### **Supplementary Materials**

### **Supplementary Methods**

## Anterior Nasal Swab Collection procedure

The following swab collection procedure was utilized: after the participant blew their nose, the collector inserted swab #1 into the individual's right nostril and rotated the swab 5 times in a circular motion around the inside wall of the nostril for a duration of 10-15 seconds, followed by a repeat of the process in the left nostril. The swab was placed into a sterile plastic tube. Immediately thereafter, swab #2 was inserted into the individual's left nostril (always opposite from the initial swab) and the process repeated (left nostril followed by right nostril). To minimize sampling bias, the study site personnel alternated which test-specific nasal swab sample was collected first (BinaxNOW or RT-PCR).

#### Kit Storage

Abbott BinaxNOW kits were stored in a temperature-controlled office (70-72°F) and transferred to the testing site as needed.

### **Testing Site**

Testing was performed in a "testing pod," initially a shipping container. The pod was initially open on one side to the outdoors, but difficulty in maintaining adequate temperature in the pod required moving testing to a fully enclosed room (mobile trailer). The testing site contained three 6' tables. Two tables were designated as "dirty" for testing purposes and one "clean" for data entry. Absorbent underpads with plastic backing (Attends ASB-2336, Greenville, NC) were placed on testing tables along with hand sanitizer, gloves, testing kits, pens, sticky notes, a

continuous temperature and humidity data logger (HOBO UX100-011A, Bourne, MA), a digital clock, and a bin for specimens to be tested. The clean table included hand sanitizer, gloves, pens, a time stamp machine, and a laptop computer for data entry. Underpads were removed daily, surfaces were disinfected with germicidal disposable wipes (PDI, Woodcliff Lake, NJ), and new underpads placed. Operators performing testing were wearing disposable gowns, N95 respirators, face shields and gloves.

#### **Quality Control**

Lot numbers were recorded for Abbott BinaxNOW kits (boxes of 40 tests), test cards, manufacturer-provided swabs [unflocked foam tipped; Puritan #25-1506 (Guilford, ME)], positive controls, and extraction reagent. Manufacture and expiration dates were also recorded. Each study subject tested was recorded for every kit of BinaxNow tests used. Positive and negative controls were run for every kit when first opened. If an opened kit was not used in full over the course of one day, a negative control was run for the kit the following day when testing resumed.

#### **BinaxNOW Testing**

At the collection site, anterior nasal swab specimens were collected using the manufacturerprovided swab (above) into a labeled 15ml conical tube and placed into a specimen collection
bag with a BinaxNow intake form (which was labeled and time/date stamped at the time of
collection) and extra labels. Specimens were then shuttled to the testing pod by a designated
individual ("runner"), either on foot (shipping container) or by car (mobile trailer). All tests were
initiated within an hour of specimen collection time. For each specimen, testing staff added 6
drops of extraction reagent to the BinaxNOW card (making sure to remain perpendicular and

avoid touching the tip of the reagent bottle to the card), inserted the swab specimen and rotated three times, closed the testing card, and affixed a patient label to the outside of the BinaxNOW card. The time the card was closed was recorded on the BinaxNOW intake form as the test start time. The test start time and time the card was to be read (16 minutes after closing the card) were also recorded on a sticky note and adhered to the outside of the BinaxNOW card. At the time of result reading, the tester silently recorded their result, initials, and time on the Binax intake form as the official result. The tester then passed the card to a second reader, who read the card result aloud (so that the tester could record results on the back of the intake form) and took a photo of the card. There was no attempt to resolve any discordance between the two readers; the first read of each card was the official result used for database and clinical reporting. If the result was determined to be positive by either reader, the reader categorized the positive line as "faint", "medium", or "strong" depending on the strength of the positive sample line compared to the control line of each card. Completed BinaxNOW cards were discarded in biohazard waste.

#### PCR assay details

Dry swabs [SteriPack Sterile Polyester Spun Swab, 3" (Lakeland, Florida)] transported in a sterile tube (Becton Dickinson, # BD 366408) at room temperature were resuspended in 1000 uL of Swab Preservation Buffer (Norgen Biotek, Inc) and allowed to elute for 15 minutes. Extraction and RT-PCR methods followed the EUA protocol for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (<a href="https://www.fda.gov/media/139858/download">https://www.fda.gov/media/139858/download</a>); the target is the N2 gene with a cycle threshold cut off value of 40. A standard curve was prepared with FDA reference panel material [heat inactivated virus from BEI Resources (<a href="https://www.beiresources.org">www.beiresources.org</a>)] using serial dilutions (in

triplicate) made in negative clinical matrix then spiked onto dry swabs, allowed to dry, and subsequently taken all the way through the process.

