



Evaluation of the Aptima™ transcription-mediated amplification assay (Hologic®) for detecting SARS-CoV-2 in clinical specimens

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Title: Evaluation of the Aptima™ Transcription-Mediated Amplification assay (Hologic®) for detecting SARS-CoV-2 in clinical specimens

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1 **Abstract**

2 Background: The spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which
3 appeared in late 2019, has been limited by isolating infected individuals. However, identifying such
4 individuals requires accurate diagnostic tools.

5 Objectives: This study evaluates the capacity of the Aptima™ Transcription-Mediated Amplification
6 (TMA) assay (Hologic® Panther System) to detect the virus in clinical samples.

7 Study design: We compared the Aptima™ assay to two in-house real-time RT-PCR techniques, one
8 running on the Panther Fusion™ module and the other on the MagNA Pure 96 and Light-Cycler 480
9 instruments. We included a total of 200 respiratory specimens: 100 tested prospectively and 100
10 retrospectively (25 -ve/75 +ve).

11 Results: The final Cohen's kappa coefficients were: $\kappa = 0.978$ between the Aptima™ and Panther
12 Fusion™ assays, $\kappa = 0.945$ between the Aptima™ and MagNA/LC480 assays and $\kappa = 0.956$ between
13 the MagNA/LC480 and Panther Fusion™ assays.

14 Conclusion: These findings indicate that the Aptima™ SARS-CoV-2 TMA assay data agree well with
15 those obtained with our routine methods and that this assay can be used to diagnose coronavirus disease
16 2019 (COVID-19).

17

18

19 **Keywords**

20 SARS-CoV-2; COVID-19; coronavirus; Hologic® Panther System

21

22 **1. Background**

23 The emergence of a new severe acute respiratory syndrome coronavirus (SARS-CoV-2) in late 2019
24 and its rapid spread worldwide led to over 6 million cases of coronavirus disease 2019 (COVID-19) by
25 1 June, 2020 (1, 2). As the rapid identification of infected individuals and their isolation is essential to
26 prevent the spread of the disease, it became necessary to develop accurate, easy-to-use molecular
27 diagnostic assays. Virology laboratories first developed and published in-house techniques (3, 4), which
28 were soon followed by commercial assays. These must be validated on clinical specimens in addition to
29 preliminary tests on culture lysates/supernatants or serially diluted RNA transcripts. Nasopharyngeal
30 swabs are generally used for diagnosing viral respiratory tract infections, while deeper samples, such as
31 tracheal aspirations or broncho-alveolar lavage fluids are used only in severe cases (5).

32

33 **2. Objectives**

34 This study evaluates the performance of the automated commercial Aptima™ SARS-CoV-2 assay
35 (Hologic® Panther™ System) on clinical samples. This test, which uses transcription-mediated
36 amplification (TMA) to detect SARS-CoV-2, was compared to two in-house reverse transcriptase –
37 polymerase chain reaction (RT-PCR) assays we presently use to diagnose COVID-19.

38

39 **3. Study design**

40 Samples

41 We tested 200 respiratory samples (198 nasopharyngeal swabs and 2 tracheal aspirations) from patients
42 suspected of having COVID-19 in April and May 2020 (54.5% men; median [IQR] age: 61 [38-83]
43 years). Half of the samples were tested with all three assays in parallel. These were the prospective
44 samples (98 nasopharyngeal swabs + 2 tracheal aspirations). The remaining 100 nasopharyngeal swabs
45 were selected based on the results obtained with the Panther Fusion™ module in open access (see
46 below). They included 25 samples that were negative, 25 that were positive with a cycle threshold (Ct)

47 value > 35, 25 that were positive with a Ct of 25-35, and 25 that were positive with a Ct < 25. These
48 retrospective samples had been stored at -20°C for up to 43 days.

49

50 Methods

51 The Aptima™ SARS-CoV-2 assay was performed following the manufacturer's instructions. Virus
52 transport medium (500 µL) was manually placed in the Panther™ tube containing 710 µL of lysis buffer.

53 The instrument used 360 µL of this mix for the lysis and capture of nucleic acids. The Aptima™ assay
54 targets two virus sequences located on the ORF1ab gene. An internal control was included.

