Berkshire & Surrey Pathology Services

A joint venture between Ashford and St. Peter's Hospitals NHS Foundation Trust, Frimley Health NHS Foundation Trust, Royal Berkshire NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust. Legal entity host Frimley Health NHS Foundation Trust

NHS Pathology Solutions

VALIDATION REPORT:
Validation of inactivation media for testing using Liat Influenza A, Influenza B and SARS-CoV-2 Multiplex
Primestore Molecular Transport Media (MTM)

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Berkshire and Surrey Pathology Services
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1. PROPOSED CHANGE

In Autumn 2020, Roche Diagnostics launched a new product which incorporates detection of SARS-CoV-2 into their already existing repertoire of other respiratory viruses. The total time for analysis of each sample is just 20 minutes, allowing for a greatly improved diagnostic turn-around-time and facilitating faster decision-making in patient pathways. However, the multiplex analysis of Flu A, Flu B and SARS-CoV-2 has been validated for use with VTM (viral transport media). The use of these samples would require all processing and pipetting to take place in a microbiological safety cabinet (MSC) at containment level 2 (CL2) or greater, to be compliant with UK government guidance. Alternatives for VTM need to be explored to permit deactivation of the live virus in samples prior to analysis, to allow analysis at true Point of Care settings.

It is noted that this would be an off-label use of the assay.

2. CLINICAL UTILITY OF NEW PROCEDURE

The aforementioned test is intended for the simultaneous rapid *in vitro* qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B virus RNA in healthcare provider-collected nasopharyngeal and nasal swabs, and self-collected nasal swabs (collected in a healthcare setting with instruction by a healthcare provider) from individuals suspected of respiratory viral infection consistent with COVID-19 or influenza by their healthcare provider, and placed into Viral Transport Media (VTM) or Universal Transport Media (UTM). These media do not deactivate the SARS-CoV-2 virus, and pipetting these samples may potentially generate aerosols, making this a high-risk procedure that should be carried out within a microbiological safety cabinet (MSC) and containment level 2 (CL2) or greater, according to UK government guidance. This would negate the use of the Liat device with the

Cobas® SARS-CoV-2 & Influenza A/B test at the point of care, or outwith a pathology laboratory.
In order to use the test at the point of care, this report examines the use of an inactivation buffer.

3. IMPACT ANALYSIS

3.1. WHAT WILL HAVE TO CHANGE?

Services will need to collect throat and nose swabs using the appropriate specimen collection swabs, and placed into Primestore MTM according to manufacturer's procedures.

Training of staff, documentation, result reporting, patient selection and the overall model of service delivery are local decisions that will be the responsibility of each site and organisation.

3.2. WHAT EFFORT WILL THE CHANGE NEED?

In order to perform the validation, cobas® SARS-CoV-2 & Influenza A/B assay tubes will be required in adequate numbers to cover all required experiments +10% contingency.
Cobas® SARS-CoV-2 & Influenza A/B QCs will be required to validate the assay tube lot number and run weekly QCs during the study period.
Validation of lower limit of detection will require purchase of standards for SARS-CoV-2 and Influenza A and B.
Access to a microbiology safety cabinet (MSC) and lab consumables.
Patient comparison work will require double swabbing (paired throat and nose swabs - one VTM and one in Primestore MTM being validated, taken simultaneously) of patients who are undergoing SARS-CoV-2 testing.
Significant human resource will be required to carry out the study.

Resource for each service is a local requirement and depends on service model decisions.

3.3. WHAT IS THE IMPACT OF THE CHANGE ON SERVICE, STAFF AND USERS?

The impact will be availability of a rapid test for SARS-CoV-2 & Influenza A/B in a truly Point of Care setting, as there will be no need for sample processing to be conducted in an MSC.

3.4. WHAT ARE THE RISKS ASSOCIATED WITH THE CHANGE?

The use of viral deactivating buffers will decrease the associated risks of testing for SARS-CoV-2. The overall implementation of a cobas® SARS-CoV-2 & Influenza A/B service, and assessment and mitigation of associated risks must be according to local policy and decisions.

