



Desktop Technical Validation Report for Roche Cobas SARS Co- V-2 + Influenza A/B for the Cobas Liat System

Published: September 2021 (Version 1.0)

Contents

Assay description.....	2
Type of sample to be used in validation.....	4
Equipment and reagents.....	5
Performance characteristics	6
Precision and robustness.....	11
Analytical specificity (Interferences and cross-reactions).....	13
Diagnostic sensitivity and specificity (Clinical validation with confirmed positives and negatives)	18
Summary	24

Assay description

1. What is the principle and method of the assay (description of the assay according to the manufacturer's Instructions for Use (IFU)?

As stipulated in the IFU 09323236190-02EN Doc. Rev. 2.0

The Cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the Cobas Liat System (cobas SARS-CoV-2 & Influenza A/B) is an automated multiplex real-time RT-PCR assay 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, nasal swabs and self-collected nasal swabs (collected in a healthcare setting with instruction by a healthcare provider) from individuals suspected of a viral respiratory infection.

Cobas SARS-CoV-2 & Influenza A/B uses real-time reverse transcriptase polymerase chain reaction (RT-PCR) technology to rapidly (approximately 20 minutes) detect and differentiate between SARS-CoV-2, influenza A, and influenza B viruses from nasopharyngeal and nasal swabs. The automation, small footprint, and easy-to-use interface of the Cobas Liat System enable performance of this test to occur at the POC or in a clinical laboratory setting.

Cobas SARS-CoV-2 & Influenza A/B is performed on the Cobas Liat Analyzer which automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time RT-PCR assays. The assay targets both the ORF1 a/b non-structural region and nucleocapsid protein gene that are unique to SARS-CoV-2, a well-conserved region of the matrix gene of influenza A, and the non-structural protein gene of influenza B. An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target virus through steps of sample purification, nucleic acid amplification, and to monitor the presence of inhibitors in the RT-PCR processes.

It should be noted that ONLY the SARS CoV-2 element of the assay is in scope for this desktop validation report, users of this assay will need to conduct their own local validation of the Flu A/B elements of the assay.

2. What is the use for which the device is intended according to the data supplied by the manufacturer on the label, in the IFU, in promotional or sales materials or statements, or as specified by the manufacturer in the performance evaluation?

As stipulated in the IFU 09323236190-02EN Doc. Rev. 2.0

Cobas SARS-CoV-2 & Influenza A/B is intended for use in the simultaneous rapid in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus nucleic acid in clinical specimens and is not intended to detect influenza C virus. SARS-CoV-2, influenza A and influenza B viral RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease. Negative results do not preclude infection from SARS-CoV-2, influenza A, and/or influenza B and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information. Cobas SARS-CoV-2 & Influenza A/B is intended for use by health professionals or trained operators who are proficient in using the Cobas Liat System at the point of care (POC) or in a clinical laboratory setting.

3. Is the test a stand-alone device/test or to be used in conjunction with other equipment and is biosafety containment required?

The test is designed to be used with the Cobas Liat Analyzer. All human samples should be considered as infectious and handled according to Good Laboratory procedures. If using the swabs and transport media recommended in the IFU (see Section 4 for details), it should be noted that the virus is not inactivated prior to testing. There is a pipetting step that is required to pipette sample from the primary tube to the assay tube for processing. If the transport media used to transport and store the sample does not inactivate the sample, this should be performed in a biosafety cabinet.

Type of sample to be used in validation

4. Stipulate the sample type (e.g. whole non-extracted virus, extracted RNA, synthetic RNA, plasmid DNA containing assay target regions) and any sample matrices (e.g. saliva, plasma, nasopharyngeal/oronasal swab [dry or in VTM] etc) in which the material is to be spiked.

Whole non-extracted virus from nasopharyngeal, oropharyngeal or nasal swabs in virus transport medium. The swab types and transport media recommended in the IFU are as follows:

For nasopharyngeal swabs - Flexible minitip FLOQSwab with Universal Transport Media (UTM[®]) from Copan Diagnostics or BD Universal Viral Transport (UVT) 3-mL collection kit with a flocced flexible minitip swab.