55 Our two in-house assays that both target virus sequences on the SARS-CoV-2 RNA-dependent RNA-
56 polymerase (RdRp) gene, use primers and probes (IP-2 and IP-4) and amplification programs from the

57 Institut Pasteur, Paris (4). The first assay uses the MagNA Pure 96 instrument (Roche Diagnostics) to
58 extract nucleic acids from 200 µL of virus transport medium eluted in 100 µL. RT-PCR is then

59 performed on the Light-Cycler 480 instrument (LC480) (Roche Diagnostics) using the AccuStart™ Taq
60 DNA polymerase (QuantaBio) and 2 µL of nucleic acids (total reaction volume: 10 µL). The second

61 assay uses the same primers and probes on the Panther Fusion™ module (Hologic®) in open access.

62 Samples were prepared as described above for the Aptima™ assay.

63

64 Data analysis

65 Because there is no reference standard method for the detection of SARS-CoV-2, we calculated the
66 concordance between assays by using Cohen's kappa coefficient (κ), the positive percent agreement, the
67 negative percent agreement and overall percent agreement, all with 95% confidence intervals (6, 7).

68

69 **4. Results and discussion**

70 Prospective study

71 The prospective study provided 2 positive and 98 negative samples, and there was perfect concordance
72 between results of the Aptima™ assay and those of the Panther Fusion™ assay and very good
73 concordance between the Aptima™ assay and the MagNA/LC480 assay. One sample was faintly
74 positive with the MagNA/LC480 assay (virus IP-4 target, Ct = 39.97 and IP-2 -ve) and negative with
75 the other two assays (sample A2 0141 0134, *cf.* Table S1 in Supplementary materials).

76

77 Retrospective study

78 All positive samples with Ct values < 35 (n = 50) with the Panther Fusion™ assay tested positive with
79 the other two assays. The MagNA/LC480 assay detected only one virus target (IP-4) in 6 of these
80 samples (initial Ct: 32-35) (*cf.* Table S2 in Supplementary materials).

81 The 25 (Ct > 35) positive samples detected by the Panther Fusion™ assay included 20 (80%) samples
82 that were positive with The Aptima™ assay and 17 (68%) that were positive with the MagNA/LC480
83 assay. These latter included 13 (65%) in which only one virus target (IP-4) was detected. Five (20%)
84 samples were negative with the Aptima™ assay and eight (32%) with the MagNA/LC480 assay, four
85 of these were negative with both assays. These nine samples were tested again with the Panther Fusion™
86 assay since sample storage can result in the partial degradation of virus RNA, and thus to reduced assay
87 sensitivity. Four were negative and five were positive or inconclusive (three with only IP-2, one with
88 only IP-4 and one with both targets) (*cf.* Table S2). These discrepancies could also be due to selection
89 bias - samples were chosen based on the Panther Fusion™ assay results.

90 All the Panther Fusion™ assay negative samples were also negative with the Aptima™ assay, except
91 for one invalid sample. One sample was positive with the MagNA/LC480 assay, but displayed atypical
92 PCR curves. A second RT-PCR on the same nucleic acid extract was negative (sample A2 0139 3655,
93 *cf.* Table S2).

94

95 Concordance between assays

96 The invalid rate, all results included, with the AptimaTM assay was 0.5% (1/200). The AptimaTM and
97 Panther FusionTM assays gave a Cohen's coefficient $\kappa = 0.978$ [0.949-1.000], a positive percent
98 agreement = 97.3% [95.0-99.6%], a negative percent agreement = 100% [100-100%] and an overall
99 percent agreement = 99.0% [97.6-100%] after re-testing of discrepancies. The AptimaTM and
100 MagNA/LC480 assays had a Cohen's coefficient $\kappa = 0.945$ [0.898-0.993], a positive percent agreement
101 = 98.6% [96.9-100%], a negative percent agreement = 96.9% [94.5-99.3%] and an overall percent
102 agreement = 97.5% [95.3-99.7%]. The MagNA/LC480 and Panther FusionTM assays had a Cohen's
103 coefficient $\kappa = 0.956$ [0.914-0.999], a positive percent agreement = 94.5% [91.4-97.7%], a negative
104 percent agreement = 100% [100-100%] and an overall percent agreement = 98.0% [96.1-99.9%] (cf.
105 Table 1).