4. VALIDATION / VERIFICATION PLAN

Is the new examination procedure CE marked?	YES ~~/ NO~~
Is the new examination procedure to be used according to the manufacturer's instructions without modification?	~~YES /~~ NO
Is the study to be performed a VERIFICATION or a VALIDATION?	VALIDATION

If the answer to both of the above questions is YES, **verification** is required.

If the answer to either of the above questions is NO, **validation** is required.

Performance Characteristic	**To be examined?**	**Describe the procedure for assessment of this performance characteristics**	**Give details of acceptable performance.**
Measurement Accuracy	NO		
Precision	NO		
Uncertainty	NO		
Patient comparison	YES	The extremely low prevalence of Influenza A and B in local population means prospective comparison of clinical samples is not feasible for these viruses. Once	90% concordance in results is expected. Discrepant results will be fully interrogated and clinically assessed. Repeat testing by a third assay may be considered, if necessary.

		flu seasons starts, retrospective comparison may be performed. Clinical validation with patient samples confirmed positive and negative for SARS-CoV-2: At least 20 known SARS-CoV-2 positive patient samples and 20 known SARS-CoV-2 negative patient samples will be analysed on each new inactivation buffer, until 20 detected and 20 not detected results are reported from the device. Results compared to a laboratory-based PCR method with CT values performed on the paired VTM sample	
Analytical Specificity	NO		
Analytical Sensitivity / Detection Limit / Quantitation Limit	YES	Lower limit of detection (LLOD): A panel of Qnostics standards (with at least 2 different known concentrations targeting the LLOD as stated by Roche) for Influenza A, Influenza B and SARS-CoV-2 will be diluted 1 in 2 in each of the deactivation buffers and analysed in duplicate to determine whether the claimed Lower Limit of Detection of the assay can be replicated.	Claimed LLoD for SARS-Cov-2 is just 12 copies/mL according to the IFU. Lowest standard available from a 3rd party supplier (Qnostics) is reportedly 50 dC/mL, which will be 25dC/mL following dilution, which we would expect to be consistently detected (2/2 duplicates). If results of duplicates are discrepant a further repetition will be analysed.
Measuring Interval	NO		

Diagnostic Sensitivity / Specificity	NO		
Carry Over	NO		
Recovery	NO		
Other	YES		

5. RESULTS

All experiments were performed as described above and the results are reported below.

5.1. PATIENT COMPARISON

Test swabs were taken using FLOQswabs placed into Primestore MTM, and incubated for at least 10 minutes at room temperature before testing.

Comparator samples used for this study were collected simultaneously (throat and contralateral nostril) using Σ-VIROCULT Viral Transport Media (VTM) swab kits from MWE (www.mwe.co.uk). They were tested in the Virology laboratory using the Hologic Panther (LLOD 10 copies/mL), the Cepheid GeneXpert system (LLOD 250 copies/mL), or the Elitech Elite (LLOD 100 copies/mL).

A total of 41 paired patient samples were analysed, 20 detected and 21 not detected (by the Liat SARS-CoV-2 assay results)

Table 2: Summary of Liat results for patient samples / pools vs all laboratory PCR methods

	Liat DETECTED	Liat NOT DETECTED
Laboratory PCR DETECTED	20	0
Laboratory PCR NOT DETECTED	0	21
	20	21

Concordance between the Liat results using Primestore MTM and all laboratory PCR methods was 100%.

The Liat CT value was read from the graphs by the same Clinical Scientist to maintain consistency and showed a range of Liat CT values for the positive samples (12 – 34).

5.2. ANALYTICAL SENSITIVITY: LOWER LIMIT OF DETECTION

5.2.1. SARS-COV-2

Lower limit of detection was run using the Qnostics SARS-CoV-2 analytical Q panel (SCV2AQP01) comprising of 8 vials of known concentration of SARS-CoV-2 and a negative sample. In order to save resources only the negative standard and the lowest 2 standards

were run. This is because validation of the assay showed that the lowest standard (8), when diluted 1 in 2 in VTM, was consistently detected for SARS-CoV-2, and 25 copies/ml is above the stated LLOD of the assay, so if the Primestore MTM is not interfering in the assay, these levels should be adequate to demonstrate this.

