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Comparative performance of the Uni-Gold™ HSV-2 Rapid: a point-of-care HSV-2 diagnostic test in unselected sera from a reference laboratory

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Abstract

Background—HSV-2 diagnosis is typically by viral culture, viral DNA amplification of lesion material or by serology in cases of subclinical presentation. These methods can be time consuming and expensive. The Uni-Gold™ HSV-2 Rapid is a fast, point-of-care diagnostic test that can be performed outside a full service laboratory.

Objective—To evaluate the ability of the Uni-Gold™ HSV-2 Rapid to correctly diagnose the presence or absence of anti-HSV-2 antibodies in patient serum samples in comparison to the University of Washington HSV Western blot (UWWB).

Study Design—Sera from 100 adult patients in the USA were tested for HSV-2 specific antibodies by Uni-Gold™ HSV-2 Rapid and results were compared to those of the UWWB to determine the test's sensitivity and specificity.

Results—Of 18 patients seropositive for HSV-2 by UWWB, 17 were correctly identified as such by the Uni-Gold™ HSV-2 Rapid. Of 76 patients who were seronegative for HSV-2 by UWWB, 75 were correctly identified by the rapid test. Six sera had indeterminate results by UWWB. Sensitivity for the Uni-Gold™ HSV-2 Rapid was 94% and specificity was 99%.

Conclusion—The Uni-Gold™ HSV-2 Rapid had high sensitivity and specificity in a small sample of unselected, adults seeking care in the Seattle, USA area. An accurate, near-person test allows immediate counselling directed toward symptom recognition, treatment, and practices that can limit the risk of HSV-2 transmission.

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Keywords

Herpes Simplex Virus; Uni-Gold™ Rapid; HSV serology

Introduction

Herpes Simplex Virus 2 (HSV-2) is a ubiquitous and contagious member of the *Herpesviridae* family and is the major causative agent of recurrent genital ulcers worldwide[1–3]. Global incidence is approximately 25 million infections per year with prevalence higher in women than men[4]. Genital herpes is typically subclinical or unrecognized by patients but can also cause considerable morbidity, especially during initial episodes[5,6]. Neonatal herpes, an infection acquired in most cases from infants' mothers during labor and delivery, poses serious risk of long term morbidity with a high risk of later complications, particularly neurodevelopmental[7,8]. In most cases of neonatal herpes, the mother is unaware of her HSV infection status. HSV-2 genital infection also results in a markedly increased risk of acquisition of HIV-1[9–11]. HSV-2 also increases the risk of transmission of HIV-1 from dually infected persons and can potentiate the progression of HIV disease[11–12]. While the Centers for Disease Control ("CDC"; USA) does not consider that serologic screening for HSV-1 and HSV-2 is indicated in the general population, the CDC does recommend that HSV-2 serologic testing be extended to asymptomatic patients who are infected with the AIDS virus, HIV-1, or who are at risk of acquiring HIV-1[13].

Accurate serological testing for HSV is based upon detection of antibodies to the structural glycoprotein G (gG) which can elicit type-specific responses. Glycoprotein G1 (gG1) and glycoprotein G2 (gG2) have proven to be excellent markers for HSV-1 and HSV-2 infection, respectively[14]. Commercially available tests can take the form of high throughput assays such as enzyme linked immunosorbant assays (ELISA), also known as enzyme immunoassays (EIA), or automated bead- or luminescence-based assays[15]. Tests suited for low-throughput settings include immunoblot methods that depend on visualization of bands where patient serum antibodies have bound to gG1 or gG2 antigen immobilised onto membrane strips[16–17]. Point-of-care tests for capillary blood or serum have been described for use in rapid testing for HSV-2 antibodies or for confirmation of test results from other formats[18–19]. The gold standard for approval of nine of these tests by the US Food and Drug Administration has been the Western blot performed at the University of Washington Virology Laboratory[20,21]. This method has high sensitivity and serotype specificity[20,22] but is expensive, requires a high level of technical expertise, and is performed only in reference laboratories which increases the time to diagnosis and, potentially treatment.

