

Certificate of Analysis (CoA)



**GOLD
STANDARD
DIAGNOSTICS**



Product: **Herpes simplex Virus 2 (HSV 2) IgM**
 Prod.No.: **RE57931**
 Lot: **HSV2M-143**
 Expiry: **2027-05-31**
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MM0540-143	2025-11	2027-05-31
CONJ	1	KM0540-143	2025-11	2027-05-31
CONTROL -	1	NM0540-143	2025-11	2027-05-31
CUT OFF	1	CM0540-143	2025-11	2027-05-31
CONTROL +	1	PM0540-143	2025-11	2027-05-31
WASH BUF 20x	1	W-1128	2025-11	2027-11-30
SOLN STOP	1	S-1059	2025-10	2027-10-31
SUB TMB	1	T-078	2025-04	2028-04-28
DIL M	1	DM-348	2025-10	2027-10-31

Component	OD Value	OD Validation Criteria
CONTROL -	0.019	< 0.200 < Cut-off
CUT OFF	0.408	0.150-1.300
CONTROL +	0.888	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
CONTROL +	21.83	12.01 - 31.65

The target value and target range of **CONTROL +** may be used optionally.
 The positive control is valid if the absorbance value of **CONTROL +** > **CUT OFF**.

Final Report issued: 2025-12-02

Approved by: 
 Quality Control

Approved on: 2025-12-02



Gold Standard Diagnostics Frankfurt GmbH
 Waldstrasse 23 A6
 63128 Dietzenbach, Germany



IBL International GmbH
 Flughafenstrasse 52a, 22335 Hamburg
 Germany