EMERGENCY RESPONSE VALIDATION

AOAC® *Performance Tested Method*℠
CERTIFICATION

The AOAC Research Institute hereby certifies that the performance has been evaluated and found to perform as stated in the applicability of the method. Approval has been granted with the following certificate number:

012103

Thermo Scientific™ SARS-CoV-2 RT-PCR Detection Workflow

manufactured by:

Oxoid Ltd. part of Thermo Fisher Scientific
Wade Road
Basingstoke
Hampshire, RG248PW

This certificate signifies that an AOAC® Certification Mark License Agreement has been executed, which authorizes the manufacturer to display the AOAC *Performance Tested Methods*℠ certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND FOUND TO PERFORM AS STATED IN THE APPLICABILITY STATEMENT" - on the above-mentioned method. Renewal may be granted at the end of one calendar year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

Issue Date: January 15, 2021
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METHOD TYPE: Emergency Response Validation, In Silico

METHOD AUTHORS
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SUBMITTING COMPANY
Oxoid Ltd. part of Thermo Fisher Scientific
Wade Road
Basingstoke
Hampshire, RG248PW

KIT NAME
Thermo Scientific™ SARS-CoV-2 RT-PCR Detection Workflow

CATALOG NUMBERS
A47533

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APPLICABILITY OF METHOD
Analytes – SARS-CoV-2 Virus

Matrixes – Stainless steel environmental surface (2" x 2")

Performance claims - The Thermo Scientific SARS-CoV-2 Real Time PCR Workflow demonstrated comparable performance to the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Diagnostic Panel Instructions for Use (Revision 4, Effective 6/12/2020;2) for the detection of SARS-CoV-2 on stainless steel.

REFERENCE METHOD
Centers for Disease Control and Prevention (2020). *CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.* Revision 5. (2)

ORIGINAL CERTIFICATION APPROVAL DATE
January 14, 2021

CERTIFICATION RENEWAL RECORD
New Approval 2021

METHOD MODIFICATION RECORD
NONE

SUMMARY OF MODIFICATION
NONE

Under this AOAC® *Performance Tested*℠ License Number, 012103 this method is distributed by:
NONE

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NONE

PRINCIPLE OF THE METHOD (1)

The Applied Biosystems™ TaqMan™ 2019-nCoV Assay Kit v1 contains a set of TaqMan™ RT-PCR assays for the detection and characterization of SARS-CoV-2. The kit includes three assays that target SARS-CoV-2 genes and one positive control assay that targets the human RNase P RPPH1 gene. Features of the TaqMan™ 2019-nCoV Assay Kit include: 2019-nCoV assays targeting three different viral genomic regions that are run together in a single PCR reaction and detected on the same channel, highly specific target sequences generated by robust bioinformatic selection that are unique to SARS-CoV-2 and show no cross-reactivity with one another, and an RNase P internal positive control run in duplex with the 2019-nCoV assays.

The TaqMan™ 2019-nCoV Assay Kit is used with the TaqMan™ 2019-nCoV Control Kit v1 to monitor assay-specific amplification. Additionally, the TaqMan™ 2019-nCoV Control Kit v1 is a synthetic positive control; the TaqMan™ 2019-nCoV Control Kit v1 contains target sequences for each of the assays included in the TaqMan™ 2019-nCoV Assay Kit v1. The control includes synthetic DNA target sequences for three SARS-CoV-2 genes (ORF1ab, S protein, and N protein) and the human RNase P RPPH1 gene. During RT-PCR, 1 µL of the 2019-nCoV Control v1 in 9.75 µL PCR-grade water is used as the sample for the positive-control reaction. The positive control is intended to demonstrate correct setup of PCR reagents and the correct extraction protocol has been conducted, as well as presence of PCR inhibitors which may negatively impact the other targets. As long as a positive reaction is observed in each well for the positive control, PCR is proven to be a success. The control can be used in SARS-CoV-2 detection to verify assay performance and to help with troubleshooting.

Both the TaqMan™ 2019-nCoV Assay Kit and the TaqMan™ 2019-nCoV Control Kit v1 use Applied Biosystems™ TaqMan® MGB probes.

