Workflow of the TaqPath COVID-19, Flu A/B, RSV Combo Kit

Now compatible for use with the QuantStudio 5 and QuantStudio 7 Flex Systems

The Applied Biosystems™ TaqPath™ COVID-19, Flu A/B, RSV Combo Kit is now compatible with the Applied Biosystems™ QuantStudio™ 5 and QuantStudio™ 7 Flex Real-Time PCR Systems.

With SARS-CoV-2 now part of the viral ecosystem, laboratories need to test for multiple respiratory viruses using one patient sample. This helps to detect and differentiate viral infections that present symptoms similar to those of COVID-19.

Influenza virus and respiratory syncytial virus (RSV), though not as contagious as SARS-CoV-2, share symptoms with the novel coronavirus, and accurate testing is needed to ensure proper patient care. The TaqPath COVID-19, Flu A/B, RSV Combo Kit is a CE-IVD–marked, highly accurate, multiplex real-time PCR test that can detect and differentiate between SARS-CoV-2, influenza A/B, and RSV A/B in a single sample, allowing you to expand your respiratory sample testing menu while keeping costs under control.

The workflow of the CE-IVD–marked TaqPath COVID-19, Flu A/B, RSV Combo Kit now includes the QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL block) and the QuantStudio 7 Flex Real-Time PCR System (384-well block), two of our most widely used PCR systems.

Study design for equivalence testing

The previously approved workflow of the TaqPath COVID-19, Flu A/B, RSV Combo Kit required the Applied Biosystems™ 7500 Fast Real-Time PCR System. To demonstrate functional equivalence of the QuantStudio 5 and QuantStudio 7 Flex Real-Time PCR Systems, a bridging study was performed. Table 1 summarizes the configuration of the PCR instruments used in the bridging study.

The study utilized eluates from contrived nasopharyngeal swab (NP) samples formulated at varying concentrations of the viral target relative to the previously determined limit of detection (LOD) of the TaqPath Combo kit on the 7500 Fast system. The performance of the TaqPath COVID-19, Flu A/B, RSV Combo Kit on each of the PCR instruments shown in Table 1 was assessed by testing each of the 5 viral targets (SARS-CoV-2, influenza A, influenza B, RSV A, and RSV B) at concentrations of 3x LOD, 1x LOD, and 0.33x LOD with 20 replicates each and 3 replicates of a negative sample devoid of analyte. Table 2 summarizes the viral targets and concentrations tested.

From left to right: QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL), QuantStudio 7 Flex Real-Time PCR System (384-well), and TaqPath COVID-19, Flu A/B, RSV Combo Kit

To demonstrate performance equivalency, the QuantStudio 5 and QuantStudio 7 Flex Real-Time PCR Systems must have LODs comparable to the LODs determined for the 7500 Fast Real-Time PCR System.

Table 1. Instruments for bridging study.

Condition	Instrument
Control	7500 Fast Real-Time PCR System (Software SDS v1.5.1 or v2.3)
Test	QuantStudio 5 Real-Time PCR System, 96-well, 0.2 mL block (QuantStudio Design and Analysis Software v1.5.1)
	QuantStudio 7 Flex Real-Time PCR System, 384-well block (QuantStudio Design and Analysis Software v1.3)

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Acceptable LODs must be within 1–3 times the LODs reported for the 7500 Fast Real-Time PCR System; this means that the 3x LOD test level must have a 100% positivity rate for all targets on all three PCR systems, while the 0.33x LOD test level must have a positivity rate below 100%. Additionally, all negative samples must produce a negative result.

Comparison study and results

The results of the bridging study conducted for the QuantStudio 5 and QuantStudio 7 Flex Real-Time PCR Systems are summarized in Tables 3 and 4, respectively. All three PCR instruments had a positivity rate of 100% at the 3x LOD test level, and the samples at 0.33x LOD yielded <100% positivity. All negative samples (0x LOD) yielded a negative result. The results demonstrate performance equivalency among the 7500 Fast, QuantStudio 5, and QuantStudio 7 Flex Real-Time PCR Systems.

Conclusions

The performance of the TaqPath COVID-19, Flu A/B, RSV Combo Kit test was evaluated on the QuantStudio 5 and 7 Flex Real-Time PCR Systems, using the previously qualified 7500 Fast system as the comparator. Based on the study, the QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL block) and the QuantStudio 7 Flex Real-Time PCR System (384-well block) met the criteria for performance equivalency and are now included in the workflow of the TaqPath COVID-19, Flu A/B, RSV Combo Kit.

Table 2. Viral target concentrations used for testing.

Test level relative to the LOD on the 7500 Fast system	Target concentration (GCE/mL) in NP sample				
	SARS-CoV-2	Influenza A (H1N1)	Influenza B (Florida)	RSV A	RSV B
3x LOD	150	1,152	3,750	600	600
1x LOD	50	384	1,250	200	200
0.33x LOD	16.7	127.9	416.3	66.6	66.6
0x LOD	0	0	0	0	0

Table 3. Positivity rates for all targets and test levels for the QuantStudio 5 Real-Time PCR System.

Target virus	Test instrument (QuantStudio 5 system)				Control instrument (7500 Fast system)			
	3x LOD	1x LOD	0.33x LOD	0x LOD	3x LOD	1x LOD	0.33x LOD	0x LOD
SARS-CoV-2	100% (20/20)	100% (20/20)	0% (0/20)	0% (0/3)	100% (20/20)	100% (20/20)	40% (8/20)	0% (0/3)
Flu A	100% (20/20)	50% (10/20)	5% (1/20)	0% (0/3)	100% (20/20)	45% (9/20)	5% (1/20)	0% (0/3)
Flu B	100% (20/20)	100% (20/20)	55% (11/20)	0% (0/3)	100% (20/20)	100% (20/20)	40% (8/20)	0% (0/3)
RSV A	100% (20/20)	100% (20/20)	75% (15/20)	0% (0/3)	100% (20/20)	100% (20/20)	65% (13/20)	0% (0/3)
RSV B	100% (20/20)	100% (20/20)	90% (18/20)	0% (0/3)	100% (20/20)	95% (19/20)	60% (12/20)	0% (0/3)

Table 4. Positivity rates for all targets and test levels for the QuantStudio 7 Flex Real-Time PCR System.

Target virus	Test instrument (QuantStudio 7 Flex system)				Control instrument (7500 Fast system)			
	3x LOD	1x LOD	0.33x LOD	0x LOD	3x LOD	1x LOD	0.33x LOD	0x LOD
SARS-CoV-2	100% (20/20)	80% (16/20)	0% (0/20)	0% (0/3)	100% (20/20)	100% (20/20)	5% (1/20)	0% (0/3)
Flu A	100% (20/20)	45% (9/20)	10% (2/20)	0% (0/3)	100% (20/20)	70% (14/20)	15% (3/20)	0% (0/3)
Flu B	100% (20/20)	100% (20/20)	65% (13/20)	0% (0/3)	100% (20/20)	100% (20/20)	50% (10/20)	0% (0/3)
RSV A	100% (20/20)	100% (20/20)	70% (14/20)	0% (0/3)	100% (20/20	100% (20/20)	90% (18/20)	0% (0/3)
RSV B	100% (20/20)	95% (19/20)	50% (10/20)	0% (0/3)	100% (20/20)	100% (20/20)	90% (18/20)	0% (0/3)

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