Standards were diluted 1 in 2 in Primestore MTM and run in duplicate.

Table 3: Lower limit of detection - SARS-CoV-2

		Liat SARS-CoV-2 Result		Standards		
Qnostics SARS-CoV2 standard no:	Run number	Result	CT value	Concentration of neat standard dC/mL	Final conc post dilution 1:2 in buffer dC/mL	Expected result*
S07	1	DET	31	100	50	DET
S07	2	DET	32			
S07	3					
S08	1	DET	32	50	25	DET
S08	2	DET	32			
S08	3					
S09	1	ND	-	Negative	Negative	ND
S09	2	ND	-			
S09	3					

ND = Not Detected

DET = Detected

* compared to Roche stated performance (LOD 12copies/mL)

These results demonstrate that the Cobas® SARS-CoV-2 assay reliably picks up the virus at a concentration of 25 copies/mL, and does not detect any virus in the negative sample, when diluted in Primestore MTM. These results are consistent with those found with VTM.

5.2.2. INFLUENZA A

Lower limit of detection was run using the Qnostics Influenza A analytical Q panel (INFAAQP01) comprising 8 vials of known dilutions of Influenza A and a negative sample. Standards were diluted 1 in 2 in Primestore MTM and run in duplicate on 2 of the Liat devices.

A further replicate was performed if results were discrepant. The standards have no assigned values, so results are compared to those when the standards were run in VTM on the Liat FluA/B/RSV assay in a previous study in our service. In order to save resources, the lowest 2 standards only were run.

Table 4: Lower limit of detection - Influenza A

		Liat Influenza A		Standards		
Qnostics Influenza A standard no:	Run number	Result	CT value	VIAL DILUTION (1 IN...)	FINAL DILUTION IN PRIMESTORE (1 IN...)	Expected result*
S07	1	DET	35	10000	20000	MIXED
S07	2	DET	34			
S07	3					
S08	1	DET	37	20000	40000	MIXED
S08	2	NDET				
S08	3	DET	37			

ND = Not Detected

DET = Detected

*compared to testing of same standard in VTM on Liat Flu A/B/RSV assay, August 2020

These results demonstrate that the Cobas® Influenza A assay shows similar performance when diluted 1 in 2 in Primestore MTM to that found with VTM.

5.2.3. INFLUENZA B

Lower limit of detection was run using the Qnostics Influenza B analytical Q panel (INFBAQP01) comprising 6 vials of known dilutions of Influenza A and a negative sample. Standards were diluted 1 in 2 in Primestore MTM and run in duplicate on 2 of the Liat devices. A further replicate was performed if results were discrepant. The standards have no assigned values, so results are compared to those when the standards were run in VTM on the Liat FluA/B/RSV assay in a previous study in our service. In order to save resources, the lowest 2 standards only were run.

Table 5: Lower limit of detection - Influenza B

		Liat Influenza B		Standards		
Qnostics Influenza B standard no:	Run number	Result	CT value	VIAL DILUTION (1 IN...)	FINAL DILUTION IN PRIMESTORE (1 IN...)	Expected result*
S05	1	DET	30	1000	2000	DET
S05	2	DET	31			
S05	3					
S06	1	DET	31	2000	4000	DET
S06	2	DET	31			
S06	3					

ND = Not Detected

DET = Detected

*compared to testing of same standard in VTM on Liat Flu A/B/RSV assay, August 2020

These results demonstrate that the Cobas® Influenza A assay shows similar performance when diluted 1 in 2 in Primestore MTM to that found with VTM.