106

107 The AptimaTM SARS-CoV-2 TMA assay was given emergency use authorization by the United States
108 Food and Drug Administration (8) and the CE mark for *in vitro* diagnostic use in Europe.

109 We conclude that the results of the commercial AptimaTM SARS-CoV-2 TMA assay agreed very closely
110 with those obtained with our in-house assays. It includes an internal control to detect inhibition of
111 amplification. The PantherTM instrument also provides random access, which allows urgent samples
112 prioritization to obtain results within 3.5 hours with the AptimaTM assay, and can deliver up to 60 results
113 per hour. This can help laboratories provide rapid, high-throughput diagnosis during the COVID-19
114 pandemic crisis.

115

116 Competing interests

117 None declared.

118

119 Funding

120 This research did not receive any specific grant from funding agencies in the public, commercial, or
121 not-for-profit sectors.

122

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Table 1. Concordance of qualitative results.

A. AptimaTM and Panther FusionTM assays

Aptima TM \ Panther Fusion TM	Positive	Negative	Total
Positive	72	0	72
Negative	2	125	127
Total	74	125	199*

B. AptimaTM and MagNA/LC480 assays

Aptima TM \ MagNA/LC480	Positive	Negative	Total
Positive	68	4	72
Negative	1	126	127
Total	69	130	199*

C. MagNA/LC480 and Panther FusionTM assays

MagNA/LC480 \ Panther Fusion TM	Positive	Negative	Total
Positive	69	0	69
Negative	4	127	131
Total	73	127	200

*One of the 200 samples was invalid with the AptimaTM assay.

