

HSV Serum Panel (English)

Product Code EL0950
Rev. F



Human serum for evaluating HSV IgG serology assays

In the U.S.: For *in vitro* diagnostic use.

INTENDED USE

The Focus Diagnostics HSV Serum Panel is intended for use by laboratories for evaluating herpes simplex virus IgG serology assays.

SUMMARY AND EXPLANATION

Herpes simplex virus (HSV) is a common human pathogen found worldwide which produces a wide variety of diseases. HSV infects neonates, children and adults, and, by the fourth decade, more than 90% of the adult population demonstrate antibodies to HSV-1. HSV transmission can result from direct contact with infected secretions from either a symptomatic or an asymptomatic host.

HSV has been characterized into 2 distinct serotypes: HSV-1 and HSV-2. HSV-1 is generally associated with infection in the tongue, mouth, lips, pharynx and eyes, whereas HSV-2 is primarily associated with genital and neonate infection.

In the U.S., most young sexually active persons with genital ulcers have genital herpes.² Genital ulcers have been associated with an increased risk for HIV infection.² Genital herpes is usually caused by HSV-2, with the minority of first genital episodes (5-30%) caused by HSV-1.² Many cases of genital herpes are transmitted by persons who are unaware that they are infected or do not recognize subtle or atypical symptoms. The Centers for Disease Control and Prevention (CDC) states that counseling is an important aspect of managing patients who have genital herpes.²

Viral isolation, direct fluorescent antibody (DFA) testing, and serology can be used to diagnose HSV infections. Positive culture and DFA are the most definitive and viral isolation allows typing of the viral isolate. However, length of culture time, specimen collection and transport difficulties, procedural complexity, and other variables are associated with DFA and culture.^{1,2} Most existing serologic methods for assessing HSV sero-status use viral lysate as antigens. However, due to significant cross-reactivity between HSV-1 and HSV-2, the viral lysate assays are unable to differentiate HSV1 infections from HSV-2 infections.³ Since most adults have had prior HSV-1 infection, often without primary or recurrent symptoms, HSV-2 serostatus is often impossible to determine with confidence using a viral lysate assay.³ Recently, HSV type-specific serological assays have been developed using the significant difference between the gG-1 protein of HSV-1 and the gG-2 of HSV-2.³

Type-specific Serologic Assays

The Centers for Disease Control and Prevention (CDC) has stated that HSV serological devices needs to be based on gG-1 (for HSV-1) or gG-2 (for HSV-2) to be accurate, and that viral lysate tests "...do not accurately distinguish HSV-1 from HSV-2 antibody, despite claims to the contrary".⁴

Because false-negative HSV cultures are common, especially in patients with recurrent infection or with healing lesions, type-specific serologic tests are useful in confirming a clinical diagnosis of genital herpes. Additionally, such tests can be used to diagnose persons with unrecognized infection and to manage sex partners of persons with genital herpes. Although serologic assays for HSV-2 should be available for persons who request them, screening for HSV-1 or HSV-2 infection in the general population is not indicated.

MATERIALS SUPPLIED

The Focus Diagnostics HSV Serum Panel contains 12 different human sera of non-detectable and detectable levels to HSV. Allow the supplied reagents to warm to room temperature before use. All un-opened materials are stable at 2 to 8°C until the expiration date stated on the reagent label.

HSV Non-Detectable Serum, 0.3 mL

REF	EL0950-0	HSV	<
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Three vials of human serum, goat serum and buffer. Each vial contains human serum with non-detectable levels to HSV-1&2 and 0.1% sodium azide as a preservative. Requires dilution before use (see Shelf Life and Handling, below).

HSV-1 Detectable Serum, 0.3 mL

REF	EL0950-1	HSV-1	>
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Three vials of human serum, goat serum and buffer. Each vial contains human serum with detectable levels to HSV-1 and 0.1% sodium azide as a preservative. Requires dilution before use (see Shelf Life and Handling, below).

HSV-2 Detectable Serum, 0.3 mL

REF	EL0950-2	HSV-2	>
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Three vials of human serum, goat serum and buffer. Each vial contains human serum with detectable levels to HSV-2 and 0.1% sodium azide as a preservative. Requires dilution before use (see Shelf Life and Handling, below).

