

Herpes Western Blot Serology Testing

Welcome to your Herpes Western Blot Serology testing information packet. This packet includes patient instructions, frequently asked questions, University of Washington billing services and policies, a letter to your provider, the Virology Clinical Lab Request form, a letter to the lab, and information regarding specimen collection and shipping supplies. This packet will help you provide necessary information to your provider and then to the laboratory to help them decide if they can order/collect this test for you.

Patient Instructions

Step 1: Getting an order from your provider.

- Bring the provider letter and Virology Clinical Lab Request form to your provider.
- This test must be ordered by your provider. A specimen cannot be accepted without a Virology Clinical Lab Request form filled out by your provider.
- Your provider should help you find an appropriate lab to draw your blood. You will need to submit the request form when you visit the lab for your blood draw.
- Talk to your provider about how they plan to notify you of your results.

Step 2: Having your blood drawn at a lab and sent to the University of Washington

- Freeze the ice pack included in your kit before your blood draw.
- Bring the laboratory letter, completed Virology Clinical Lab Request form, and kit with ice pack to the lab for your blood draw.
- Have a check or money order ready to include with your specimen. (See payment information on the back of this sheet).
- The cost of shipping the specimen to the University of Washington is <u>not</u> included in your kit and is <u>not</u> covered by UW. The specimen needs to be shipped overnight and the lab drawing your blood may require you to pay for shipping. You will need to make arrangements with the lab drawing your blood.

Step 3: Receiving Results

- Your provider will notify you of your test results within 3 weeks.
- To find out if your specimen arrived in the lab you may track the package through the shipping company or contact your provider.

Additional information on the back of this page

Additional Information

Please note: It is recommended that the patient waits at least 3 months from the time they may have been infected to be tested.

Step 1: Getting an order from your provider

The University of Washington cannot accept specimens without an order from a provider. This packet contains all the information and resources your provider may need to decide if this test is right for you. The ordering provider's name and NPI (National Provider Identifier) number need to be legibly written on the Virology Clinical Lab Request form. Specimens submitted without a UW Virology Clinical Lab Request form, or valid NPI number, will be rejected. If your sample is collected by a provider in the State of New York, a special permit must be obtained by the provider and forwarded to UW with your sample. The UW cannot accept your sample without this restricted laboratory permit issued by the NY Department of Health (DOH).

Step 2: Blood draw and shipping

Ask your provider which lab you should visit to have your blood drawn. Your provider will most likely have agreements with labs and will be able to help you find a lab to draw your blood. If you are looking for a lab on your own, ask the lab if they can draw "outside orders" for patients. Once drawn, the specimen will need to be sent to the University of Washington via overnight shipping with the sender responsible for shipping costs. The three most common ways to send a specimen are: 1) the laboratory sends the specimen to us, 2) the laboratory gives the specimen to the patient and the patient sends the package to the University of Washington overnight, or 3) the patient brings a pre-printed shipping label with them to the blood draw for the lab to send the packaged specimen. Shipping arrangements will need to be discussed between you and the laboratory collecting your blood.

Step 3: Receiving Results

Your results are Protected Health information. We cannot give any information over the phone including whether or not we have received your specimen. Refer to the shipping company's tracking number to know if the package has been delivered. The fastest way to receive results is through your provider. During your initial provider visit, ask how you will be informed of your results. The only way that a patient may receive results through UW Laboratory Medicine directly is with a written request submitted on the "Patient Authorization to Disclose, Release and/ or Obtain Protected Health Information" request form. The patient must submit the request form along with a copy of their photo ID. It could take up to 3 weeks after receiving the request form for the patient to receive test results in the mail. You may print this request form from our website at http://depts.washington.edu/labweb/. Your request form will be rejected, if the request form is not properly filled out, the patient's photo ID does not accompany the form, or we are unable to verify the information.

Payment information

The price for the first Herpes Western Blot test with UW is \$253.31. A second sample may be required for follow up testing. Your provider will make the determination if follow up testing is needed. If this is the case, the first sample will be repeated along with a second sample. This is called paired testing and the price of running the paired sample is \$409.13. You may send a check or money order with the specimen or contact Client Account Services at 206-616-8900 to pay by credit card.