For nasal swabs - Regular FLOQSwab with Universal Transport Media (UTM[®]) from Copan Diagnostics OR BD Universal Viral Transport (UVT) 3-mL collection kit with a regular flocced swab Copan Universal Transport Medium (UTM-RT[®]), without bead.

Other recommended swabs and transport media - Thermo Fisher Scientific Remel M4RT, M4, M5, M6 or M4RT[®] tube, without beads.

If the transport media above are not available 0.3mL 0.9% physiological saline solution is recommended.

Of the eight NHS sites who conducted a verification of the assay, two sites used Primestore VTM, as this medium is inactivating, allowing the Liat platform to be used in clinical areas. The sites noted a slight increase in CT values compared to using non-inactivating media, but due to the sensitivity of the assay this was not thought to be a cause for concern and was unlikely to change the outcome of any test results.

5. Stipulate if the material is required to be extracted i.e. volume received, volume extracted, volume eluted, elution buffer to be used in the assay.

The Cobas Liat platform provides sample extraction as part of the automated workflow.

6. If possible, stipulate if any interfering substances such as preservatives are likely to be present. Shelf life and number of freeze thaw events should also be stated, if known. Where dry swabs are to be used, samples will need to be collected prospectively; two swabs per participant, one for a new test and one to be tested using reference method; or one swab for a new test collected within 24 hours of a positive reference method swab.

Equipment and reagents

7. List all the equipment required that are not supplied by the manufacturer with calibration/service requirements and dates where applicable.

All equipment and instrumentation are supplied.

8. List all the reagents required that are not provided by the manufacturer with shelf-life expiry dates and storage conditions. Include positive and negative control materials.

Specimen collection kits – see Section 4 for details.

Performance characteristics

9. Analytical Sensitivity and Linearity of SARS COV-2 targets

10. Dilution series: This should be calculated using a validated standard dilution series. If this is not possible (as standard material is not available), use 5 clinical positive replicates, with a 5 log₁₀ dilution, plus 5 negatives, plus the use of inhibition controls. If feasible, repeat over several days, different users/machines (feasibility may be limited due to availability of positive material). Where dry swabs are to be used, known amounts of standard material should be added to the swab, and then tested as per IFU. Reference to be made on the reporting of results and for example CT values.

- Data from IFU 09323236190-02EN Doc. Rev. 2.0

To determine the LoD for SARS-CoV-2, a heat inactivated cultured virus of an isolate from a US patient (USA-WA1/2020, lot number 324047, 3.16E+06 TCID₅₀/mL, ZeptoMetrix, NY, USA) was serially diluted in pooled negative nasopharyngeal swab matrix. Five concentration levels were tested with 20 replicates except for the highest concentration level, which was tested with 10 replicates. Three lots of assay tubes (approximately equal numbers of replicates per lot), and two independent dilution series (equal numbers of replicates per dilution series) were used in the study.

As shown in Table 1, the concentration level with observed hit rates greater than or equal to 95% was 0.012 TCID₅₀/mL (12 copies/mL) for SARS-CoV-2.

Table 1: LoD Determination Using USA-WA1/2020 Strain

Strain	Concentration (TCID ₅₀ /mL)	Concentration (copies/mL)	Total Valid Results	Hit Rate (%)	Mean CT*
USA-WA1/2020 (stock concentration 3.16E+06 TCID ₅₀ /mL)	0.048	49	10	100	32.6
	0.024	24	20	100	33.5
	0.012	12	20	100	35.2
	0.06	6	20	70	35.9
	0.03	3	20	25	36.7

*Calculations only include positive results.

- Data from Site 6

Lower limit of detection (LLOD) was determined using the Qnostics SARS-CoV-2 Analytical Q panel (SCV2AQP01) comprising 8 vials of known concentration of SARS-CoV-2 and a negative sample. These were diluted 1 in 2 in Σ -VIROCULT VTM and run in triplicate on 6 Liat devices. Table 2 shows the results of the dilution series.