Supplementary materials

Table S1. Prospective study: detailed results

Sample ID	Panther Fusion™			MagNA/ LC480			Aptima™		Remarks
	Result	IP-2 Ct	IP-4 Ct	Result	IP-2 Ct	IP-4 Ct	Result	RLU	
A2 0140 3201	Negative	-	-	Negative	-	-	Negative	309	
A2 0140 3294	Negative	-	-	Negative	-	-	Negative	324	
A2 0140 3315	Negative	-	-	Negative	-	-	Negative	320	
A2 0140 3416	Negative	-	-	Negative	-	-	Negative	299	
A2 0140 3444	Negative	-	-	Negative	-	-	Negative	320	
A2 0140 4263	Negative	-	-	Negative	-	-	Negative	309	
A2 0140 4273	Negative	-	-	Negative	-	-	Negative	309	
A2 0140 4329	Negative	-	-	Negative	-	-	Negative	300	
A2 0140 4370	Negative	-	-	Negative	-	-	Negative	312	
A2 0140 4374	Negative	-	-	Negative	-	-	Negative	301	
A2 0140 4557	Negative	-	-	Negative	-	-	Negative	319	
A2 0140 4558	Negative	-	-	Negative	-	-	Negative	316	Tracheal aspiration
A2 0140 4559	Negative	-	-	Negative	-	-	Negative	306	
A2 0140 4576	Negative	-	-	Negative	-	-	Negative	295	
A2 0140 4577	Negative	-	-	Negative	-	-	Negative	293	
A2 0140 4680	Negative	-	-	Negative	-	-	Negative	304	
A2 0140 4684	Negative	-	-	Negative	-	-	Negative	305	
A2 0140 4686	Negative	-	-	Negative	-	-	Negative	296	
A2 0140 4708	Negative	-	-	Negative	-	-	Negative	305	
A2 0140 4709	Negative	-	-	Negative	-	-	Negative	298	
A2 0140 4710	Negative	-	-	Negative	-	-	Negative	318	
A2 0140 4715	Negative	-	-	Negative	-	-	Negative	305	
A2 0140 4722	Negative	-	-	Negative	-	-	Negative	295	
A2 0140 4788	Negative	-	-	Negative	-	-	Negative	314	
A2 0141 3129	Negative	-	-	Negative	-	-	Negative	320	
A2 0141 3134	Negative	-	-	Negative	-	-	Negative	329	
A2 0141 3136	Negative	-	-	Negative	-	-	Negative	323	
A2 0141 3141	Negative	-	-	Negative	-	-	Negative	309	
A2 0141 3143	Negative	-	-	Negative	-	-	Negative	318	
A2 0141 3247	Negative	-	-	Negative	-	-	Negative	320	
A2 0141 0056	Negative	-	-	Negative	-	-	Negative	289	
A2 0141 0057	Negative	-	-	Negative	-	-	Negative	319	
A2 0141 0076	Negative	-	-	Negative	-	-	Negative	312	
A2 0141 0078	Negative	-	-	Negative	-	-	Negative	298	
A2 0141 0080	Negative	-	-	Negative	-	-	Negative	317	
A2 0141 0081	Negative	-	-	Negative	-	-	Negative	316	
A2 0141 0102	Negative	-	-	Negative	-	-	Negative	313	
A2 0141 0103	Negative	-	-	Negative	-	-	Negative	315	
A2 0141 0104	Negative	-	-	Negative	-	-	Negative	308	
A2 0141 0134	Negative	-	-	Positive	-	39.97	Negative	296	Thoracic scan not in favor of COVID-19
A2 0141 0390	Negative	-	-	Negative	-	-	Negative	318	
A2 0141 0766	Negative	-	-	Negative	-	-	Negative	308	
A2 0141 0953	Negative	-	-	Negative	-	-	Negative	299	
A2 0141 1553	Negative	-	-	Negative	-	-	Negative	319	
A2 0141 1730	Negative	-	-	Negative	-	-	Negative	317	
A2 0141 1739	Negative	-	-	Negative	-	-	Negative	316	
A2 0141 1748	Negative	-	-	Negative	-	-	Negative	311	
A2 0141 1893	Positive	34.6	34.1	Positive	30.21	32.85	Positive	1 154	Tracheal aspiration
A2 0141 1894	Negative	-	-	Negative	-	-	Negative	307	
A2 0141 1918	Negative	-	-	Negative	-	-	Negative	328	
A2 0141 2097	Negative	-	-	Negative	-	-	Negative	309	
A2 0141 2103	Negative	-	-	Negative	-	-	Negative	307	
A2 0141 2104	Negative	-	-	Negative	-	-	Negative	302	
A2 0141 2115	Negative	-	-	Negative	-	-	Negative	304	
A2 0141 2129	Negative	-	-	Negative	-	-	Negative	305	
A2 0141 2358	Negative	-	-	Negative	-	-	Negative	310	
A2 0141 2519	Negative	-	-	Negative	-	-	Negative	303	
A2 0141 2532	Positive	38	37	Positive	41.92	33.52	Positive	1 104	
A2 0141 2535	Negative	-	-	Negative	-	-	Negative	302	
A2 0141 2537	Negative	-	-	Negative	-	-	Negative	305	
A2 0141 2540	Negative	-	-	Negative	-	-	Negative	309	
A2 0141 2543	Negative	-	-	Negative	-	-	Negative	288	
A2 0141 2545	Negative	-	-	Negative	-	-	Negative	317	

