

Product identification			
Product name	R-DiaSARS-CoV-2		
Product reference	DDGR-88-L100	Production date	2021-09
Batch number	2021J01/I	Expiry date	2022-09

Analysis procedure	
Extraction equipment (Supplier)	MagNA Pure 96 (Roche)
Volume extracted (µL)	200.0 IQC + 10.0 EIC
Volume eluted (µL)	100.0
Volume PCR samples (µL)	10.0
Volume PCR mix (µL)	15.0
Master Mix reference	DMML-R4-A100
Real Time PCR equipment (Supplier)	LightCycler 480 II (Roche)

QC results					
Testing			Channel	Specifications	Results
Positive Control (Ct/Cp):			FAM	30.0 ± 3.3	29.9
Positive Control (Ct/Cp):			ROX	N/A	N/A
IQC (Ct/Cp)	N° N/A	Lot N° 2021I16/II	FAM	31.5 ± 3.3	32.0
IQC (Ct/Cp)	N° N/A	Lot N° N/A	ROX	N/A	N/A
IQC (Ct/Cp)	N° N/A	Lot N° N/A	FAM	N/A	N/A
IQC (Ct/Cp)	N° N/A	Lot N° N/A	ROX	N/A	N/A
Negative Control (Ct/Cp)			N/A	Negative	Negative
EIC (Ct/Cp) relative to IQC n°	Lot N° 08000J		Cy5	≤36.0	33.3
EIC (Ct/Cp) relative to IQC n°	Lot N° N/A		Cy5	N/A	N/A

Approval			
	Name and function	Signature	Date
QC	Philippe Nord QC Specialist		05-11-2021
QA	Samira LAMARI QA Officer		24 -11- 2021