Table 2: Dilution Series and LLOD using Qnostics SARS-CoV-2 Analytical Q Panel (Site 6 data)

Qnostics SARS-CoV2 standard no:	Run Number	Liat SARS-CoV-2 result	Liat SARS-CoV-2 CT value	Concentration of neat standard dC/mL	Final conc post dillution 1:2 in VTM dC/mL	Expected result*
S01	1	DET	19	1000000	500000	DET
S01	2	DET	19			
S01	3	DET	19			
S02	1	DET	23	100000	50000	DET
S02	2	DET	23			
S02	3	DET	23			
S03	1	DET	26	10000	5000	DET
S03	2	DET	26			
S03	3	DET	26			
S04	1	DET	28	5000	2500	DET
S04	2	DET	28			
S04	3	DET	28			
S05	1	DET	30	1000	500	DET
S05	2	DET	32			
S05	3	DET	30			
S06	1	DET	31	500	250	DET
S06	2	DET	31			
S06	3	DET	30			
S07	1	DET	36	100	50	DET
S07	2	DET	32			

S07	3	DET	32			
S08	1	DET	32	50	25	DET
S08	2	DET	32			
S08	3	DET	32			
S09	1	ND	-	Negative	Negative	ND
S09	2	ND	-			
S09	3	ND	-			

ND = Not Detected

DET = Detected

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.

- Data from Site 7

Roche claims a Limit of detection of 1.2×10^{-2} TCID₅₀/ml (a measure of infectious virus) rather than providing a copy number for comparative analysis in their IFU. To confirm analytical sensitivity and lower limit of detection, the positive QNostic Analytical Panel 01 for SARS-COV-2 controls were tested, these include 9 member panel with 1 negative control (confirmed negative for all targets) and 8 part dilution series of SARS-CoV-2 quantified in digital copies/ml ranging from 1,000,000 copies/ml down to 50 copies/ml. A single test was performed on each panel member finding an analytical sensitivity of 50 copies/ml, the lowest part of the dilution series, in line with the results obtained for the Hologic Panther assay. The data from this dilution series is presented in Table 3.

Table 3: Dilution Series and LLOD using Qnostics SARS-CoV-2 Analytical Q Panel (Site 7 data)

Target Concentration (dC/mL)	LIAT SARS CoV-2 Result
1000000	Detected
100000	Detected
10000	Detected
5000	Detected
1000	Detected
500	Detected
100	Detected
50	Detected
Negative	Not Detected

11. Linearity and efficiency: Ideally for linearity, the use of a standardised reference panel should be used to ensure effective benchmarking and assure that dilutions are accurate. If an alternative route for establishing linearity is undertaken, the method will need to be documented. For LAMP assays the linearity will need to be standardised via dilutions in appropriate matrixes using untreated virus. Plot the data from section 10 and calculate linearity and efficiency. Compare the data with that supplied by the manufacturer, if applicable.

12. Lowest Limits of Detection (LLOD): Where a validated standard dilution series was used LLOD should be calculated, using data from section 11, in copies/ml (to align with the relevant MHRA TPP). Where clinical positive material is used, copies/ml cannot be calculated; median CT value or dPCR should be given for the lowest dilution detected from the samples used in 4.1.1.

Table 4: Reported lowest limit of detection (LLOD) from three data sources described in section 10

Source	LLOD (Copies/mL)
IFU 09323236190-02EN Doc. Rev. 2.0 (Table 1)	12 copies/mL
Site 6 Verification report (using QNostics Analytical panel) (Table 2)	25 copies/mL
Site 7 Verification report (using QNostics Analytical panel) (Table 3)	50 copies/mL

Precision and robustness

13. Intra-assay precision: Use the data for 5 replicate values from a single day from section 10 to calculate Standard Deviation & Coefficient of Variation measurement, with the values for the latter to be <10%. To include the use of inhibition controls

- Data from Site 6

Roche cobas SARS-CoV-2 & Influenza A/B Quality Control Kit samples were used to evaluate intra- and inter-assay precision. A positive and a negative QC was analysed in triplicate on Day 1, and then again on Day 2 and Day 3, all on one Liat machine. The data is presented in Table 5.

Table 5: Summary of QC materials ran over a period of 3 consecutive days.