DISCUSSION OF THE VALIDATION STUDY (1)

Inclusivity

Of the 15,756 target SARS-CoV-2 genomes analyzed, 99% of the strains/isolates are perfectly matched to at least two of the three assays, more than 90% have 100% homology to all three assays (ORF1ab, N-gene, S-gene) in the SARS-CoV-2 Kit.

15,756 out of 15,756 tested genomes are predicted to be detected by at least one of the three SARS-CoV-2 assays: 100 % of the strains/isolates matched with at least one of the three assays (ORF1ab, N-gene, S-gene) in the SARS-CoV-2 Kit.

Exclusivity

Of the 65 non-target genomes analyzed against the primers and probes of the TaqMan™ 2019-nCoV Assay Kit v1, none showed matching sequences.

Matrix Study

Data from the matrix study demonstrated that all four options for the Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow, KingFisher Flex Purification System with 96 Deep-Well Head used to extract RNA with the PrepSEQ Nucleic Acid Extraction Kit procedure with the Applied Biosystems 7500 Fast or the Applied Biosystem QuantStudio 5 Real-Time PCR Systems and the MagMAX Express-96 Deep Well Magnetic Particle Processor used to extract RNA with the PrepSEQ™ Nucleic Acid Extraction Kit extraction procedure with the Applied Biosystems 7500 Fast or the Applied Biosystems QuantStudio 5 Real-Time PCR Systems were able to detect low levels of SARS-CoV-2 viral RNA on stainless steel. Each option gave statistically comparable or slightly better results than the CDC 2019-nCoV RT-PCR method, based on POD analysis. It should be noted that for the CDC to call a sample positive, both the N1 and N2 targets must give positive responses. For the Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow, at least one of the targets must give a positive response to call a sample positive. In this study, the N2 target for the CDC method gave significantly more positive responses than the N1 (18 vs 11, dPOD = -0.35, CIs = -0.57, -0.07). The reason for this difference has not been determined but could depend on degradation of virus during the application and drying onto the surface for this study. However, experiments to examine this have not been conducted as part of this evaluation. When comparing the Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow results to the CDC N2 results only, no statistically significant differences were seen (data not shown), even with the largest differences between the methods (14 positive results vs 18 positive results, dPOD = -0.20, CIs = -0.43, 0.05). It should also be noted that the test samples shipped to FSNS arrived at an elevated temperature (16°C vs 2–8°C), and although there do not appear to be any adverse effects on the results, there was a potential for the candidate method samples to be compromised. As presented in this study, the data show that all evaluated options for the Thermo Scientific SARS-CoV-2 Workflow are a comparable alternative to the CDC 2019-nCoV Real-Time RT-PCR method for detecting SARS-CoV-2 on stainless steel surfaces.

Inclusivity, Exclusivity and Background Organism Summary (1)

In Silico Analysis	
Inclusivity	
15,756 unique SARS-CoV-2 strain accessions[a]	
Exclusivity	
Human coronavirus (229E, OC43, NL63, HKU1, NL63), SARS-coronavirus, MERS-coronavirus, Porcine delta coronavirus (CH/JXJGS01/2016)	
Background Organisms	
Viruses:	Influenza A (H1N1, H3N2, H5N1, H7N9), Influenza B, Human adenovirus – type 1 (Ad71), Human metapneumovirus, Respiratory syncytial virus (Long a), Rhinovirus, Parainfluenza 1 (C35), Parainfluenza 2 (Greer), Parainfluenza 3 (C-43), Parainfluenza4 (M-25), Enterovirus (EV68, Human bocavirus, Varicella-zoster virus, Norovirus, Herpes virus, Avian influenza (H1, H4, H6, H9), Avian infectious bronchitis virus, Bovine Coronavirus, Mouse hepatitis, Porcine transmissible gastroenteritis virus
Bacteria and fungi:	*Acinetobacter* spp., *Bacillus thuringiensis, Bacillus cereus* spores, *Bordetella pertussis, Candida albicans, Chlamydia pneumoniae, Clostridium difficile, Escherichia coli* K12, *Enterococcus, Haemophilus influenzae, Klebsiella pneumoniae, Legionella pneumophila, Listeria monocytogenes, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii* (PJP), *Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus salivarius, Torulopsis glabrata*
Eukaryotes:	*Homo sapiens* (HeLa), *Aedes aegypti* (mosquito), *Aedes albopictus* (mosquito), *Dermatophagoides pteronyssinus* (dust mite), *Xenopsylla cheopis* (flea), *Drosophila* (fruit fly), *Musa domestica* (house fly), *Cercopithecus aethiops* (Kidney Vero cells)

