

## PERFORMANCE CHARACTERISTICS

### Precision:

The precision of the assay was evaluated by testing three different sera of eight replicates over a period of one week. The intra-assay and inter-assay C.V. are summarized below:

	Negative	Low positive	Positive
Intra-assay	3.2%	3.8%	4.2%
Inter-assay	7.1%	6.2%	8.5%












### LIMITATIONS OF THE ASSAY

- As with other serological assays, the results of these assays should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.
- Samples obtained too early during primary infection may not contain detectable antibody.
- A single serum sample should not be used to aid in the diagnosis of recent infection. Paired samples should be collected and tested simultaneously to look for seroconversion.

### BIBLIOGRAPHY

- Nahmias, A.J., J. Dannenbarger, C. Wickliffe and M. Muther. Clinical aspects of infection with herpes simplex viruses 1 and 2 in the human herpes viruses. An interdisciplinary Perspective (Nahmias, A.J., W.R. Dawdle and R.F. Schinazi eds) New York, Elsevier, pp 3-9, 1981.
- Vestergaard, B.F., P.C. Grauballe and H. Spanggaard. Titration of herpes simplex virus antibodies in human sera by the enzyme-link immunosorbent assay (ELISA). Acta Pathol. Microbiol. Scand. Sect. B 85:446-448, 1977.
- Coleman, R.M., L. Pereira, P.D. Bailey, D. Dondero, C. Wickliffe, and A.J. Nahmias. Determination of herpes simplex virus type-specific antibodies by enzyme-linked immunosorbent assay. J. Clin. Microbiol. 18 (1983) 287.

### SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Batch Number / Lot Number
 Manufacturer	 <i>In vitro</i> Diagnostic Medical Device	 This side up	 Contains sufficient for <n> tests
 Use by	 Catalogue Number	 Do not reuse	

Manufactured by:  
**Zephyr Biomedicals**

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0322/VER-01

# electra™

●●●●●●●●●● HSV 1,2 IgG

Chemiluminescence Assay for Qualitative Detection of HSV 1,2 IgG antibody in Human Serum  
FOR IN VITRO DIAGNOSTIC USE ONLY  
Store at 2°C to 8°C

### INTENDED USE

**ELECTRA™ HSV 1,2 IgG** is intended for the Qualitative detection of IgG antibody herpes simplex virus (HSV) infection, or for evaluating paired sera for the presence of a significant increase in herpes specific IgG. For In Vitro Diagnostic Use only.

### INTRODUCTION

Herpes Simplex Virus is a common pathogen and its primary infection is usually asymptomatic. There are two immunologically distinct types of HSV: Type 1 and Type 2. HSV 1 is generally associated with oral infection and lesions above the waist, and HSV 2 is associated with genital infections and lesions below the waist. Clinical cases primarily are 1) eczema herpeticum with eczematous skin changes with numerous lesions, 2) Gingivo-stomatitis and 3) Herpes sepsis, almost only found in newly born premature infants. Electra HSV 1,2 IgG is an accurate serologic method to detect HSV specific antibody in serum sample.

### PRINCIPLE

**ELECTRA™ HSV 1,2 IgG** CLIA is for use on **ELECTRA™** analyzers. **ELECTRA™ HSV 1,2 IgG** CLIA works on the principle of chemiluminescence wherein light is produced by a chemical reaction from a substance as it returns from an electronically excited state to the ground state. When catalyzed by HRP, the oxidation of luminol by hydrogen peroxide produces an electronically excited form of 3-aminophthalate which on relaxation emits light with maximum intensity at  $\lambda=425\text{nm}$ . Purified HSV antigen is coated on the surface of microwells. Diluted patient serum is added to the wells, and the HSV IgG specific antibody, if present binds to the antigen. All unbound materials are washed away. After adding enzyme conjugate, it binds to the antibody-antigen complex. Excess enzyme conjugate is washed off and substrate A and substrate B mixture is added. The light generated is measured as relative light units (RLU) and is proportional to the amount of IgG specific antibody in the sample. The results are read by a microwell luminometer compared in a parallel manner with calibrator and controls.

### MATERIALS AND COMPONENTS

#### Materials provided with the test kit:

- Coated Microwells: Purified HSV 1,2 antigen coated wells.
- Sample Diluent
- Negative Control: Range stated on the label
- Positive Control: Range stated on the label.
- Wash Buffer Concentrate (20X)
- Enzyme Conjugate: Ready to use.
- Calibrator
- Substrate A: Chemiluminescent substrate containing enhanced luminol solution.
- Substrate B: Chemiluminescent substrate containing stabilized peroxide solution.

#### Materials required but not provided:

- Precision pipettes: 10-100 $\mu\text{l}$ , 20-200 $\mu\text{l}$ , 100-1000 $\mu\text{l}$
- Disposable pipette tips
- Distilled water
- Disposable Gloves
- ELECTRA™** Analyser

### STORAGE AND STABILITY

- ELECTRA™ HSV 1,2 IgG** kit is stable at 2-8°C up to the expiry date printed on the label.
- Coated Microwells should be used within one month upon opening the pouch provided that once opened, the pouch must be resealed to protect from moisture. If the colour of the desiccant has changed from blue to white at the time of opening the pouch, another coated Microwells pouch should be used.
- Diluted Wash Buffer is stable up to one week when stored at 2-8°C.
- Working Substrate (A+B) must be used immediately.

### SPECIMEN COLLECTION & PREPARATION

- Collect Blood specimen by venipuncture according to standard procedure.
- Serum only should be used.
- Avoid grossly hemolytic, lipemic or turbid samples.
- Preferably use fresh samples. However specimens can be stored up to 48 hours at 2-8°C, for short duration.
- For longer storage, specimens can be frozen at -20°C. Thawed samples must be mixed prior to testing.