Day	QC / run	Date	Liat Result		
			Flu A	Flu B	SARS-CoV-2
Day 1	NEG QC - 1	26/11/2020	Negative QC valid		
	POS QC - 1	26/11/2020	Positive QC valid		
	NEG QC - 2	26/11/2020	Negative QC valid		
	POS QC - 2	26/11/2020	Positive QC valid		
	NEG QC - 3	26/11/2020	Negative QC valid		
	POS QC - 3	26/11/2020	Positive QC valid		
Day 2	NEG QC - 1	27/11/2020	Negative QC valid		
	POS QC - 1	27/11/2020	Positive QC valid		
Day 3	NEG QC - 1	28/11/2020	Negative QC valid		
	POS QC - 1	28/11/2020	Positive QC valid		

These results indicate that the assay precision as far as it has been tested in this small study is as expected.

14. Inter-assay precision: Use the data for 5 replicate values from multiple days from section 10 for Standard Deviation & Coefficient of Variation with the values for the latter to be <15%.

See Section 13 and Table 5 above.

15. Repeatability: Spike 30 negative samples from different individuals with known amount of agent/positive material (suggested 3x the LLOD), all should be positive.

Analytical specificity (Interferences and cross-reactions)

16. Cross-reactivity to non-target samples/organisms. A range of samples either direct clinical samples or spiked samples that are known positives for other diseases, both closely related (i.e., other coronaviruses), syndromic diseases (i.e., other respiratory viruses and bacteria) and common diseases (i.e. HIV, HBV, HCV, VZV, EBV, CMV) should be tested.

- Data from IFU 09323236190-02EN Doc. Rev. 2.0

In-silico Analysis

The in silico analysis for possible cross reactions with all the organisms listed in was conducted by mapping binding regions of the primers and probes in Cobas SARS-CoV-2 & Influenza A/B to the sequences available from NCBI and GISAID databases. The percent homology of sequences that partially aligned with the SARS-CoV-2 N and RdRp targets is shown in the table below. If any two of the primers were mapped to a sequence on opposite strands with short distance apart, potential amplifications were flagged. No potential unintended cross reactivity is expected based on this in silico analysis except for SARS-CoV-1 which has been additionally tested as shown in Table 6.

Table 6: Organisms with homology to SARS-CoV-2 N and RdRp primers and probes

Strain	Percentage homology to N			Percentage homology to RdRp		
	Forward primer	Probe	Reverse primer	Forward primer	Probe	Reverse primer
Human coronavirus HKU1	-	-	-	-	-	81.5%
SARS Coronavirus (SARS-CoV-1)	100%	81.48%	94.74%	95.8%	87.5%	96.3%

Strain	Percentage homology to N			Percentage homology to RdRp		
	Forward primer	Probe	Reverse primer	Forward primer	Probe	Reverse primer
MERS-coronavirus	80.0%	-	-	-	-	-
Haemophilus influenzae	95.0%	-	-	-	-	-
Legionella pneumophila	80.0%	-	-	-	-	-
Streptococcus pyogenes	80.0%	-	-	-	-	-
Mycoplasma pneumoniae	-	-	-	83.3%	-	-
Candida albicans	90.0%	-	-	83.3%	-	-
Staphylococcus epidermidis	85.0%	-	-	-	-	-
Staphylococcus salivarius	-	-	89.47%	-	-	-
Human coronavirus 229E/OC43/NL63	No alignment found*			No alignment found*		
Adenovirus (e.g., C1 Ad 71)	No alignment found*			No alignment found*		

Strain	Percentage homology to N			Percentage homology to RdRp		
	Forward primer	Probe	Reverse primer	Forward primer	Probe	Reverse primer
Human metapneumovirus (hMPV)	No alignment found*			No alignment found*		
Influenza A (all available sequences)	No alignment found*			No alignment found*		
Influenza B (all available sequences)	No alignment found*			No alignment found*		
Enteroviruses (e.g., EV68)	No alignment found*			No alignment found*		
Respiratory syncytial virus (RSV)	No alignment found*			No alignment found*		
Rhinovirus	No alignment found*			No alignment found*		
Chlamydia pneumoniae	No alignment found*			No alignment found*		
Mycobacterium tuberculosis	No alignment found*			No alignment found*		
Streptococcus pneumoniae	No alignment found*			No alignment found*		

Strain	Percentage homology to N			Percentage homology to RdRp		
	Forward primer	Probe	Reverse primer	Forward primer	Probe	Reverse primer
Bordetella pertussis	No alignment found*			No alignment found*		
Pneumocystis jirovecii (PJP)	No alignment found*			No alignment found*		
Pseudomonas aeruginosa	No alignment found*			No alignment found*		

Cross-reactivity with SARS CoV-1 (Wet testing)

Cross reactivity with SARS-CoV-1 was evaluated by testing inactivated SARS-CoV-1 whole virus. Gamma irradiated cultured SARS-CoV-1 (Urbani strain, lot number 58542036, BEI Resources, VA, USA) was diluted into pooled negative nasopharyngeal swabs in UTM-RT at 1.0E+05 PFU/mL. As shown in Table 7, SARS-CoV-1 did not interfere with the Cobas SARS-CoV-2 & Influenza A/B assay performance.