A2 0141 2549	Negative	-	-	Negative	-	-	Negative	309	
A2 0141 2550	Negative	-	-	Negative	-	-	Negative	300	
A2 0141 2861	Negative	-	-	Negative	42.16	-	Negative	305	Atypical curve for IP-2
A2 0141 3115	Negative	-	-	Negative	-	-	Negative	321	
A2 0141 3122	Negative	-	-	Negative	-	-	Negative	319	
A2 0141 3125	Negative	-	-	Negative	-	-	Negative	316	
A2 0141 3126	Negative	-	-	Negative	-	-	Negative	301	
A2 0141 3128	Negative	-	-	Negative	-	-	Negative	314	
A2 0141 3433	Negative	-	-	Negative	-	-	Negative	302	
A2 0141 3661	Negative	-	-	Negative	-	-	Negative	312	
A2 0141 3662	Negative	-	-	Negative	-	-	Negative	315	
A2 0141 3665	Negative	-	-	Negative	-	-	Negative	315	
A2 0141 3666	Negative	-	-	Negative	-	-	Negative	319	
A2 0141 3668	Negative	-	-	Negative	-	-	Negative	311	
A2 0141 3683	Negative	-	-	Negative	-	-	Negative	309	
A2 0141 3778	Negative	-	-	Negative	-	-	Negative	310	
A2 0141 3779	Negative	-	-	Negative	-	-	Negative	311	
A2 0141 3867	Negative	-	-	Negative	-	-	Negative	300	
A2 0141 4131	Negative	-	-	Negative	-	-	Negative	302	
A2 0142 0420	Negative	-	-	Negative	-	-	Negative	307	
A2 0142 0478	Negative	-	-	Negative	-	-	Negative	323	
A2 0142 0969	Negative	-	-	Negative	-	-	Negative	298	
A2 0142 0979	Negative	-	-	Negative	-	-	Negative	310	
A2 0142 1301	Negative	-	-	Negative	-	-	Negative	292	
A2 0142 1361	Negative	-	-	Negative	42.09	-	Negative	294	Atypical curve for IP-2. Urinary tract infection on the same date
A2 0142 1397	Negative	-	-	Negative	-	-	Negative	313	
A2 0142 1398	Negative	-	-	Negative	-	-	Negative	302	
A2 0142 1552	Negative	-	-	Negative	-	-	Negative	304	
A2 0142 1555	Negative	-	-	Negative	-	-	Negative	309	
A2 0142 1556	Negative	-	-	Negative	-	-	Negative	297	
A2 0142 1558	Negative	-	-	Negative	-	-	Negative	317	
A2 0142 1559	Negative	-	-	Negative	-	-	Negative	314	
A2 0142 1560	Negative	-	-	Negative	-	-	Negative	294	
A2 0142 1687	Negative	-	-	Negative	-	-	Negative	313	
A2 0142 1688	Negative	-	-	Negative	-	-	Negative	304	
A2 0142 1689	Negative	-	-	Negative	-	-	Negative	316	
A2 0142 1692	Negative	-	-	Negative	-	-	Negative	304	