HSV-1&2 Detectable Serum, 0.3 mL

REF	EL0950-12	HSV-1&2	>
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Three vials of human serum, goat serum and buffer. Each vial contains human serum with detectable levels to HSV-1&2 and 0.1% sodium azide as a preservative. Requires dilution before use (see Shelf Life and Handling, below).

SHELF LIFE AND HANDLING

1. Reagents are stable through the end of the month indicated by the label expiration date when stored at 2 to 8°C.
2. Do not use reagents beyond their expiration dates.
3. Do not expose reagents to strong light during storage or incubation.
4. Allow reagents to warm to room temperature before use.
5. Focus suggests diluting the sera according to the assay's package insert. For example, for the HerpeSelect ELISAs, samples are diluted 1:101 in Sample Diluent. For example, label tubes and dispense 1 mL of diluent into each labeled tube. Add 10 µL of the sample to each appropriate tube containing the 1 mL diluent and mix well by vortex mixing.

WARNINGS AND PRECAUTIONS

1. Values are not assigned by the manufacturer. Each laboratory should establish its own analyte values and ranges.
2. Controls should be used according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
3. All blood products should be treated as potentially infectious. Source materials from which this product (including controls) was derived have been screened for Hepatitis B surface antigen, Hepatitis C antibody and HIV-1/2 (AIDS) antibody by FDA-approved methods and found to be negative. However, as no known test methods can offer 100% assurance that products derived from human blood will not transmit these or other infectious agents, all controls, serum specimens and equipment coming into contact with these specimens should be considered potentially infectious and decontaminated or disposed of with proper biohazard precautions. CDC and the National Institutes of Health recommend that potentially infectious agents be handled at the Biosafety Level 2.^{5,6}
4. Sodium azide at a concentration of 0.1% has been added to some reagents as an antibacterial agent. To prevent buildup of explosive metal azides in lead and copper plumbing, those reagents (see MATERIALS SUPPLIED, above) should be discarded into sewerage only if diluted and flushed with large volumes of water. Use copper-free and lead-free drain systems where possible. Occasionally decontaminate the drains with 10% sodium hydroxide (CAUTION: caustic), allow to stand for 10 minutes, then flush with large volumes of water.
5. Cross-contamination of patient specimens can cause erroneous results. Add patient specimens and handle strips carefully to avoid mixing of sera from adjoining incubation tray wells. Decant carefully.
6. Bacterial contamination of serum specimens or reagents can produce erroneous results. Use aseptic techniques to avoid microbial contamination.
7. Use proper pipetting techniques, maintaining the pipetting pattern throughout the procedure to ensure optimal and reproducible values.

REFERENCES

1. Aurelian, L. Herpes Simplex Viruses. 473-497. In Specter, S & G Lancz (eds.). Clinical Virology Manual. 2nd Ed. Elsevier, New York. (1992).
2. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2002. MMWR 2002;51 (No. RR-6).
3. Arvin, A, C Prober. Herpes Simplex Viruses. 876-883. In Murray, P, E Baron, M Pfaller, F Tenover, and R Tenover (eds.). Manual of Clinical Microbiology. 6th Ed. ASM, Washington, D.C. (1995).
4. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines — 2002, May 10, 2002 / 51(RR06);1-80.
5. NCCLS. Procedures for the Handling and Processing of Blood Specimens; Approved Guideline (NCCLS H18-A2). 2nd ed. (1999).
6. CDC-NIH Manual. (1999) Biosafety in Microbiological and Biomedical Laboratories. 4th ed. And National Committee for Clinical Laboratory Standards (NCCLS). Protection of Laboratory Workers from Instruments, Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue (NCCLS M29-A).

TECHNICAL ASSISTANCE

If questions arise concerning the kit or its reagents, please contact Focus Diagnostics' Technical Services personnel.
Telephone: (800) 838-4548 (U.S.A. only) (714) 220-1900 (International)
Fax: (714) 484-0109

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ORDERING INFORMATION

Telephone: (800) 838-4548 (U.S.A. only) (714) 220-1900 (International)
Fax: (714) 220-1820 (U.S.A. only) (714) 527-8859 (International)

Visit our web site at: www.focusdx.com



Cypress, California 90630, U.S.A.