6. Do not heat inactivate before use.
7. Specimen containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. Specimen should be free from particulate matter and microbial contamination.

#### PRECAUTIONS

- (1) Bring all reagents and specimen to room temperature before use.
- (2) Do not pipette any material by mouth.
- (3) Do not eat, drink or smoke in the area where testing is done.
- (4) Use protective clothing and wear gloves when handling samples.
- (5) Use absorbent sheet to cover the working area.
- (6) Immediately clean up any spills with sodium hypochlorite.
- (7) All specimens and controls should be considered potentially infectious and discarded appropriately.
- (8) Neutralize acid containing waste before adding hypochlorite.
- (9) Do not use kit after the expiry date.
- (10) Do not mix components of one kit with another.
- (11) Always use new tip for each specimen and reagent.
- (12) Do not allow liquid from one well to mix with other wells.
- (13) Do not let the strips dry in between the steps.

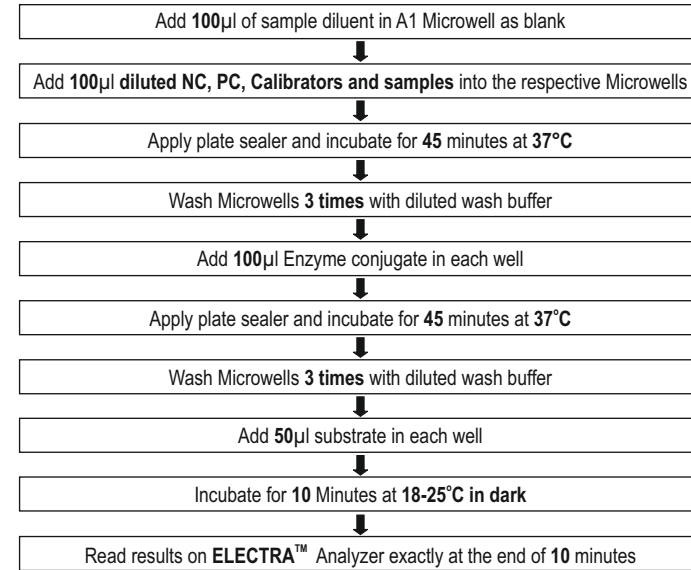
#### REAGENT PREPARATION

- All reagents should be brought to room temperature (18-25°C) and mixed by gently inverting or swirling prior to use. Do not induce foaming.
- Dilute wash buffer 20 times (for example add 5ml concentrated buffer to 95 ml distilled or deionized water). Mix well before use.
- Prepare a Working Substrate by Mixing Substrate A and Substrate B in equal volume (1:1 ratio) before addition to the micro-wells.

No. of Strips	1	2	3	4	5	6	7	8	9	10	11	12
Substrate- A $\mu$ l	250	450	650	850	1050	1250	1450	1650	1850	2050	2250	2450
Substrate- B $\mu$ l	250	450	650	850	1050	1250	1450	1650	1850	2050	2250	2450

#### TEST PROCEDURE

1. Place the desired number of coated strips into the holder.
2. Prepare 1:40 dilutions by adding 5 $\mu$ l of the test samples, negative control, positive control and calibrator to 200 $\mu$ l of sample diluent. Mix well.
3. Dispense 100 $\mu$ l of diluted serum samples, negative control, positive control and calibrator into the appropriate wells. For the reagent blank, dispense 100 $\mu$ l of sample diluent in A1 well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 45 minutes at 37°C.
4. Wash each well three times by filling approximately 350 $\mu$ l diluted wash buffer & blot dry.
5. Dispense 100 $\mu$ l of enzyme conjugate into each well and incubate for 45 minutes at 37°C.
6. Wash each well three times by filling approximately 350 $\mu$ l diluted wash buffer & blot dry.
7. Add 50  $\mu$ l of working Substrate (A+B) in all the micro-wells. Keep away from direct light while adding the substrate.
8. Cover the **ELECTRA™** microplate and incubate for 10 minutes at room temperature (18-25°C) in dark.
9. Read the **ELECTRA™** micro-plate exactly at 10 minutes in **ELECTRA™ Analyzer**.



#### RUN CRITERIA

The test run may be considered valid provided the following criteria are met:

1. If the RLU of the Calibrator is lower than 10,00,000 the test is not valid and must be repeated.
2. The HSV 1,2 IgG Index for Negative and Positive Control should be in the range stated on the labels.

#### CALCULATION OF RESULTS

1. To obtain Cut off Value (COV): Multiply the RLU of the Calibrator by Factor (f) (which is lot specific & will be printed on the label of the calibrator vial).
2. Calculate the HSV 1,2 IgG index of each determination by dividing the RLU values of each sample by obtained RLU value of Cut off.

For example:

If Factor (f) value on label = 0.5

This factor (f) is a variable. It is specific for a lot manufactured and printed on label of Calibrator.

Obtained Calibrator RLU = 7854396  
 Cut-off RLU = 7854396 x 0.5 = 3927198  
 Patient sample RLU = 8108166  
 HSV 1,2 IgG Index = 8108166/3927198 = 2.06 (Positive result)

Patient sample RLU = 471179  
 HSV 1,2 IgG Index = 471179/3927198 = 0.11 (Negative result)

#### INTERPRETATION OF THE RESULT

IgG Index Value	Result
IgG Index value <0.90	Negative for IgG antibody to HSV 1,2
IgG Index value 0.91 – 1.19	Equivocal, sample should be retested
IgG Index value >1.2	Positive for IgG antibody to HSV 1,2