Ct: cycle threshold, RLU: relative light unit

Table S2. Retrospective study: detailed results

Sample ID	Panther Fusion™			MagNA/ LC480			Aptima™		Remarks
	Result	IP-2 Ct	IP-4 Ct	Result	IP-2 Ct	IP-4 Ct	Result	RLU	
A2 0107 0148	Positive	17	16.3	Positive	14.61	13.94	Positive	1 184	
A2 0119 3110	Positive	17	16.3	Positive	16.47	15.89	Positive	1 195	
A2 0101 1006	Positive	17.2	16.6	Positive	15.97	15.43	Positive	1 199	
A2 0112 2628	Positive	18.9	18	Positive	18	17.44	Positive	1 205	
A2 0108 2220	Positive	20.1	18.7	Positive	20.39	19.79	Positive	1 212	
A2 0102 0932	Positive	20.5	20.4	Positive	18.11	17.47	Positive	1 199	
A2 0104 1775	Positive	20.7	19.8	Positive	20.29	19.75	Positive	1 165	
A2 0115 2872	Positive	20.9	20.1	Positive	19.65	18.98	Positive	1 213	
A2 0127 3208	Positive	20.9	20.3	Positive	19.97	19.48	Positive	1 218	
A2 0102 0926	Positive	21.1	20.6	Positive	19.84	19.39	Positive	1 208	
A2 0109 1073	Positive	21.3	20.2	Positive	19.09	18.49	Positive	1 196	
A2 0121 0093	Positive	21.5	20.6	Positive	24.36	25	Positive	1 225	
A2 0102 1924	Positive	21.6	21.1	Positive	20.37	19.77	Positive	1 176	
A2 0112 1237	Positive	22	21.4	Positive	17.87	17.47	Positive	1 197	
A2 0134 3890	Positive	22.2	20.8	Positive	21.45	21.04	Positive	1 162	
A2 0119 3653	Positive	22.3	21.4	Positive	20.66	20.26	Positive	1 203	
A2 0133 4010	Positive	22.6	21.4	Positive	20.05	19.6	Positive	1 199	
A2 0127 1294	Positive	22.6	21.8	Positive	23.48	22.98	Positive	1 179	
A2 0134 3894	Positive	22.9	21.1	Positive	19.31	18.83	Positive	1 160	
A2 0117 0995	Positive	22.9	22	Positive	22.32	21.66	Positive	1 236	
A2 0110 1108	Positive	23.8	23.1	Positive	22.61	22.09	Positive	1 177	
A2 0101 1775	Positive	24.1	23.2	Positive	21.92	21.46	Positive	1 206	
A2 0134 3892	Positive	24.2	22.5	Positive	21.81	21.36	Positive	1 178	
A2 0104 0696	Positive	24.4	23.5	Positive	21.71	21.28	Positive	1 172	
A2 0110 0732	Positive	24.9	23.9	Positive	23.93	23.46	Positive	1 169	
A2 0117 0554	Positive	26	25	Positive	25.99	24.51	Positive	1 229	
A2 0127 4030	Positive	26.1	25	Positive	24.88	23.44	Positive	1 183	
A2 0121 3538	Positive	26.2	25.5	Positive	25.03	23.48	Positive	1 227	
A2 0139 0972	Positive	26.3	25.2	Positive	25.93	24.32	Positive	1 199	
A2 0111 1588	Positive	29.2	28.6	Positive	30.98	28.42	Positive	1 207	
A2 1030 1508	Positive	29.4	29	Positive	29.85	27.64	Positive	1 206	
A2 0120 01268	Positive	29.9	28.8	Positive	31.99	29.29	Positive	1 176	
A2 0114 0831	Positive	29.9	29.2	Positive	30.6	28.46	Positive	1 195	
A2 0133 0933	Positive	30.1	30.1	Positive	28.16	26.41	Positive	1 176	
A2 0127 3245	Positive	30.5	30.5	Positive	30.33	28.33	Positive	1 198	
A2 0112 1472	Positive	30.6	30.1	Positive	31.1	28.77	Positive	1 188	
A2 0112 1256	Positive	30.6	30.7	Positive	27.37	25.62	Positive	1 178	
A2 0138 1165	Positive	30.7	29.5	Positive	29.23	26.98	Positive	1 170	
A2 0128 0906	Positive	31	30.1	Positive	30.96	28.57	Positive	1 189	
A2 0117 1424	Positive	31.1	30.2	Positive	31.98	28.52	Positive	1 226	
A2 0115 01876	Positive	32.3	31.4	Positive	34.03	30.6	Positive	1 205	
A2 0111 1816	Positive	32.7	32.4	Positive	-	34.51	Positive	1 189	
A2 0111 1530	Positive	33	32.2	Positive	-	34.69	Positive	1 163	
A2 0127 3308	Positive	33	32.6	Positive	31.89	36.71	Positive	1 215	
A2 0112 3084	Positive	33.3	33.4	Positive	33.85	30.34	Positive	1 199	
A2 0113 0845	Positive	33.4	33.2	Positive	34.83	29.86	Positive	1 203	
A2 0126 1194	Positive	33.5	32.8	Positive	-	34.24	Positive	1 053	
A2 0130 1276	Positive	33.8	34.6	Positive	-	34.45	Positive	1 173	
A2 0123 1103	Positive	34.3	33	Positive	-	32.57	Positive	911	
A2 0116 0798	Positive	34.3	33.3	Positive	-	34.38	Positive	1 155	
A2 0105 0606	Positive	35.8	36.3	Positive	36.46	32.72	Positive	1 217	
A2 0139 3620	Positive	36.1	36.5	Positive	-	34.97	Positive	1 168	
A2 0115 2415	Positive	36.4	36.7	Positive	37.75	32.76	Positive	1 166	
A2 0132 0785	Positive	36.5	36	Positive	-	35.05	Positive	1 212	
A2 0102 0884	Positive	36.8	35.2	Negative	-	-	Negative	309	Negative when re-tested in Fusion
A2 0134 2287	Positive	36.8	36	Positive	-	36.95	Positive	1 132	
A2 0112 1257	Positive	37	38.8	Negative	-	-	Positive	1 219	Positive when re-tested in Fusion (IP-2 Ct = 36.9; IP-4 Ct = 37)
A2 0126 1676	Positive	37.1	36.8	Positive	-	36.15	Negative	381	Negative when re-tested in Fusion
A2 0111 1929	Positive	37.3	36	Positive	-	36.33	Positive	998	
A2 0143 1744	Positive	37.7	35.6	Positive	-	33.53	Positive	1 187	
A2 0123 1447	Positive	37.8	36.9	Positive	-	35	Positive	1 232	
A2 0119 3083	Positive	37.8	39.2	Positive	-	39.73	Positive	1 219	
A2 0127 3568	Positive	38.3	35.6	Negative	-	-	Positive	1 141	Negative when re-tested in Fusion
A2 0139 1414	Positive	38.3	38.6	Negative	-	-	Positive	828	Inconclusive when re-tested in Fusion (IP-2 Ct = 44.9, atypical curve; IP-4 negative)
A2 0107 2250	Positive	38.7	38	Positive	-	38.16	Positive	1 172	

