

Certificate of Analysis (CoA)



**GOLD
STANDARD
DIAGNOSTICS**



Product: **Herpes simplex Virus 2 (HSV 2) IgM**
 Prod.No.: **RE57931**
 Lot: **HSV2M-142**
 Expiry: **2026-12-31**
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MM0540-142	2025-06	2026-12-31
CONJ	1	KM0540-142	2025-06	2026-12-31
CONTROL -	1	NM0540-142	2025-06	2026-12-31
CUT OFF	1	CM0540-142	2025-06	2026-12-31
CONTROL +	1	PM0540-142	2025-06	2026-12-31
WASH BUF 20x	1	W-1113	2025-04	2027-04-30
SOLN STOP	1	S-1044	2025-03	2027-03-31
SUB TMB	1	T-078	2025-04	2028-04-28
DIL M	1	DM-345	2025-05	2027-05-31

Component	OD Value	OD Validation Criteria
CONTROL -	0.015	< 0.200 < Cut-off
CUT OFF	0.441	0.150-1.300
CONTROL +	0.929	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
CONTROL +	23.69	13.03 - 34.35

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: 2025-07-10

Approved by: 
 Quality Control

Approved on: 2025-07-10



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