FREQUENTLY ASKED QUESTIONS

1. Do I need a provider's order to have my blood drawn?

Yes. Samples will be rejected without an order from your provider. Refer to Step 1 in the patient instructions section.

2. How can I receive my results?

Your provider will receive results either by mail or fax.

3. When can my provider expect results?

Your provider will receive results anywhere between two to three weeks.

4. What should I do with the cold pack?

Freeze the cold pack and take the frozen pack with you for the blood draw. Refer to step 2 in the patient instructions section.

5. What tube would the lab use to draw my blood?

The laboratory will accept serum collected in a gold top (included in kit), red top, or serum separator tube (tiger top). Please see "Laboratory Letter" for additional specimen processing instructions.

6. Inside the kit, there is a white label. What should I do with this label?

This label is to be completed with patient name and date of birth and then placed on the tube containing the blood. Please have the lab refer to the attached "Specimen Labeling and Acceptance Policy" page of this packet for additional information.

7. How do I pay for the test?

You may include a check or money order with your specimen at the time of shipment. This can be paid to University of Washington Medical Center. To pay by credit card, please refer to the "Billing Services and Policies" page in this packet for more information.

8. Do you have a list of clinics / laboratories in my area that would be able to draw my blood?

No, we do not keep a list of clinics or laboratories for patient blood draw. Check with your provider or call any local laboratories that will draw and process your sample.

9. Can the results be mailed to my home address?

Yes, please refer to the Receiving Results section of the Additional Information page. However, the fastest way to receive results is through your provider.



BILLING SERVICES AND POLICIES Herpes Western Blot Serology Test

For patients outside of Washington state:

Client Account Services is not able to provide third party (insurance) billing for patients outside the state of Washington. The patient may pay for services rendered at the time that testing is submitted by either including a money order or personal check for \$253.31 inside the kit provided. Check or money order can be paid to University of Washington Medical Center. Credit card payments may be made by calling 206-616-8900. Cash is not an acceptable form of payment.

If complete patient information &/or prepayment is not received, our default is to bill the client (sending location) for the testing performed.

Third party billing can be provided for Washington state clients. In order to have claims submitted to local insurance carriers please record the following information on the request form(s):

- 1. Patient's complete mailing address
- 2. Patient's phone number, including area code
- 3. Insurance name and address
- 4. Subscriber name
- 5. Subscriber ID and Group Numbers (Please include any alpha letter prefix with the subscriber ID number)
- 6. ICD-10 diagnosis code
- 7. Ordering provider's first and last name
- 8. Ordering provider's NPI (National Provider Identifier)

If possible please submit a front and back copy of the patient's insurance card with the request form.

Medicaid: Please include a signed copy of the patient's Medicaid coupon for the current month.

L&I: Please include the patient's claim number. If private L&I coverage is used please provide name and address of carrier.

Questions: Contact Client Support Services at 1-800-713-5198.

This information will expedite processing, resulting, and billing.



PROVIDER LETTER Herpes Western Blot Serology Test

Dear Ordering Provider:

You are receiving this letter because your patient has requested a Herpes Western Blot Serology test kit through the University of Washington. Although we send these test kits out to anyone who requests, an order from a provider needs to accompany the sample in order for us to process testing. The "Patient Instructions" included in the information packet direct the patient to bring this letter to their appointment to discuss testing options. If this test is new to you this letter will have some great resources to tell you about our Herpes Western Blot Serology testing and you may want to visit our herpes website for additional information at http://depts.washington.edu/herpes/.

Ordering the test: Please complete the attached UW Virology Clinical Lab Request form in its entirety. Please include the clearly written name and NPI number of the ordering provider; this information is required to complete testing. If you are a provider in the State of New York, you must also obtain a restricted laboratory permit from the NY Department of Health and this permit must accompany the sample. Please ensure there are two patient identifiers on the form. The most common forms of patient ID are name and date of birth. Select the first test in the bottom box on the right side under "Herpes Group" named "HSV 1& 2 Antibody by Western Blot" on the Virology Clinical Lab Request form for the Herpes Western Blot Serology. Testing may be delayed if the test is not clearly marked.