A2 0135 2938	Positive	38.7	38.5	Positive	-	40.73	Positive	687	
A2 0107 2076	Positive	39	36.1	Positive	-	32.86	Positive	1 179	
A2 0112 1304	Positive	39.1	37.3	Negative	-	-	Negative	492	Negative when re-tested in Fusion
A2 0105 1636	Positive	39.1	37.6	Negative	-	-	Positive	587	Inconclusive when re-tested in Fusion (IP-2 Ct = 39.6; IP-4 negative)
A2 0143 1740	Positive	39.3	35.8	Positive	41.51	36.02	Positive	1 153	
A2 0119 2494	Positive	40.2	37.9	Negative	-	-	Negative	485	Positive when re-tested in Fusion (IP-4 Ct = 36.5; IP-2 negative)
A2 0130 0936	Positive	40.7	37.7	Positive	-	34.39	Positive	1 018	
A2 0107 2065	Positive	40.8	36.6	Positive	-	39.12	Positive	724	
A2 0112 1254	Positive	41.2	38.7	Positive	33.94	30.77	Positive	1 197	
A2 0115 1779	Positive	41.9	36.2	Negative	-	-	Negative	430	Inconclusive when re-tested in Fusion (IP-2 Ct = 40.2, atypical curve; IP-4 negative)
A2 0139 0111	Negative	-	-	Negative	-	-	Negative	323	
A2 0139 0156	Negative	-	-	Negative	-	-	Negative	306	
A2 0139 0172	Negative	-	-	Negative	-	-	Negative	313	
A2 0139 0179	Negative	-	-	Negative	-	-	Negative	299	
A2 0139 1670	Negative	-	-	Negative	-	-	Negative	293	
A2 0139 1907	Negative	-	-	Negative	-	-	Negative	314	
A2 0139 2034	Negative	-	-	Negative	-	-	Negative	309	
A2 0139 2041	Negative	-	-	Negative	-	-	Negative	304	
A2 0139 2115	Negative	-	-	Negative	-	-	Invalid	Invalid	Error RDFS: distribution check failed
A2 0139 2201	Negative	-	-	Negative	-	-	Negative	304	
A2 0139 2206	Negative	-	-	Negative	-	-	Negative	323	
A2 0139 2340	Negative	-	-	Negative	-	-	Negative	297	
A2 0139 2545	Negative	-	-	Negative	-	-	Negative	298	
A2 0139 3385	Negative	-	-	Negative	-	-	Negative	295	
A2 0139 3655	Negative	-	-	Positive	35.2	32.95	Negative	288	Atypical curves. Negative when re-tested in MagNA/ LC480.
A2 0139 3657	Negative	-	-	Negative	-	-	Negative	310	
A2 0139 3849	Negative	-	-	Negative	-	-	Negative	299	
A2 0139 3850	Negative	-	-	Negative	-	-	Negative	298	
A2 0144 0437	Negative	-	-	Negative	-	-	Negative	320	
A2 0144 0439	Negative	-	-	Negative	-	-	Negative	309	
A2 0144 1039	Negative	-	-	Negative	39.38	-	Negative	306	3 consecutive negative samples for this patient. Thoracic scan not in favor of COVID-19
A2 0144 1245	Negative	-	-	Negative	-	-	Negative	315	
A2 0144 1469	Negative	-	-	Negative	-	-	Negative	305	
A2 0144 1498	Negative	-	-	Negative	-	-	Negative	316	
A2 0144 1545	Negative	-	-	Negative	-	-	Negative	300	

Ct: cycle threshold, RLU: relative light unit