[a] Accessions acquired from the Global Initiative on Sharing Avian Influenza Data (GISAID) database from December 2019 to 26 June 2020. Originally 15,764 were listed, but 8 strain accessions were removed by the submitter.

Table 12. Inclusivity (1)

Strain Name	GenBank Accession	Assay	Forward Primer Homology (%)	Reverse Primer Homology (%)	Probe Homology (%)
hCoV-19/Australia/VIC505/2020|EPI_ISL_426776|2020-03-22	EPI_ISL_426776	N gene	96	100	100
hCoV-19/Australia/VIC644/2020|EPI_ISL_426940|2020-03-28	EPI_ISL_426940	ORF1ab	96	100	100
hCoV-19/Australia/VIC644/2020|EPI_ISL_426940|2020-03-28	EPI_ISL_426940	S gene	100	96	100
hCoV-19/Australia/VIC648/2020|EPI_ISL_426944|2020-03-28	EPI_ISL_426944	ORF1ab	88	100	100
hCoV-19/Australia/VIC951/2020|EPI_ISL_430646|2020-03-26	EPI_ISL_430646	ORF1ab	96	100	100
hCoV-19/Australia/VIC951/2020|EPI_ISL_430646|2020-03-26	EPI_ISL_430646	S gene	100	96	100
hCoV-19/Brazil/CV17/2020|EPI_ISL_429677|2020-03-11	EPI_ISL_429677	ORF1ab	88	100	100