Most available serologic tests for HSV-2 antibody must be performed in a laboratory; which adds transport and processing time. The time factor and expense of laboratory-based tests makes HSV-2 serology especially difficult to apply widely in low or middle income countries where testing is especially needed to categorize risk for HIV-1 acquisition or progression in infected persons. In developed countries, patient follow up and commencement of appropriate treatment and counselling could be aided by the availability of inexpensive, accurate near-patient tests kits[23,24].

The Uni-Gold™ HSV-2 Rapid is a fast (approximately 15 minute) test that can be performed at the point of care or in a laboratory to detect antibodies to HSV-2 gG2 in human whole blood or serum, respectively. The test has been approved by the Food and Drug Administration for use in general practice, specialised clinics and reference laboratories. It is easy to perform and does not require highly trained laboratory personnel to complete or to interpret. The finger sized device contains purified HSV-2 specific gG2 antigen and control human IgG fixed to a nitrocellulose membrane.

Whole blood or serum is added to the cassette and allowed to pass through a blood separation membrane. Buffer is added to a separate well to initiate sample migration across the nitrocellulose membrane. As the sample migrates across the membrane, antibody-gold conjugate against human IgG contacts and binds human IgG in the sample. As sample migration continues, the immunogold complex binds to human IgG in the control zone of the device; eliciting a pink line to indicate a valid test. The HSV-2 test zone (with gG-2 antigen) captures the immunogold complex that is bound to anti-gG-2 antibodies that are present in the sample. The presence or absence of a pink band in the HSV-2 test zone indicates a seropositive or seronegative result, respectively.

This study was initiated to determine the sensitivity and specificity of the Uni-Gold™ HSV-2 Rapid as determined against the University of Washington HSV-2 Western blot (UWWB).

Methods

Comparative Test Evaluation

Leftover sera from 100 adult patient samples submitted for diagnostic testing in the University of Washington Virology laboratory were stripped of identifying labels, divided, coded, and frozen at -20C. Lab use assessment studies have shown that the adult population for whom sera are submitted for HSV Western blot testing is typically divided between 65% female and 35% male (data not shown). Serum aliquots were thawed and one was used to test by UWWB and the other was tested by the Uni-Gold HSV-2 Rapid test. Pediatric sera (age <18 years) were not included. A single technologist performed and read the Unigold HSV-2 Rapid tests; she was blinded as to the results of the study HSV Western blot results. The study was done under the auspices of the University of Washington Institutional Review Board.

Uni-Gold™ HSV-2 Rapid Assay Procedure—To perform the rapid test, 15 μL of serum was added to the sample well. After 30 seconds, the housing unit was opened and 5 drops of isotonic saline solution (supplied in the kit) were added to the buffer well. The device was left open and flat for 15 minutes, then observed visually. The presence of a pink/red line in both the control lane and the test lane was considered positive for the presence of HSV-2 specific antibodies. An HSV-2 seronegative result was recorded if only the control line was apparent. The test was to be considered invalid if a pink/red line failed to appear in the control lane of the device. No samples produced an invalid result.

UW Western Blot Procedure—The UWWB was performed as described, in detail, previously[22]. Of 100 samples tested, eight had indistinct profiles and were subjected to additional testing, as follows described previously[25]. In brief, sera were divided into two portions and adsorbed against HSV-1 and HSv-2 antigens, respectively. The two adsorbates then were used in a repeat UWWB test. Two of the eight sera with indistinct profiles were positive for HSV-1, only, after additional testing. The remaining six sera showed an indistinct HSV-2 gG-2 band, even after re-testing, or had fewer than 4 bands corresponding to HSV-2 immunogens. These six sera were scored as "indeterminate for HSV-2". Of the six sera that were indeterminate for HSV-2, three were also indeterminate for HSV-1, 1 was positive for HSV-1 and 2 were negative for HSV-1 antibodies.