APPENDIX 1: MATERIALS USED IN STUDY

COBAS LIAT TEST KITS & QC MATERIAL

Test kits	Ref: 09211101190 LOT 00625Z
QC material	Ref: 09211128190 LOT G17203 Exp 30-4-21
POS QC lot number	G15144/G15478
NEG QC Lot number:	G15077

QNOSTICS MATERIAL

Target	Code	Lot No(s)
SARS-CoV-2	SCV2AQP01	9.3
Influenza A	INFAAQP01	6.2

Influenza B	INFBAQP01	6.2

LIAT DEVICES:

Device	Serial No
ASPH1	M1-E-14805
ASPH2	M1-E-13179
RSFT1	M1-E-15547
RSFT2	M1-E-17037
FPH1	M1-E-15560
FPH2	M1-E-10733

APPENDIX 2: RAW DATA

(A) ENVIRONMENTALS

Device	Date	Operator	Assay tube lot number	time loaded into assay tube	Device	time run	RESULT FLU A	RESULT FLU B	RESULT SARS-CoV-2	RSV
DAY 0	19.11.20	Fiona	501Z	14:20	ASPH1	14:21	ND	ND		ND
WEEK 1 DAY 1	23.11.20	LW/CG	625Z	13:30	ASPH1	13:30	ND	ND	ND	
WEEK 1 DAY 2	24.11.20	FR	625Z	8:24	RSFT2	8:25	ND	ND	ND	
WEEK 1 DAY 3	25.11.20	FR	625Z	8:00	FPH2	8:03	ND	ND	ND	
WEEK 2	30.11.20	LW/CG	625Z		FPH1		ND	ND	ND	
WEEK 3	7.12.20	LW	625Z	10:40	FPH1	10:40	ND	ND	DET	
WEEK 3 Liats	7.12.21	LW	625Z	14:00	ASPH1	14:10	ND	ND	ND	
WEEK 3 Touch	7.12.20	LW	625Z	14:02	ASPH2	14:10	ND	ND	ND	

(B) WEEKLY QCS

Device	POS / NEG QC?	Date	Operator	QC lot number	Assay tube lot number	time loaded into assay tube	time run	RESULT FLU A	RESULT FLU B	RESULT SARS-CoV-2
WEEK:										
SPH 1	NEG	23/11/20	Larisa	G15077	6252	11:17	11:17	Negative control valid		
SPH 1	POS	23/11/20	Larisa	G15144/G15	6252	11:10	11:40	Positive control valid		
SPH 2	NEG	23/11/20	Chalin	G15077	6252	11:45	11:45	Negative control valid		
SPH 2	POS	23/11/20	Chalin	G15144/G15	6252	12:23	12:32	Error. Kit validated via Tookit. Pt postive (VIRO VTM) ran on 23.11.20 - OK		
RSFT1	NEG	23/11/20	Chalin	G15077	6252	11:55	11:55	Negative control valid		
RSFT1	POS	23/11/20	Chalin	G15144/G15	6252	12:26	12:32	Positive control valid		
RSFT2	NEG	23/11/20	Chalin	G15077	6252	11:55	11:55	Negative control valid		
RSFT2	POS	23/11/20	Larisa	G15144/G15	6252	12:28	12:32	Positive control valid		
FPH1	NEG	23/11/20	Larisa	G15077	6252	11:45	11:45	Negative control valid		
FPH1	POS	23/11/20	Larisa	G15144/G15	6252	12:23	12:32	Positive control valid		
FPH2	NEG	23/11/20	Larisa	G15077	6252	11:45	11:45	Negative control valid		
FPH2	POS	23/11/20	Larisa	G15144/G15	6252	12:26	12:32	Positive control valid		
WEEK:										
SPH 1	NEG	30/11/202	Larisa	G15077	6252	15:40	15:40	negative control valid		
SPH 1	POS	30/11/20	Larisa	G15144/G15	6252	14:52	15:14	Positive control valid		
SPH 2	NEG	30/11/20	Larisa	G15077	6252	15:41	19:41	Negative control valid		
SPH 2	POS	30/11/20	Larisa	G15144/G15	6252	14:53	15:15	Positive control valid		
RSFT1	NEG	30/11/20	Larisa	G15077	6252	15:42	15:42	Negative control valid		
RSFT1	POS	30/11/20	Larisa	G15144/G15	6252	14:52	15:15	Positive control valid		
RSFT2	NEG	30/11/20	Larisa	G15077	6252	15:43	15:43	Negative control valid		
RSFT2	POS	30/11/20	Larisa	G15144/G15	6252	15:09	15:16	Positive control valid		
FPH1	NEG	30/11/20	Larisa	G15077	6252	15:44	15:44	Negative control valid		
FPH1	POS	30/11/20	Larisa	G15144/G15	6252	15:09	15:17	Positive control valid		
FPH2	NEG	30/11/20	Larisa	G15077	6252	15:45	15:45	Negative control valid		
FPH2	POS	30/11/20	Larisa	G15144/G15	6252	14:52	15:18	Positive control valid		