hCoV-19/Brazil/CV41/2020|EPI_ISL_429694|2020-03-18	EPI_ISL_429694	ORF1ab	88	100	100
hCoV-19/Brazil/CV46/2020|EPI_ISL_429699|2020-03-20	EPI_ISL_429699	N gene	78	78	100
hCoV-19/Canada/ON_PHL3917/2020|EPI_ISL_418322|2020-03-08	EPI_ISL_418322	ORF1ab	88	100	100
hCoV-19/Canada/ON_PHL3917/2020|EPI_ISL_418322|2020-03-08	EPI_ISL_418322	S gene	96	100	100
hCoV-19/Canada/ON_PHL3919/2020|EPI_ISL_418323|2020-03-14	EPI_ISL_418323	ORF1ab	88	100	100
hCoV-19/Canada/ON_PHL3919/2020|EPI_ISL_418323|2020-03-14	EPI_ISL_418323	S gene	96	100	100
hCoV-19/England/20104035803/2020|EPI_ISL_417238|2020-03-03	EPI_ISL_417238	ORF1ab	88	100	100
19/England/201361007/2020|EPI_ISL_421784|2020-03-26	EPI_ISL_421784	ORF1ab	100	96	100
hCoV-19/England/201380276/2020|EPI_ISL_421826|2020-03-23	EPI_ISL_421826	ORF1ab	100	96	100
hCoV-19/England/201380277/2020|EPI_ISL_421827|2020-03-24	EPI_ISL_421827	ORF1ab	100	96	100
hCoV-19/England/20139021104/2020|EPI_ISL_421880|2020-03-26	EPI_ISL_421880	S gene	96	100	100
hCoV-19/England/20146017604/2020|EPI_ISL_423580|2020-04-02	EPI_ISL_423580	ORF1ab	100	96	100
hCoV-19/France/OCC-4/2020|EPI_ISL_434619|2020-03	EPI_ISL_434619	ORF1ab	100	100	95
hCoV-19/France/OCC-4/2020|EPI_ISL_434619|2020-03	EPI_ISL_434619	S gene	96	100	100
hCoV-19/Iceland/143/2020|EPI_ISL_417794|2020-03-12	EPI_ISL_417794	N gene	96	100	100
hCoV-19/Iceland/194/2020|EPI_ISL_417821|2020-03-16	EPI_ISL_417821	ORF1ab	88	100	100
hCoV-19/Iceland/28/2020|EPI_ISL_417767|2020-03-03	EPI_ISL_417767	N gene	96	100	100
hCoV-19/Iceland/545/2020|EPI_ISL_424565|2020-03-26	EPI_ISL_424565	ORF1ab	100	96	100
hCoV-19/Iceland/86/2020|EPI_ISL_417870|2020-03-10	EPI_ISL_417870	N gene	96	100	100
hCoV-19/India/nimh-0834/2020|EPI_ISL_428485|2020-04-12	EPI_ISL_428485	N gene	100	100	0
hCoV-19/Mexico/Chiapas-InDRE_02/2020|EPI_ISL_424666|2020-02-29	EPI_ISL_424666	S gene	100	68	100
hCoV-19/Netherlands/Gelderland_8/2020|EPI_ISL_422644|2020-03-13	EPI_ISL_422644	ORF1ab	88	100	100
hCoV-19/Netherlands/Gelderland_8/2020|EPI_ISL_422644|2020-03-13	EPI_ISL_422644	N gene	100	100	0
hCoV-19/USA/CA-CDPH-UC25/2020|EPI_ISL_417329|2020-03-04	EPI_ISL_417329	N gene	100	100	0
hCoV-19/USA/CA-CZB027/2020|EPI_ISL_429068|2020-03-25	EPI_ISL_429068	S gene	100	76	100
hCoV-19/USA/CA-CZB04/2020|EPI_ISL_429069|2020-03-25	EPI_ISL_429069	S gene	100	76	100
hCoV-19/Wales/PHWC-2433A/2020|EPI_ISL_419398|2020-03-18	EPI_ISL_419398	N gene	96	100	100
hCoV-19/Wales/PHWC-243FE/2020|EPI_ISL_419408|2020-03-17	EPI_ISL_419408	ORF1ab	100	96	100
hCoV-19/Wales/PHWC-243FE/2020|EPI_ISL_419408|2020-03-17	EPI_ISL_419408	S gene	96	100	100
hCoV-19/Wales/PHWC-24C11/2020|EPI_ISL_419500|2020-03-20	EPI_ISL_419500	S gene	100	100	0
hCoV-19/Wales/PHWC-254CD/2020|EPI_ISL_420979|2020-03-22	EPI_ISL_420979	ORF1ab	100	96	100
hCoV-19/Wales/PHWC-254CD/2020|EPI_ISL_420979|2020-03-22	EPI_ISL_420979	S gene	72	100	100
hCoV-19/Wales/PHWC-2704F/2020|EPI_ISL_422376|2020-03-28	EPI_ISL_422376	S gene	72	100	100
SARS-CoV-2/human/IRN/HGRC-01-IPI-8206/2020	MT281530.2	ORF1ab	88	100	100
SARS-CoV-2/human/USA/CT-UW-5036/2020	MT375469.1	ORF1ab	92	100	100
SARS-CoV-2/human/USA/WA-UW-1963/2020	MT326080.1	ORF1ab	100	64	100
SARS-CoV-2/human/USA/WA-UW-2225/2020	MT345837.1	S gene	96	100	100

Thermo Scientific™ SARS-CoV-2 RT-PCR, AOAC® *Performance Tested℠* Emergency Response certification number 012103

Table 13. Exclusivity (1)

Assay_name	Blast_subject_id	fwd_pcnt_homology	probe_pcnt_homology	rev_pcnt_homology
66792_S	*Aedes albopictus* NW_021837454.1	0	100%	0

Table 17. Statistical comparison of Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow method results using KingFisher™ Flex 96 Deep Well System with Applied Biosystems™ 7500 Fast Food Safety Real-Time PCR System (1)