Results

Uni-Gold HSV-2 Rapid Test Performance

Of the 100 sera tested, 18 tested seropositive and 76 tested seronegative for HSV-2 antibody presence by the UWWB. The final 6 samples were found to be indeterminate for their status of antibodies to HSV-2 (N=3) or for the presence of HSV antibodies (N=3) by UWWB (Table 1). Of the 18 patients seropositive for HSV-2, 17 were correctly identified as such by Uni-Gold™ HSV-2 Rapid (Table 1). Of 76 sera that were seronegative for HSV-2 by UWWB, 75 were correctly identified as such (Table 1). Therefore, sensitivity was 94% for Uni-Gold™ HSV-2 Rapid and specificity was 99% (Table 1). All three sera indeterminate for HSV antibodies of either type by UWWB were negative by Uni-Gold™ HSV-2 Rapid. Of the 3 that were indeterminate only for HSV-2 by UWWB, two were faintly positive in the Uni-Gold™ HSV-2 Rapid and one was negative (Table 2).

Discordant Results

Uni-Gold™ HSV-2 Rapid had one false seronegative out of 18 UWWB seropositive results. Of 76 UWWB seronegative sera, one was scored as faintly positive by the Uni-Gold™ HSV-2 Rapid test. Test concordance was 98% (92/94). Of interest, the Uni-Gold™ HSV-2 Rapid gave a negative but valid test result for 3 sera that had nonspecific banding that could not be identified definitively as being related to HSV by UWWB after preadsorption of the sera (Table 2). This suggests a possible specificity advantage of the Uni-Gold™ HSV-2 Rapid test.

Discussion

The results of this study indicate that the Uni-Gold™ HSV-2 Rapid may prove to be suitable for determining HSV-2 serostatus. Larger numbers of study samples with defined subject populations (such as those with virologically confirmed HSV-2 infection) and with capillary blood rather than serum will be helpful to determine the utility of the test in clinical practice settings. By design, our study did not determine the effect of other viral infections, such as HIV-1, on the ability of the rapid assay to detect antibodies to HSV-2.

Sensitivity was 94% and specificity was 99% compared to the UWWB with overall concordance of 98%. One false seronegative and one false seropositive result occured out of 94 sera with definitive HSV-2 results by UWWB. Because the time required to seroconvert

following primary infection with HSV-2 varies between individuals and between tests[26], the specimens with discordant results may have been drawn prior to the generation of anti-HSV-2 antibodies detectable by either the UWWB (in the case of the false positive test by Uni-Gold™ HSV-2 Rapid) or the Uni-Gold™ HSV-2 Rapid (in the single false negative case). Study of this test's performance in newly infected HSV-2 patients could shed light on the time to seroconversion by Uni-Gold™ HSV-2 Rapid. Also, two of the six sera that were indeterminate for HSV-2 by UWWB were faintly positive for HSV-2 by Uni-Gold™ HSV-2 Rapid. We have shown previously that early seroconversion often results in "atypical" band profiles that are reported as "indeterminate" for HSV-2 antibodies by Western blot[26]. Thus, the Uni-Gold™ HSV-2 Rapid may have a sensitivity advantage. Further studies of culture- or PCR-confirmed seroconverters would be needed to show if the Uni-Gold™ HSV-2 Rapid is routinely able to detect antibodies before the Western blot becomes fully positive[26].

Until such data are available, if recently acquired HSV-2 is suspected and a negative Uni-Gold™ HSV-2 Rapid result is obtained, a second sample should be drawn 4 to 12 weeks later for repeat testing since we know seroconversion to gG-2 can require extended time[26]. Conversely, either confirmatory testing or repeat testing at a later date is recommended when a positive Uni-Gold™ HSV-2 Rapid result occurs in a patient considered to be at low risk of HSV-2 infection[21,24,26].