(C) PATIENT COMPARISON

									Liat result		Laboratory PCR results				
Sample ID	MRN	SAMPLE DATE AND TIME	Sample storage prior to Liat study	Date & time sample loaded to assay tube	Date and time assay tube loaded to Liat	Operator	Assay tube lot No	Liat machine ID	SARS-CoV-2	CT VALUE SARS-CoV -2	SARS-CoV-2 REPORT	Comparator	Elitech CT Value	Cepheid E gene CT VALUE	Cepheid N2 gene CT VALUE
MTMP01	1862551	12/8/2020 10:53	room temp	12/8/2020 13:46	12/8/2020 14:02	Larisa	625Z	ASPH1	ND	-	ND	Hologic Panther			
MTMP02	327547A	12/8/2020 10:50	room temp	12/8/2020 13:51	12/8/2020 14:02	Larisa	625Z	ASPH2	ND	-	ND	Hologic Panther			
MTMP03	243674P	12/8/2020 10:50	room temp	12/8/2020 13:55	12/8/2020 14:03	Larisa	625Z	RSFT1	ND	-	ND	Hologic Panther			
MTMP04	513081A	12/8/2020 11:05	room temp	12/8/2020 13:58	12/8/2020 14:03	Larisa	625Z	FPH1	ND	-	ND	Hologic Panther			
MTMP05	1869894	08/12/2020 NS	room temp	12/8/2020 14:23	12/8/2020 14:32	Larisa	625Z	ASPH1	DET	34	DET	Elitech Elite	31.02		
MTMP06	1190086	08/12/2020 NS	room temp	12/8/2020 14:26	12/8/2020 14:32	Larisa	625Z	ASPH2	DET	24	DET	Cepheid GeneXpert		31.7	33.1
MTMP07	1187556	08/12/2020 NS	room temp	12/8/2020 14:30	12/8/2020 14:33	Larisa	625Z	RSFT1	DET	12	DET	Elitech Elite	16.61		
MTMP08	343367A	12/8/2020 11:05	room temp	12/8/2020 14:20	12/8/2020 14:33	Larisa	625Z	FPH1	ND	-	ND	Hologic Panther			
MTMP09	1442211	12/8/2020 11:15	RT & fridge from 2(	12/8/2020 15:40	12/8/2020 15:51	Larisa	625Z	ASPH1	ND	-	ND	Hologic Panther			
MTMP10	1136258	12/8/2020 11:00	RT & fridge from 2(	12/8/2020 15:41	12/8/2020 15:51	Larisa	625Z	ASPH2	DET	27	DET	Elitech Elite	27.06		
MTMP11	440508A	12/8/2020 10:40	RT & fridge from 2(	12/8/2020 15:43	12/8/2020 15:52	Larisa	625Z	RSFT1	DET	28	DET	Elitech Elite	33.01		
MTMP12	068000P	12/8/2020 11:00	RT & fridge from 2(	12/8/2020 15:47	12/8/2020 15:52	Larisa	625Z	FPH1	DET	32	DET	Elitech Elite	36.54		
MTMP13	1255138	12/8/2020 10:46	RT & fridge from 2(	12/8/2020 16:01	12/8/2020 16:16	Larisa	625Z	ASPH1	ND		ND	Hologic Panther			
MTMP14	621233A	12/8/2020 10:57	RT & fridge from 2(	12/8/2020 16:01	12/8/2020 16:17	Larisa	625Z	ASPH2	ND	-	ND	Hologic Panther			
MTMP15	1867870	12/8/2020 10:56	RT & fridge from 2(	12/8/2020 16:03	12/8/2020 16:18	Larisa	625Z	RSFT1	ND	-	ND	Hologic Panther			
MTMP16	537150A	12/8/2020 11:13	RT & fridge from 2(	12/8/2020 16:04	12/8/2020 16:18	Larisa	625Z	FPH1	ND	-	ND	Hologic Panther			
MTMP17	306022A	12/8/2020 13:45	RT & fridge from 4(	12/8/2020 16:35	12/8/2020 16:43	Larisa	625Z	ASPH1	DET	31	DET	Elitech Elite	35.44		
MTMP18	023428P	12/8/2020 14:00	RT & fridge from 4(	12/8/2020 16:36	12/8/2020 16:44	Larisa	625Z	ASPH2	DET	25	DET	Elitech Elite	30.36		
MTMP19	153042P	12/8/2020 13:52	RT & fridge from 4(	12/8/2020 16:38	12/8/2020 16:44	Larisa	625Z	RSFT1	DET	33	DET	Elitech Elite	34.7		
