

Product identification			
Kit name	H-DiaCMVQ™		
Product reference	DDGH-10-L200	Manufacturing date	2020-12
Batch number	07000L	Expiry date	2021-12

Analysis procedure	
Volume PCR samples (µL)	Positive control: 5.0 Standards: 5.0
Volume PCR mix (µL)	20.0
Master Mix reference	DMML-D2-Q100
Real Time PCR equipment (Supplier)	LightCycler 480 II (Roche)

QC results				
Parameter	Channel	Specifications	Results	Conformity
WHO1 (Log ₁₀ IU/mL CMV)	FAM	5.54 ≤ Mean Log ₁₀ IU/mL CMV ≤ 6.85	6.14	Pass/Fail
WHO2 (Log ₁₀ IU/mL CMV)	FAM	3.98 ≤ Mean Log ₁₀ IU/mL CMV ≤ 5.34	4.63	Pass/Fail
WHO3 (Log ₁₀ IU/mL CMV)	FAM	2.79 ≤ Mean Log ₁₀ IU/mL CMV ≤ 4.68	3.72	Pass/Fail
Positive Control (Log ₁₀ IU/mL CMV)	FAM	5.26 ≤ Mean Log ₁₀ IU/mL CMV ≤ 7.71	6.47	Pass/Fail
IQC (Log ₁₀ IU/mL CMV)	FAM	As mentioned in the certificate of analysis	3.95	Pass/Fail
EIC DNA (Ct)	CY5	≤ 36.0	27.8	Pass/Fail
Standard 1 (Ct/Cp)	FAM	17.9 ≤ Mean Ct ≤ 20.9	19.4	Pass/Fail
Standard 2 (Ct/Cp)	FAM	21.2 ≤ Mean Ct ≤ 24.2	22.9	Pass/Fail
Standard 3 (Ct/Cp)	FAM	24.5 ≤ Mean Ct ≤ 27.5	26.3	Pass/Fail
Standard 4 (Ct/Cp)	FAM	27.8 ≤ Mean Ct ≤ 30.8	29.5	Pass/Fail
Standard 5 (Ct/Cp)	FAM	31.1 ≤ Mean Ct ≤ 34.1	32.5	Pass/Fail
Negative Control (Ct/Cp)	N/A	Negative	Negative	Pass/Fail
Slope	N/A	-3.6 to -3.0	-3.3	Pass/Fail
Efficiency	N/A	1.9 to 2.1	2.0	Pass/Fail

Quality Control:  Date: 16 JUN 2021

Quality Assurance:  Date: 16 JUN 2021

Carine COUVRUER
QA Officer