Receiving results: Test results will be received by the ordering provider between 2-3 weeks from the testing date. Results of sexually transmitted disease testing can only be faxed if the ordering location has a Secure Fax Form on file with Client Support Services. The patient should receive results through the ordering provider's care team. Contact information for the ordering provider should be added under "send report to" on the Virology Clinical Lab Request form. Please enter contact information for the ordering provider's department that handles results. All information must be clearly legible. Please be aware that we cannot confirm sample receipt or discuss test results with the patient over the phone.

Future testing with UW: The University of Washington is the only lab performing the current gold standard Herpes by Western Blot Serology testing. As a courtesy to the patient we supply test kits to anyone who asks. However, the test kit is not necessary to order this test. There are no special tubes or processing requirements. If you are interested in future Herpes Western Blot Serology testing or any other testing with the University of Washington you can access the test catalog and all the requisitions for our different labs at http://depts.washington.edu/labweb/. Under "Reference Lab Services" you will see "Online Testing Guide" and "Test Order Forms".

Please note that if complete patient information &/or prepayment is not received, our default is to bill the client (sending location) for the testing performed.

We hope you find this letter and website to be informative. Please contact Client Support Services at 1-800-713-5198 if you have questions regarding testing with us. If you have technical questions about the Herpes Western Blot Serology, you may contact the Virology Research Line at 206-520-4340.

Sincerely, Client Support Services Team

Additional test information on the back of this page

Additional Herpes Western Blot Serology Test Information

Background

Accurate assays to detect antibodies to HSV-1 and HSV-2 are useful to diagnose subclinical infections and to supplement virus detection methods in cases of atypical presentation or when sampling conditions are not optimal for virus recovery.

CDC guidelines stipulate that only a type-specific serology based on glycoprotein gG2 be used. Even commercial, FDA-cleared ELISA tests may have false positive results for HSV type 2 antibodies, especially in samples with low positive readings. In addition, false negative HSV type 1 antibody results occur because the ELISA tests are less sensitive than HSV Western blot.

The HSV Western Blot uses HSV-1 and HSV-2 proteins which have been separated by size so that type-specific antibody profiles can be recognized with a specificity of >99%. This method may be used to distinguish maternal from infant antibody profiles and to distinguish serum and cerebrospinal fluid profiles of HSV antibodies. This test has been exhaustively validated in studies of well-characterized patient populations. It is the current gold standard HSV serology and provides a highly accurate confirmatory test for results by ELISA.

The University of Washington offers paired testing for convalescent specimens. It is recommended to wait at least 3 weeks to collect a convalescent specimen. For more information on ordering paired testing contact Client Support Services at 1-800-713-5198.

References

Centers for Disease Control and Prevention. Sexually transmitted disease treatment guidelines 2002. MMWR 2005;51:1-80.

Morrow RA, Friedrich D. Inaccuracy of certain commercial enzyme immunoassays in diagnosing genital infections with herpes simplex virus type 1 or 2. Amer J Clin Pathol 2003; 120:839-844

Morrow RA, Friedrich D, Meier A, Corey L. Use of biokit HSV-2 rapid assay to improve the positive predictive value of Focus HerpeSelect HSV-2 ELISA, BMC Infect Dis 2005; 5:84.