Table 7: Cross-reactivity with SARS CoV-1 (Wet Testing)

SARS CoV-1 Concentration tested	Cobas SARS CoV-2 + Influenza A/B			
	SARS CoV-2	Influenza A	Influenza B	IPC
	Result	Result	Result	CT
1.00E+05 PFU/mL	Not detected	Not detected	Not detected	31.6

- Data from Site 7

Analytical Interference

To Investigate the assay for the possibility of analytical interference, the Zeptomatrix NATrol FluA/B positive control (LOT: 320483) was mixed 1:1 with the Zeptomatrix NATrol SARS-CoV-2 external run control (LOT: 324332) to a final copy number of 250 copies/ml of SARS to 1000 copies/ml of FluA/B control. A comparator was set up as 1:1 of SARS control with molecular water. All of the mixed and unmixed controls were detectable in line with expected results, no evidence of interference was found in this analysis. The data is presented in Table 8.

Table 8: Analytical interference of SARS CoV-2 + Influenza A/B

Control	Liat Results		
	COVID	FLU A	FLU B
SARS-COV-2 + Flu	Detected	Detected	Detected
A/B control	Detected	Detected	Detected
SARS-COV-2 control	Detected	Not detected	Not detected
+ molecular grade			
Water	Detected	Not detected	Not detected

Diagnostic sensitivity and specificity (Clinical validation with confirmed positives and negatives)

17. Samples selected for this validation will be appropriate to the assay. Low medium and high viral load samples will be equally distributed to avoid increasing or lowering DSe and DSp.
 18. Diagnostic sensitivity: Confirmed clinical samples from patients (positive RT-qPCR result) should be used. Preferably, depending on the availability of samples, ~150 samples should be included to align with MHRA TPP. Clinical sensitivity (95% CI) and positive predictive value (PPV) should be calculated in comparison with a CE marked reference method that itself has sensitivity and specificity and a limit of detection within the specifications of the MHRA TPP. The CT values or equivalent for both the assessed and comparator assays must be included in the validation report.
- Data from multiple verification reports from NHS labs in the UK (8 sites)

169 RT-PCR positive samples and 995 RT-PCR negative samples were evaluated in this analysis using a number of different comparator assays. Table 9 shows the sensitivity and specificity of the assay using the combined results of the analyses.

Table 9: Diagnostic sensitivity and specificity of the Liat SARS CoV-2 + Influenza A/B assay (SARS CoV-2 component only)

		Comparator Assay Result		
		Pos	Neg	
Roche Result	Pos	165	8	173
	Neg	4	987	991
		169	995	1164

sensitivity	97.63
Specificity	99.20
PPV	95.38
NPV	99.60

The assay gives a sensitivity of 97.6% (95% CI 94.1-99.1, 165/169 RT-PCR positive samples). PPV = 95.4%.

Table 10 below shows the spread of CT values across the dynamic range of the assay, where the CT data for both the assay and the comparator assay were available. Three sites (sites 6-8) did not have any CT data, as they used comparator assays that did not give a CT value.

The sensitivity of the assay meets the acceptable criteria in the MHRA TPP for Laboratory Based SARS CoV-2 Viral Detection Tests (<https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-laboratory-based-sars-cov-2-viral-detection-tests>) for RNA extracted assays, with sensitivity of greater than 95% (with 95% two-sided confidence interval entirely above 90%). The desirable criteria in the TPP states a sensitivity of greater than 99% (with 95% two-sided confidence interval entirely above 97%).

The sensitivity of the assay meets the desirable criteria in the MHRA TPP for Point of Care SARS CoV-2 assays (<https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-point-of-care-sars-cov-2-detection-tests>) with sensitivity greater than 97% (within confidence intervals of 93-100%).

