



Product identification			
Product name	R-DiaSARS-CoV-2		
Product reference	DDGR-88-L100	Production date	2020-09
Batch number	2020I29/I	Expiry date	2021-09

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	30.2
Positive Control (Ct/Cp):			ROX	N/A	N/A
IQC (Ct/Cp)	N° N/A	Lot N° R2020D20_I	FAM	31.5 ± 3.3	32.4
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° N/A		Lot N° 2020H03/II	Cy5	≤36.0	30.7
EIC (Ct/Cp) relative to IQC n° N/A		Lot N° N/A	Cy5	N/A	N/A

Certificate of Analysis

Approval			
	Name and function	Signature	Date
QC	Philippe Nord QC Specialist		21-10-2020
QA	Julianna KERESZTES QA Officer		21 OCT 2020