Supplementary Table 1
Abbott BinaxNow results, RT-PCR Ct values, and symptoms in RT-PCR-positive adults

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Age	Sex	PCR Result	Ct (N2)	Ct (RP)	Binax Result	CDVID-19 symptoms?	Sore throat?	Cough?	chills?	Body Aches?	Short of Breath?	Fever?	Runny Nose?	Congestion?	Nausea?	Vomiting?	Diarrhea?	Loss of Taste or Smell?	# Days Since Symptom Onset
		2	~		Ë	22 %	ž			Bod	hart	_	E E	8	z	Š	ä	88	d # D
21	F	POS	34.26	19.58	NEG	ASx					- 51							_	n/a
23	M	POS	35.48	25.16	NEG	ASx													n/a
26	M	POS	35.43	25.88	NEG NEG	ASx													n/a
27	M	POS	35.17	24.26	NEG	ASx													n/a
28	F	POS	34.66	26.29	NEG	ASx													n/a
30	M M	POS	35.19 32.76	20.77	NEG NEG	ASx ASx													n/a n/a
34	M	POS	32.36	22.42	NEG	ASx													n/a
38	F	POS	31.22	21.78	NEG	ASx													n/a
39	M	POS	37.03	28.61	NEG	ASx													n/a
48 50	M F	POS	35.29 34.87	27.46 21.31	NEG NEG	ASx ASx									-				n/a n/a
50	F	POS	34.73	24.63	NEG NEG NEG NEG NEG	ASx													n/a
56	F	POS	32.3	26.75	NEG NEG	ASx													n/a
60	F	POS	31.6	26.5	NEG	ASx													n/a
71	M	POS	33.2	19.62	NEG NEG	ASx ASx													n/a
91 21	M	POS	34.56 14.62	24.54	POS	ASX													n/a n/a
22	F	POS	32.89	30.74	POS	ASx													n/a
22	М	POS	27.74	22.13	POS	ASx													n/a
23	F	POS	18.75	25.23	POS	ASx													n/a
23 24	F M	POS	26.75 29.67	24.18 21.5	POS POS	ASx ASx									-				n/a n/a
25	M	POS	14.1	19.83	POS	ASX													n/a n/a
27	F	POS	20.69	27.21	POS	ASx													n/a
28	M	POS	23.63	27.99	POS	ASx													n/a
29	F	POS	22.21	24.08	POS	ASx													n/a
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35	F	POS	17.39	23.93	POS	ASx													n/a
38	M F	POS	26.95	24.65	POS POS	ASx ASx													n/a n/a
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45	M	POS	12.82	20.87	POS	ASx													n/a
48	F	POS	16.4	24.47	POS	ASx													n/a
49 50	F M	POS	22.3 16.35	23.42 24.14	POS POS	ASx ASx													n/a n/a
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51	M	POS	17.16	23.86	POS	ASx													n/a
53	F	POS	25.78	23.3	POS	ASx													n/a
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57	F	POS	21.66	24.84	POS	ASX													n/a
60	M	POS	28.65	26.5	POS	ASx													n/a
61	F	POS	15.64	26.47	POS	ASx													n/a
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67	F	POS	15.4	24.6	POS	ASX													n/a
71	F M	POS	28.45 32.83	22.76 25.58	POS	ASx ASx													n/a n/a
79	F	POS	20.55	24.67	POS	ASX													n/a
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F, female; M, male; POS, positive; Ct, cycle threshold; N2, SARS-CoV-2 target; RP, host control target; ASx, asymptomatic; Sx, symptomatic; n/a, not applicable

Abbott BinaxNow results, RT-PCR Ct values, and symptoms in RT-PCR-positive children

