/7/365 numbers in the event you need emergency assistance

Q22. What are the sensitivities and specificities of your assays?

	Sensitivity	Specificity
Western Blot	96%	92%
ELISA	98%	95%
Virus Isolation	70%	N/A*
PCR	**	100%***

*: Will detect several types of virus. Non–negatives are confirmed by PCR.

**: Will detect 10 to 20 copies of viral DNA.

***: Can also currently test for HSV–1, HSV–2, SA8, and HVP–2 with 100% Specificity for each.