MTMP20	1858125	12/8/2020 13:49	RT & fridge from 4(	12/8/2020 16:39	12/8/2020 16:45	Larisa	625Z	FPH1	DET	33	DET	Elitech Elite	39.35		
MTMP21	1723222	12/8/2020 13:55	RT & fridge from 4(	12/8/20 16:51	12/8/20 17:06	Larisa	625Z	ASPH1	DET	28	DET	Elitech Elite	28.73		
MTMP22	853058P	12/8/2020 13:57	RT & fridge from 4(	12/8/20 16:52	12/8/20 17:06	Larisa	625Z	ASPH2	DET	13	DET	Elitech Elite	17.13		
MTMP23	81189700	12/8/2020 11:20	RT & fridge from 4(	12/8/20 16:54	12/8/20 17:07	Larisa	625Z	RSFT1	ND	-	ND	Hologic Panther			
MTMP24	P REYNOLD	12/8/2020 14:25	RT & fridge from 4(	12/8/20 16:55	12/8/20 17:07	Larisa	625Z	FPH1	DET	13	DET	cepheid GeneXpert		20.1	22.5
MTMP25	491657A	12/8/2020 13:59	FRIDGE O/N	12/9/20 10:00	12/9/20 10:01	FR	625Z	ASPH1	ND	-	ND	Hologic Panther			
MTMP26	184383P	12/8/2020 13:50	FRIDGE O/N	12/9/20 10:07	12/9/20 10:07	CG	625Z	ASPH2	DET	30	DET	Elitech Elite	39.12		
MTMP27	1537960	12/8/2020 13:56	FRIDGE O/N	12/9/20 10:11	12/9/20 10:11	CG	625Z	RSFT1	DET	32	DET	Elitech Elite	28.03		
MTMP28	316736A	12/8/2020 12:10	FRIDGE O/N	12/9/20 10:15	12/9/20 10:15	CG	625Z	FPH1	ND	-	ND	Hologic Panther			
MTMP29	1869970	12/8/2020 12:30	FRIDGE O/N	12/9/20 10:20	12/9/20 10:20	CG	625Z	ASPH1	ND	-	ND	Hologic Panther			
MTMP30	1366819	12/8/2020 N/A	FRIDGE O/N	12/9/20 10:24	12/9/20 10:24	CG	625Z	ASPH2	ND	-	ND	Hologic Panther			
MTMP31	181871P	12/8/2020 19:05	FRIDGE O/N	12/9/20 10:30	12/9/2020 10:33	CG	625Z	RSFT1	ND	-	ND	Hologic Panther			
MTMP32	1366179	12/8/2020 N/A	FRIDGE O/N	12/9/20 10:34	12/9/2020 10:37	CG	625Z	FPH1	ND	-	ND	Hologic Panther			
MTMP33	1068994	12/8/2020 N/A	FRIDGE O/N	12/9/2020 10:41	12/9/2020 10:42	CG	625Z	ASPH1	INVALID	RERUN					
MTMP33	1068994	12/8/2020 N/A	FRIDGE O/N	12/9/2020 11:06	12/9/2020 11:06	CG	625Z	ASPH1	ND	-	ND	Hologic Panther			
MTMP34	663763A	12/8/2020 12:05	FRIDGE O/N	12/9/2020 10:45	12/9/2020 10:50	CG	625Z	ASPH2	ND	-	ND	Hologic Panther			
MTMP35	853418P	12/8/2020 12:40	FRIDGE O/N	12/9/2020 10:49	12/9/2020 10:55	CG	625Z	RSFT1	ND	-	ND	Hologic Panther			
MTMP36	811034P	12/8/2020 23:30	FRIDGE O/N	12/9/2020 10:52	12/9/2020 10:58	CG	625Z	FPH1	ND	-	ND	Hologic Panther			
MTMP37	471777A	12/10/2020 14:50	FRIDGE	12/10/2020 16:35	12/10/2020 16:36	FR	625Z	ASPH1	DET	30	DET	Hologic Panther		24.3	26.4
MTMP38	168701P	12/10/2020 14:55	FRIDGE	12/10/2020 16:38	12/10/2020 16:39	FR	625Z	ASPH2	DET	22	DET	Hologic Panther		24.9	27.4
MTMP39	023428P	12/1/02020 14:45	FRIDGE	12/10/2020 16:44	12/10/2020 16:45	FR	625Z	RSFT1	DET	34	DET	Hologic Panther	28.37		
MTMP40	1096859	12/10/2020 14:45	FRIDGE	10/12/2020 16:50	12/10/2020 16:51	FR	625Z	FPH1	DET	32	DET	Hologic Panther		37.2	34.7
MTMP41	1537960	12/10/2020 13:40	FRIDGE	10/12/2020 16:55	12/10/2020 16:58	FR	625Z	ASPH1	DET	32	DET	Elitech Elite	38.47		