Our study has several limitations. First, the sample size was small (100 sera) and the patients uncharacterized. We did not seek the demographic data of the patients whose sera were tested nor do we know the reason why sera were submitted for testing or whether virological testing for HSV was done. Larger studies with more complete data on the population tested seem justified considering the promising findings in this study. Testing for HSV-2 may be important in the prenatal population to assess women for their risk of acquiring HSV-2 close to term; a risk factor for neonatal herpes transmission[7]. Sera from pregnant women may or may not have been included in our sample; additional studies will be needed to directly assess the accuracy and applicability of the Uni-Gold™ HSV-2 Rapid for prenatal testing. Similarly, we did not determine the HIV-1 serostatus of subjects in our sample. Some studies have shown that HIV-1 infection may affect the accuracy of a test for HSV-2 antibodies[28,29]. Accuracy of HSV-2 EIA results is generally higher in studies using American or European samples; sera from sub-Saharan Africa have a higher rate of falsely positive results when compared with Western blot[30]. Our study tested only a small sample of patients seeking care mainly in the Seattle area or the Pacific Northwest of the United States. Another limitation is that the Uni-Gold™ HSV-2 Rapid is designed for use with either capillary blood as well as serum but our study tested only serum, not capillary blood. Finally, the Uni-Gold™ HSV-2 Rapid test interpretation is subjective; others have shown in a large series of samples from two different sites that different readers can interpret color changes in rapid assays differently[31]. Our design used one technologist to perform and read all the Uni-Gold™ HSV-2 Rapid tests. More extensive studies are needed to determine the reproducibility of the test and to guide users as to whether faint color can be safely interpreted as a positive test.

The Uni-Gold™ HSV-2 Rapid requires little training or laboratory background to perform and is a point-of-care test that takes approximately 15 minutes to complete. The cost is

significantly lower at $12 per test kit than the cost of the other point-of-care test currently on the market from Biokit or SureVue at $31 per test kit. The kits can be stored and transported over a wide range of temperatures (35°F-86°F or 2°C-30°C). Low cost and availability of test results during an office visit are strong arguments for the use of point-of-care tests. Our data suggest that the Uni-Gold™ HSV-2 Rapid may prove to be an excellent option for use in low- or middle-income countries for which HIV-1 control is of significant public health concern[32] as well as in clinic settings in the United States.

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Highlights

- The Uni-Gold HSV-2 Rapid (UHR) is a 15 min diagnostic test for HSV-2 in humans
- Sera from 100 unselected adults in US were tested for HSV-2 specific antibodies via UHR
- UHR sensitivity and specificity was 94% and 99% respectively compared to western blot
- UHR is a reliable, low-cost alternative to other point-of-care HSV-2 diagnostic tests

Table 1

Outcome of the UW Western blot and Uni-Gold HSV-2 Rapid tests.

Western Blot Result		N	Uni-Gold HSV-2 Rapid Result	N	Uni-Gold HSV-2 Rapid Performance
HSV-1	**HSV-2**				
Negative	Negative	43	Negative	43	Specificity: 98.7 NPV=98.7
Positive	Negative	33	Negative Faint positive	32 1	
Negative	Positive	13	Positive	13	Sensitivity: 94.4 PPV: 94.4
Positive	Positive	5	Positive Negative	4 1	
Negative	Indeterminate	2	Faint positive Negative	1 1	
Positive	Indeterminate	1	Faint positive	1	
Indeterminate	Indeterminate	3	Negative	3	

NPV, negative predictive value; PPV, positive predictive value.

Table 2

Results of Rapid Tests in Sera that Have Indeterminate HSV-2 Results by UWWB.

UW Western Blot Result	N	Unigold™ HSV-2 Rapid	
		Result	N
Indeterminate for HSV-1 Indeterminate for HSV-2	3	Neg	3
Positive for HSV-1 Indeterminate for HSV-2	1	Pos	1
Negative for HSV-1 Indeterminate for HSV-2	2	Pos	2
Total	6		