				Thermo SARS-CoV-2 KF/7500 Fast[c]			CDC 2019-nCoV RT-PCR					
Matrix	Inoculation Strain	GC[a] per Test Area	n[b]	X[d]	POD_C[e]	95% CI	n	x	POD_R[f]	95% CI	$dPOD_C$[g]	95% CI[h]
Stainless Steel	SARS-CoV-2 USA-WA1/2020	0	5	0	0.00	0.00, 0.43	5	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.8×10^3	20	14	0.70	0.48, 0.86	20	11	0.55	0.34, 0.74	0.150	-0.14, 0.41
		1.8×10^4	5	5	1.00	0.57, 1.00	5	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

[a]GC = Genomic copies determined by qRT-PCR.
[b]n = Number of test areas.
[c]KF/7500 Fast = Samples extracted using KingFisher™ Flex 96 Deep Well System, RT-PCR by the Applied Biosystems™ 7500 Fast Food Safety Real-Time PCR System.
[d]x = Number of positive test areas.
[e]POD_C = Candidate method (Thermo SARS-CoV-2 Workflow) positive outcomes divided by the total number of trials.
[f]POD_R = Reference method (CDC 2019-nCoV RT-PCR) positive outcomes divided by the total number of trials.
[g]$dPOD_C$= Difference in POD values between the candidate method confirmed and reference method confirmed results.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

Table 18. Statistical comparison of The Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow method results using KingFisher™ Flex 96 Deep Well System with Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System (1)

				Thermo SARS-CoV-2 KF/QS5[c]			CDC 2019-nCoV RT-PCR					
Matrix	Inoculation Strain	GC[a] per Test Area	n[b]	X[d]	POD_C[e]	95% CI	n	x	POD_R[f]	95% CI	$dPOD_C$[g]	95% CI[h]
Stainless Steel	SARS-CoV-2 USA-WA1/2020	0	5	0	0.00	0.00, 0.43	5	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.8×10^3	20	14	0.70	0.48, 0.86	20	11	0.55	0.34, 0.74	0.15	-0.14, 0.41
		1.8×10^4	5	5	1.00	0.57, 1.00	5	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

[a]GC = Genomic copies determined by qRT-PCR.
[b]n = Number of test areas.
[c]KF/QS5 = Samples extracted using the Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow, KingFisher Flex 96 Deep Well System, RT-PCR by the Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System.
[d]x = Number of positive test areas.
[e]POD_C = Candidate method (Thermo SARS-CoV-2 Workflow) positive outcomes divided by the total number of trials.
[f]POD_R = Reference method (CDC 2019-nCoV RT-PCR) positive outcomes divided by the total number of trials.
[g]$dPOD_C$= Difference in POD values between the candidate method confirmed and reference method confirmed results.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

Table 19. Statistical comparison of The Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow method results using MagMAX™ Express-96 Deep well Magnetic Particle Processor and Applied Biosystems™ 7500 Fast Food Safety Real-Time PCR System (1)

				Thermo SARS-CoV-2 MM/7500 Fast[c]			CDC 2019-nCoV RT-PCR					
Matrix	Inoculation Strain	GC[a] per Test Area	n[b]	X[d]	POD_C[e]	95% CI	n	x	POD_R[f]	95% CI	$dPOD_C$[g]	95% CI[h]
Stainless Steel	SARS-CoV-2 USA-WA1/2020	0	5	0	0.00	0.00, 0.43	5	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.8×10^3	20	16	0.80	0.58, 0.92	20	11	0.55	0.34, 0.74	0.25	-0.04, -0.49
		1.8×10^4	5	5	1.00	0.57, 1.00	5	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

