

HSV 1&2 ELITe MGB® Assay used with ELITe InGenius®

M800584

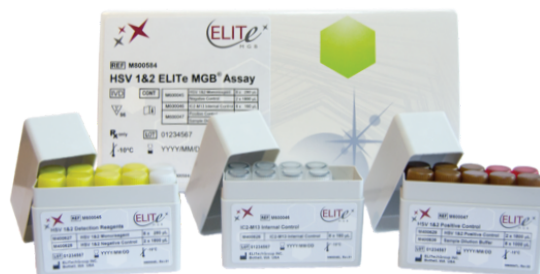
IVD Rx only ⓘ This document is a simplified version of the official instructions for use. Please refer to the complete document before use: www.elitechgroup.com

A. Intended use

The HSV 1&2 ELITe MGB® Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and differentiation of Herpes Simplex Virus 1 and 2 (HSV-1 and HSV-2) DNA in cutaneous or mucocutaneous lesion specimens from symptomatic patients.

The HSV 1&2 ELITe MGB Assay is indicated for use as an aid in diagnosis of HSV infection in symptomatic patients and is indicated for use on the ELITe InGenius® System.

This test is not intended for use with cerebrospinal fluid (CSF) specimens. The assay is not intended to be used for prenatal screening.



B. Amplified sequence

	Gene	Fluorophore
Target 1	HSV-1 Glycoprotein D	AP593
Target 2	HSV-2 Glycoprotein G	FAM
Internal Control	IC2-M13: Artificial DNA Template	AP525

C. Validated matrix

- › Cutaneous lesions swabs
- › Mucocutaneous lesions swabs

D. Assay Kit content

The HSV 1&2 ELITe MGB Assay contains all the PCR reagents and associated controls.

HSV 1&2 Monoreagent	Positive Control	Negative Control	IC2-M13 Internal Control	Sample Dilution Buffer
<p>Mixture of Reagents: buffer, enzyme, dNTPs 8 x 280 µL</p>	<p>HSV-1 & HSV-2 DNA template mix 2 x 1800 µL</p>	<p>DNase and RNase-free water 2 x 1800 µL</p>	<p>Artificial DNA template 8 x 160 µL</p>	<p>For highly concentrated samples only 8 x 1000 µL</p>

- › Reactions per kit: 96
- › Storage temperature: ≤ -10°C
- › Freeze-thaw cycles per tube: 8
- › Maximum shelf-life: 12 months

E. Material required not provided in the kit

- › ELITe InGenius Instrument: INT030-K
- › ELITe InGenius SP200 Extraction Cassette: INT032SP200
- › ELITe InGenius PCR Cassette: INT035PCR
- › ELITe InGenius SP200 Consumable Set: INT032CS
- › ELITe InGenius Waste Box: F2102-000
- › Filter Tips 300 Axygen: M100294
- › Sarstedt 2.0 mL tube: 72.694.005
- › Sarstedt 0.5 mL tube: 72.730.005

F. ELITe InGenius protocol

- | | | | |
|-----------------------------------|--------|---------------------------------|------------|
| › Sample volume | 200 µL | › Monoreagent Mix volume | 20 µL |
| › IC2-M13 Internal Control volume | 10 µL | › Frequency of Positive control | every day* |
| › Total eluate volume | 50 µL | › Frequency of Negative control | every day* |
| › PCR eluate input volume | 10 µL | | |

*During first run of the day only

G. Performance

Limit of Detection	
HSV-1	59.0 TCID ₅₀ /mL
HSV-2	5.4 TCID ₅₀ /mL

Matrix	Clinical Performance					
	Positive Percent Agreement		Negative Percent Agreement			
Cutaneous Swab	HSV-1:	98.7%	78/79*	HSV-1:	98.5%	459/466*
	HSV-2:	96.2%	125/130*	HSV-2:	98.6%	409/415*
Mucocutaneous Swab	HSV-1:	99.2%	126/127*	HSV-1:	97.6%	487/499*
	HSV-2:	97.6%	164/168*	HSV-2:	98.2%	449/457*

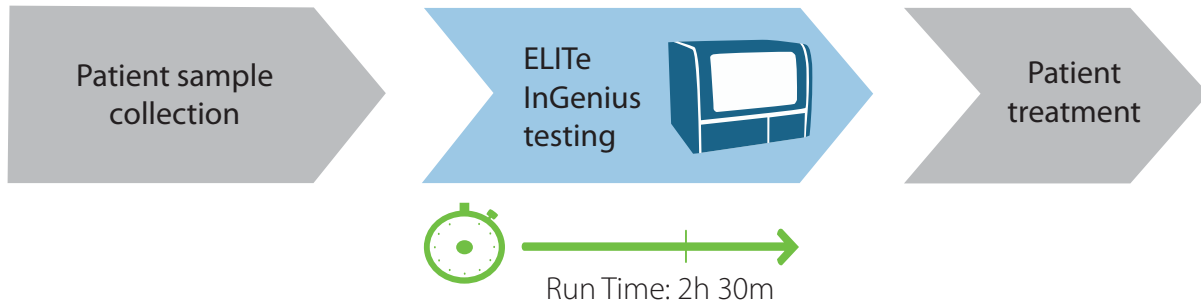
HSV 1&2 ELITe MGB® Assay

Rapid and reliable detection of herpes simplex virus is crucial to help manage the disease, which has seen a worldwide increase over the last several decades, making it a major public health concern.¹

In combination with the ELITe InGenius sample-to-result instrument, the HSV 1&2 ELITe MGB Assay provides accurate results with the benefits of a fully automated, easy-to-use benchtop solution. Quickly and reliably detect the herpes simplex virus 1 and herpes simplex virus 2.

Assay Workflow

ELITe InGenius



Clinical Performance

Matrix	Virus	PPA	NPA
Cutaneous Lesions	HSV-1	98.7%	98.5%
	HSV-2	96.2%	98.6%
Mucocutaneous Lesions	HSV-1	99.2%	97.6%
	HSV-2	97.6%	98.2%

Ordering Information

Reference	Product	Quantity
M800584	HSV 1&2 ELITe MGB® Assay	96 tests

All PCR reagents and associated positive, negative and internal controls are included in the kit. ELITe InGenius extraction reagents and consumables are available separately.

Leading-edge real-time PCR technology driving advanced assay solutions

Proprietary technology developed by ELITechGroup MDx, including MGB (Minor Groove Binder) and SuperBase® chemistries, enable advanced solutions for real-time PCR assay development. Through partnerships with leading laboratories and manufacturers, ELITechGroup MDx has developed unique instrumentation and a broad menu of assays to support laboratories for infections, disease testing and patient monitoring.

The ELITechGroup HSV 1&2 ELITe MGB® Assay is indicated for use as an aid in diagnosis of HSV infection in symptomatic patients. The HSV 1&2 ELITe MGB® Assay is indicated for use on the ELITe InGenius® system. The HSV 1&2 ELITe MGB® Assay is not intended for use with cerebrospinal fluid (CSF) specimens. The assay is not intended to be used for prenatal screening.

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¹ <http://www.clinlabnavigator.com/herpes-simplex-virus.html>