PT NAME (Last, First) PT D.O.B. Approved and current. Effective starting 2/6/2019. R PT NAME (Last, First)			CLINICAL LAB REQUEST University of Washington Medical Center 1959 NE Pacific St, NW 220 Seattle, WA, 98195	220			
			REFERENCE LABORATORY SERVICES (206) 520-4600 Specimen Questions, Pick-up, Results/Billing http://depts.washington.edu/rspvirus	BY:			
			Virology http://depts.washington.edu//abweb				
			Universal transport media (liquid) recommended. No microbiology gel for viral cultures. Flocked swabs (mini-tipped for NP swab) recommended. No foam swabs for viral cultures. Culturette recommended for PCR detection from mucosal surfaces.				
		F 🗆	4. Reflex tests * instructions can be found on back. Additional charges will be incurred for reflex testing.				
ORDERING PHYSIC	CIAN	NPI#	MOLECULAR VIROLOGY Herpes Viruses (serum, plasma, fluids) Other Viruses (serum, plasma, fluids) Tissues, Bone Marrow, Swabs, Other Bi	iopsies			
OF LIDER OR OUT			CMV by DCD Quart Eve Eluid** CMVEVE ARRIVED AR	DVQLT			
SENDER SPECIMEN #			CMV Regist III 56	BKVQL WVQ.T			
			CMV Resist. UL97 and UL54 BK VIRUS DNA by PCR (Urine) BKON FRV by PCR Owl	EVQLT			
DATE & TIME COLL	LECTED	☐ AM	CMV RESISCULS/, ULD4 and ULD0 CMVULR	1S12QL			
		☐ PM	CHIT DJ TOT GOOD.	H6QLT			
<u> </u>	Serum	☐ Whole Blood	BBV by PCR, Quant. BBVQ INFLUENZA A/B & RSV by PCR LBDV HHV8 by PCR Qual	HH8QLT			
	Plasma	Urine	EBV by PCR, Quant Blood Spot EBVESQ JC (PML Virus) by PCR Parvn B19 by PCR Qual :	B19QLT			
Specimen Type	☐ CSF	☐ Stool	HHV6 Chromosome Integration HHSABC JC (PML Virus) by PCR, Quant., Urine SCOVEN Tissue Viral Identification HHV6 by PCR, Quant. HHSON PARVO B19 DNA by PCR B19PCO Tissue Viral Identification	TVIRDE			
	Other:		HHV6 by PCR, Quant, with Reflex H-5855 PRESDIRATORY VIRILIS PANEL by PCR.				
			to HHV6 Chromosome Integration STOOL VIRUS PCR PANEL SVIPCR — VZV by PCR, Qual.				
Acute Serur			HHV8 by PCR, Quant. HH8CN ZIKA by PCR ZIKA	ZVSWE			
	Convalescent (requested	by Virology)	HSV1 & HSV2 by PCR, Quant. HSV20N RESP. VIRUS Follow-Up, PCR, Quant. RESP. VIRUS Follow-Up, PCR, Quant. Hepatitis Viruses (serum, plasma)				
ICD/DIAGNOSIS			Virus to testFluBMPVPIV3RSV HBV Drug Resistance by Sequencing	HBVDR			
R			(This is not a screening test, must be known positive)	BVGDR HBVGT			
CEND DEDORT TO	(Hospital, Clinic, Physic	nion)	nbv Genotype Sequence				
SEND REPORT TO	(nospital, Clinic, Physic	ciaii)					
			HCV RNA Genotype				
D			Notice at the second of the se				
			** Viral Quant Panel, Eye Fluid (CMV, HSV, VZV)				
			The weather ends by the Country to the terms of the terms				
			HIV				
TELEPHONE			HIV Screen (HIV1 Ag, HIV1/2 Ab) (with confirmation of reactives) HVAGAB — HIV-1 P24 Antigen Quantitation HIVFS				
FAX			HIV-1 RNA Quantitation HIV-1 Total Nucleic Acid Assay (Qualitative)				
Fax Results? Yes No			hIV-1 Genotypic Resistance (Call 206 685-8037) HIVGRA HIV-2 RNA Quantitation	HV2VL			
PATIENT ADDRESS			HIV-1 Integrase Resistance (Call 206 685-8037) HVINTA — HIV-2 DNA/RNA, Qualitative				
CITY	STATE	ZIP	VIRAL CULTURES 2VIRO VIRAL RAPID ASSAYS ("shell vials") 2VIRO				
			Viral Culture (Complete ID, respiratory,enteric,herpes group) Adenovirus (includes viral culture)				
TELEPHONE			Herpes Group Culture (HSV1/2,CMV,VZV) — CMV (includes herpes group culture)				
			Tissue - Immunocompromised pt (Viral Culture & CMV Rapid Assay)				
SUBSCRIBER NAM	E		Identification of Outside Isolate				
SUBSCRIBER ID. #			SEROLOGIES HERPES GROUP				
			HEPATITIS HSV 1 & 2 Antibody by Western blot				
GROUP#			A Antibody (IgM) HAV/GV HSV SeroconversionPanel (paired sera)				
			A Antibody(IgC)				
Premera Blue Cros	s Regence DS	SHS (attach current coupon)	b surface Artiger				
•			B Surface Antibody HBSA Waricella ZosterTiter (paired sera)				
Medicare (answer required to question below)			B *e* Antigen / Antibody MISCELLANEOUS				
Is this a hospital outpatient or inpatient?			O A-shada				
Yes No							
(see reverse for additional information) OTHER INSURANCE NAME/ADDRESS							
OTHER INSURANC	E NAME/ADDRESS		Rubella Immune Status OTHER REQUESTS / COMMENTS	ulb			
			OTHER REQUESTS / COMMENTS				
4			8.2 .				
			MEDICAL NECESSITY INFORMATION				