[a]GC = Genomic copies determined by qRT-PCR.
[b]n = Number of test areas.
[c]MM/7500 Fast = Samples extracted using MagMAX™ Express-96 Deep well Magnetic Particle Processor, RT-PCR by the Applied Biosystems™ 7500 Fast Food Safety Real-Time PCR System.
[d]x = Number of positive test areas.
[e]POD_C = Candidate method (Thermo SARS-CoV-2 Workflow) positive outcomes divided by the total number of trials.
[f]POD_R = Reference method (CDC 2019-nCoV RT-PCR) confirmed positive outcomes divided by the total number of trials.
[g]$dPOD_C$= Difference in POD values between the candidate method confirmed and reference method confirmed results.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

Table 20. Statistical comparison of The Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow method results using MagMAX™ Express-96 Deep well Magnetic Particle Processor and Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System (1)

Matrix	Inoculation Strain	GC[a] per Test Area	n[b]	Thermo SARS-CoV-2 MM/QS5[c]			CDC 2019-nCoV RT-PCR					
				X[d]	POD_C[e]	95% CI	n	x	POD_R[f]	95% CI	$dPOD_C$[g]	95% CI[h]
Stainless Steel	SARS-CoV-2 USA-WA1/2020	0	5	0	0.00	0.00, 0.43	5	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.8×10^3	20	15	0.75	0.53, 0.89	20	11	0.55	0.34, 0.74	0.20	-0.09, 0.45
		1.8×10^4	5	5	1.00	0.57, 1.00	5	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

[a]GC = Genomic copies determined by qRT-PCR.
[b]n = Number of test areas.
[c]MM/QS5 = Samples extracted using MagMAX™ Express-96 Deep well Magnetic Particle Processor, RT-PCR by the Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System.
[d]x = Number of positive test areas.
[e]POD_C = Candidate method (Thermo SARS-CoV-2 Workflow) positive outcomes divided by the total number of trials.
[f]POD_R = Reference method (CDC 2019-nCoV RT-PCR) confirmed positive outcomes divided by the total number of trials.
[g]$dPOD_C$= Difference in POD values between the candidate method confirmed and reference method confirmed results.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

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Table 21. The Thermo Scientific SARS-CoV-2 Real-Time PCR Workflow and CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel test kit method summary results (1)

Matrix	Inoculation Strain	GC[a] per Test area	n[b]	Thermo SARS-CoV-2 workflow				CDC 2019-nCoV RT-PCR[g]		
				KF/7500 Fast[c]	KF/QS5[d]	MM/7500 Fast[e]	MM/QS5[f]	N1 Positive	N2 Positive	Final Result
Stainless Steel	SARS-CoV-2 USA-WA1/2020	0	5	0	0	0	0	0	0	0
		1.8×10^3	20	14	14	16	15	11	18	11
		1.8×10^4	5	5	5	5	5	5	5	5

[a]GC = Genomic copies determined by qRT-PCR.
[b]n = Number of test areas.
[c]KF/7500 Fast = Samples extracted using KingFisher™ Flex 96 Deep Well System, RT-PCR by the Applied Biosystems™ 7500 Fast Food Safety Real-Time PCR System.
[d]KF/QS5 = Samples extracted using KingFisher™ Flex 96 Deep Well System, PCR by the Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System.
[e]MM/7500 Fast = Samples extracted using MagMAX™ Express-96 Deep well Magnetic Particle Processor, RT-PCR by the Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System.
[f]MM/QS5 = Samples extracted using MagMAX™ Express-96 Deep well Magnetic Particle Processor, RT-PCR by the Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR System.
[g]CDC 2019-nCoV RT-PCR = Both the N1 and N2 targets must give positive responses to call a sample positive. For the Thermo SARS-CoV-2 workflow, at least one must be detected to call a sample positive.

REFERENCES CITED

1. Brzoska, P., Crabtree, D., Evans, K., Leonte, A.M., Manolis, A., Salavirta, H., Stephenson, P., and Sohier, D., Validation of the Thermo Scientific™ SARS-CoV-2 RT-PCR Detection Workflow for the Detection of SARS-CoV-2 from Stainless Steel Environmental Surface Swabs, AOAC® *Performance Tested℠* Emergency Response Validation certification number 012103.
2. Centers for Disease Control and Prevention (2020). *CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.* Revision 5. 07/13/2020. https://www.fda.gov/media/134922/download (Accessed October 2020).