(D) ANALYTICAL SENSITIVITY / LOWER LIMIT OF DETECTION

								Liat SARS-CoV-2 Result		Standards		
Qnostics SARS-CoV 2 standard no:	Run number	Date	Diluted by	Time standard diluted	Time sample loaded onto assay tube	Time assay tube loaded onto Liat	Liat machine ID	(Det / Not Det / Inv / Error)	CT value	Concentration of neat standard dC/mL	Final conc post dilution 1:2 in buffer dC/mL	Expected result*
S07	1	4/12/2020	FR	11:40	11:48	12:00	FPH1	DET	31	100	50	DET
S07	2				11:49	12:01	FPH2	DET	32			
S07	3											
S08	1	4/12/2020	FR	11:39	11:46	11:58	RSFT1	DET	32	50	25	DET
S08	2				11:47	11:59	RSFT2	DET	32			
S08	3											
S09	1	4/12/2020	FR	11:37	11:41	11:56	ASPH1	ND	-	Negative	Negative	ND
S09	2				11:42	11:57	ASPH2	ND	-			
S09	3											

								Liat Influenza A		Standards		
Qnostics Influenza A standard no:	Run number	Date	Diluted by	Time standard diluted	Time sample loaded onto assay tube	Time assay tube loaded onto Liat	Liat machine ID	Result	CT value	VIAL DILUTION (1 IN...)	FINAL DILUTION IN PRIMESTORE (1 IN...)	Expected result*
S07	1					15:53	ASPH2	DET	35			
S07	2					15:58	ASPH1	DET	34	10000	20000	MIXED
S07	3	29.12.20	LARISA	14:00	15:52							
S08	1					16:18	ASPH2	DET	37			
S08	2					16:24	ASPH1	NDET		20000	40000	MIXED
S08	3	29.12.20	LARISA	14:00	16:18	17:05	ASPH2	DET	37			

								Liat Influenza B		Standards		
Qnostics Influenza B standard no:	Run number	Date	Diluted by	Time standard diluted	Time sample loaded onto assay tube	Time assay tube loaded onto Liat	Liat machine ID	Result	CT value	VIAL DILUTION (1 IN...)	FINAL DILUTION IN PRIMESTORE (1 IN...)	Expected result*
S05	1					16:40	ASPH2	DET	30			
S05	2	29.12.20	LARISA	14:02	16:34	16:45	ASPH1	DET	31	1000	2000	DET
S05	3											
S06	1					17:15	ASPH1	DET	31			
S06	2	29.12.20	LARISA	14:02	17:15	17:28	ASPH2	DET	31	2000	4000	DET
S06	3											