MEDICAL NECESSITY INFORMATION

When ordering tests for which Medicare reimbursement will be sought, physicians should only order tests which are medically necessary for diagnosis or treatment of the patient. You should be aware that Medicare generally does not cover routine screening tests, and will only pay for tests that are covered by the program and are reasonable and necessary to treat or diagnose the patient.

CMS MEDICAL NECESSITY INFORMATION

It is our policy to provide health care providers with the ability to order only those lab tests medically necessary for the individual patient and to ensure that the convenience of ordering standard panels and custom profiles does not impact this ability. While we recognize the value of this convenience, indiscriminate use of panels and profiles can lead to ordering tests that are not medically necessary. Therefore, all tests offered in our panels and profiles can be ordered individually as well. If a component test is not listed individually on the request form, it may be written in the "OTHER REQUESTS" box. We encourage you to order individual tests or a less inclusive profile when not all of the tests included in the panel or profile are medically necessary for the individual patient.

Medicare Billing Information

Medicare billing policy prevents us from submitting a Medicare claim for laboratory testing referred to us on hospital inpatients or hospital outpatients. For these samples, we will bill the sending location.

*Reflexive Test Descriptions

CMV with Drug Resistance Testing (UL97 and UL54 Genes)

Sample will be tested for CMV. If the CMV, Quant. is positive by PCR, a UL97 and UL54 resistance is performed. This test can also be ordered without reflexive testing (CMVQN).

HHV6 PCR Quant w/reflex to HHV6 Chromosome Integration

If the HH6 Quant is positive by PCR, HHV6 Chromosome Integration is performed. This test can also be ordered without reflexive testing (HH6QN).

HIV Screen with Reflexive Confirmation testing

Reactive HIV Screens (HIV1Ag, HIV-1 and 2 Ab) are confirmed in accordance with the CDC recommended 4th generation algorithm. Possible confirmatory assays include the Geenius HIV-1 and 2 Antibody Supplemental assay, HIV-1 RNA and HIV-2 RNA.

Hepatitis C Antibody

If Hepatitis C antibody is positive, Hepatitis C RNA by PCR is performed. This test can also be ordered without reflexive testing (HCABX).

Hepatitis B Surface Antigen

If Hepatitis B surface antigen is positive, Hepatitis B DNA Quantitation is performed. This test can also be ordered without reflexive testing (HBSAGX).

UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE

Client Support Services Division
UWMC Department of Laboratory Medicine
1959 NE Pacific Street, Rm NW220
Seattle, WA 98195
(206) 520-4600 or 1-800-713-5198

Specimen Labeling and Acceptance Policy

In order to meet TJC's Patient Safety Goal, Client Support Services requires our clients to have at least **two unique patient identifiers** present on every specimen's label. The most common and appropriate patient identifiers are:

- Name
- Birth date
- Social Security Number
- Assigned Patient ID number
- Assigned Specimen ID number

The patient's floor, clinic, or hospital ID numbers are **not** valid identifiers. The identifiers used must appear on **both** the specimen and the requisition.

In addition, each patient's specimen(s) and requisition sheet must be contained in a **single**, separate specimen bag. We cannot accept specimens and paperwork from multiple patients if they are gathered together in a single bag.

The ordering provider's name and NPI (National Provider Identifier) must be included on the requisition.

We will notify you promptly if discrepant specimens or paperwork are received in our processing area.

We would like to take this opportunity to thank you for your continued support of the University of Washington Department of Laboratory Medicine. It is always our goal to provide you with the highest quality laboratory testing available.

We look forward to continuing to meet your laboratory needs. Please contact us with any questions or concerns at 1-800-713-5198.