The sensitivity also meets the TVG criteria for Category 1 performance (sensitivity >97%).

19. Diagnostic specificity: Confirmed clinical samples from patients (negative RT-qPCR result) should be used. Preferably, depending on the availability of samples, ~250 samples should be included to align with MHRA TPP. Clinical specificity (95% CI) and negative predictive value (NPV) should be calculated in comparison with a CE marked reference method that itself has sensitivity and specificity in line with the MHRA TPP. The CT values or equivalent for both the assessed and comparator assays must be included in the validation report.

See Table 9 above. The specificity of the assay is 99.2% (95% CI 98.4-99.6, 987/995 RT-PCR negative samples). NPV = 99.6%.

The specificity of the assay meets the desired criteria in the MHRA TPP for Laboratory Based SARS CoV-2 Viral Detection Tests (<https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-laboratory-based-sars-cov-2-viral-detection-tests>) for RNA extracted assays, with specificity of greater than 99% (with 95% two-sided confidence interval entirely above 97%).

The specificity of the assay meets the desired criteria in the MHRA TPP Point of Care SARS CoV-2 assays (<https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-point-of-care-sars-cov-2-detection-tests>) with specificity greater than 99% (within confidence intervals of 97-100%).

The specificity also meets the TVG criteria for Category 1 performance (specificity >99%).

Table 10 CT spread of the assay against the comparator assay across the dynamic range

CT	Study Site 1			Study Site 2			Study Site 3		
	Seegene / Cepheid/ Bosphore	Pos match on Roche	sens %	Viasure result	Pos match on Roche	sens %	AusDx result	Pos match on Roche	sens %
<25	4	4	100.0	12	12	100.0	6	6	100.0
25-30	1	0	0.0	3	3	100.0	2	2	100.0
30-35	8	8	100.0	3	3	100.0	0	0	n/a
>35	5	4	80.0	9	9	100.0	0	0	n/a
Undefined	11	10	90.9	1	1	100.0	4	4	100.0

CT	Study Site 4			Study Site 5			TOTALS		
	Cepheid / Seegene	Pos match on Roche	sens %	Altona result	Pos match on Roche	sens %	Total comparator result	Total Pos match on Roche Liat	Total Sens %
<25	4	4	100.0	16	16	100.0	42	42	100.0
25-30	10	10	100.0	11	11	100.0	27	26	96.3
30-35	7	7	100.0	5	5	100.0	23	23	100.0
>35	4	4	100.0	1	1	100.0	19	18	94.7
Undefined	0	0	n/a	0	0	n/a	16	15	93.8

Summary

It should be noted that ONLY the SARS CoV-2 element of the assay is in scope for this desktop validation report, users of this assay will need to conduct their own local validation of the Flu A/B elements of the assay.

Two NHS sites that provided verification data for this report use an inactivating VTM that is not one of the VTMs recommended in the IFU, and so it should be noted that this is an off-label use. However, bridging studies conducted as part of the verification found that, although there was a slight increase in CT values when using inactivating VTM compared to one of the VTMs recommended in the IFU, because the assay has a high sensitivity the difference is not thought to change the overall result.

The Roche Cobas SARS CoV-2 + Influenza A/B assay for the Roche Cobas Liat has been independently verified at eight NHS labs in the UK. The collated data from the verification reports are presented in this desktop validation report. The assay meets both the MHRA TPP for Laboratory Based SARS CoV-2 Viral Detection tests for RNA extracted assays and the MHRA TPP for Point of Care Assays with a diagnostic sensitivity of 97.6% (95% CI 94.1-99.1) and a diagnostic specificity of 99.2% (95% CI 98.4-99.6). A comparison with both TPP's is presented as this assay may be used in both situations.

The lowest limit of detection was found by Site 6 to be 25 copies/mL and Site 7 to be 50 copies/mL for both targets. This meets the desired criteria of ≤ 100 copies/mL in both the MHRA TPP for Laboratory Based SARS CoV-2 tests for RNA extracted assays and the MHRA TPP for Point of Care assays.

© Crown copyright 2021

Published to GOV.UK in pdf format only.

www.gov.uk/dhsc

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