Sincerely,

Client Support Services Team

Angela Yu Client Support Services Supervisor Rus Sullivan Client Support Services Manager



LABORATORY LETTER Herpes Western Blot Serology Test

Dear Laboratory:

You are receiving this letter because the patient has requested a Herpes Western Blot Serology test kit from the University of Washington and has obtained an order from their provider. The patient will provide you with this letter and the completed request form which will help you decide whether your lab will be able to draw and process the patient's blood. The patient will be responsible for payment of this test directly to the UW. All communication regarding this blood draw, including results, will be through the ordering provider. Cost of shipping is not covered by the University of Washington, and will need to be arranged between the patient and the lab processing the specimen.

Review the requisition: Please review the UW Virology Clinical Lab Request Form to make sure it includes two patient identifiers, the ordering provider's name and NPI number, and the ordering location's address and phone number. The lab needs to fill in the "Date & Time Collected" and "Specimen Type" on the request form. You may also include the specimen # if there is one. (See Specimen Acceptance Policy on the back of this sheet)

Payment: The patient has the option to submit payment with the specimen and may have a check or money order payable to University of Washington Medical Center for you to submit along with the specimen. This can be attached to the request form.

What is in the kit: The test kit will include a return shipping box, ice pack, absorbent pad, biohazard specimen bag, a gold top (SST) tube, an aliquot tube, an aliquot label, a biohazard label, and a category B label.

Collecting the specimen: This test requires refrigerated serum. Draw venous blood in SST provided. The tube will need to be centrifuged and aliquoted into the plastic aliquot tube. We have very strict labeling policies so please ensure that there are two identifiers clearly legible on the aliquot tube that exactly match the same two identifiers on the request form (See the Specimen Labeling and Acceptance Policy on the back of this sheet). An aliquot label has been provided in the kit.

Packaging: Send serum in a labeled, leak-proof, unbreakable tube. Wrap the tube in absorbent material and place in provided return shipping box or other crush-proof shipping container. Include a completed UW Virology Clinical Lab Request Form, placed in a separate plastic bag, and send it with the specimen in the shipping container.

Shipping the specimen: The specimen will need to be shipped overnight with an ice pack. UW does not cover shipping costs. If the lab wants the patient to pay for shipping, the patient may take a preprinted shipping label to the blood draw. If the patient does not provide a shipping label, and your lab's policies allow, the box can be given back to the patient for them to ship to UW overnight.

The University of Washington is the only lab performing the current gold standard Herpes by Western Blot Serology testing. As a courtesy to the patient we supply test kits to anyone who asks. However, the test kit is not necessary to perform this test. There are no unusual tubes or processing requirements. If you have providers that want to order this test you can view our online test catalog at http://depts.washington.edu/labweb/. Under "Reference Lab Services" you will see "Online Testing Guide".

We hope this letter has been informative. For questions about collecting the Herpes Western Blot Serology please contact Client Support Services at 800-713-5198.

Sincerely,

Client Support Services Team

Packaging and Labeling of Etiologic Agents-Herpes Western Blot

Federal Express is setting the standard in order to ensure the safe transport of all blood, urine and any diagnostic specimens containing fluids.

Recently, there has been a significant increase in such shipments. These include, but are not limited to, human or animal materials such as excreta, secreta, blood and its components, tissue and tissue fluids being shipped for purposes of diagnosis.

Starting June 1, 1998 Federal Express requires that the shippers of all blood, urine and other liquid diagnostic specimens package such items to include the following essentials:

- 1. A watertight primary receptacle.
- 2. A watertight secondary packaging
- 3. An absorbent material must be placed between the primary receptacle and the secondary packaging. If multiple primary receptacles are placed in a secondary packaging, they must be wrapped individually to ensure that contact between them is prevented. The absorbent material, such as cotton wool, must be sufficient to absorb the entire contents of all primary receptacles. It is the responsibility of the shipper to ensure adequate absorbent material is used.
- 4. A sturdy outside packaging constructed of corrugated fiberboard, wood, metal or plastic must be used. Styrofoam, plastic bags, and paper envelopes are unacceptable outer packaging.

FEDERAL EXPRESS WILL REFUSE TO ACCEPT PACKAGES NOT MEETING THESE REQUIREMENTS.

The illustration depicts an acceptable method for packaging and labeling of blood, urine or any diagnostic specimens containing fluids. The four requirements outlined must be used for shipping all such materials via Federal Express.