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		PCR Result	≈		Binax Result	COVID-19 symptoms?	Sore throat?	~	۰	Body Aches?	Short of Breath?	ç	Runny Nose?	Congestion?	a?	Vomiting?	Diarrhea?	ast SIIS	# Days Since Symptom Onset
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1	М	POS	34.26	21.97	NEG	ASx													n/a
2	М	POS	37.1	26.4	NEG	ASx													n/a
3	F	POS	31.7	21.76	NEG	ASx													n/a
3	F	POS	26.7	19.84	NEG	ASx													n/a
3	F	POS	36.51	24.03	NEG	ASx													n/a
3	М	POS	28.93	21.76	NEG	ASx													n/a
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3	М	POS	32.44	24.73		ASx													n/a
3	F	POS	32.31	22.46	NEG	ASx													n/a
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6	F	POS	26.82	22.58	NEG	ASx													n/a
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7	F	POS	33.01	20.2	NEG	ASx													n/a
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			32.83	24.29															n/a
13	F	POS	26.89	21.82	NEG	ASx													n/a
14	F	POS	32.78	23.33	NEG	ASx													n/a
15	F	POS	36.84	20.19	NEG	ASx													n/a
15		POS			NEG	ASx						-							
	F		33.39	22.53															n/a
16	М	POS	36.5	19.31	NEG	ASx													n/a
16	F	POS	33.08	22.33	NEG	ASx													n/a
16	F	POS	33.5	19.98	NEG	ASx													n/a
16	F	POS	35.4	22.32	NEG	ASx			_			-							n/a
				22.32	NEG														
17	F	POS	34.88	24.47		ASx													n/a
17	М	POS	34.47	25.58	NEG	ASx													n/a
18	F	POS	32.22	21.37	NEG	ASx													n/a
18	F	POS	33.9	26.17	NEG	ASx													n/a
0	М	POS	13.48	23.3	POS	ASx													n/a
0	F	POS	17.72 32.61	27.64	POS	ASx													n/a
0	F	POS	32.61	20.25	POS	ASx													n/a
1	F	POS	27.24	21.61	POS	ASx													n/a
			27.34	21.61															
1	М	POS	14.35	20.71	POS	ASx													n/a
1	М	POS	19.05	26.8	POS	ASx													n/a
2	F	POS	29.77	25.68	POS	ASx													n/a
2	F	POS	25.61	19.76	POS	ASx													n/a
				20.02		AC.				1		-						-	
2	М	POS	16.75	20.83	POS	ASx													n/a
2	F	POS	21.51	20.22	POS	ASx													n/a
2	F	POS	22.88	20.41	POS	ASx													n/a
3	F	POS	23.96	22.89	POS	ASx													n/a
3	F	POS	20.94		POS	ASx													n/a
			20.94	20.45						-		-						-	
3	М	POS	25.56	20.35	POS	ASx													n/a
4	М	POS	21.68	19	POS	ASx													n/a
5	М	POS	27.84	18.48	POS	ASx													n/a
6	F	POS	29.61	19.83	POS	ASx													n/a
										1		-						-	
6	М	POS	17.63	21.84	POS	ASx													n/a
6	М	POS	13.11	20.96	POS	ASx													n/a
6	М	POS	21.53	24.64	POS	ASx													n/a
7	M	POS	27.57	22.55	POS	ASx													n/a
			21.37							<b>-</b>								<b>—</b>	
7	F	POS	21.51	22.87	POS	ASx													n/a
7	М	POS	14.5	23.54	POS	ASx		1			I		1	I					n/a
7	М	POS	22.1	28.85	POS	ASx													n/a
7	F	POS	27.82	23.9	POS	ASx													n/a
																		-	
7	F	POS	29.83	20.78	POS	ASx				1									n/a
7	F	POS	18.13	24.45	POS	ASx													n/a
8	F	POS	18.38	28.23	POS	Asx				1								1	n/a
8	F	POS	15.28	22.14	POS	ASx													n/a
8	F	POS				ASx				1		<b>-</b>							n/a
۰		F U 3	14.66	20.35	POS	MOX		1		1		L	1				l	l	11/4

8	F	POS	32.73	21.97	POS	ASx												n/a
8	М	POS	22.99	22.95	POS	ASx												n/a
8	F	POS	22.4	24.28	POS	ASx												n/a
9	F	POS	19.96	22.67	POS	ASx												n/a
9	F	POS	15.45	21.72	POS	ASx												n/a
9	F	POS	23.99	19.95	POS	ASx												n/a
9	М	POS	34.59	22.05	POS	ASx												n/a
9	M	POS	20.54	23.4	POS	ASx												n/a
9	F	POS	14.54	21.84	POS	ASx												n/a
10	M	POS			POS	ASx												
			35.88	25.08														n/a
10	F	POS	26.85	24.5	POS	ASx												n/a
11	F	POS	16.98	24.86	POS	ASx												n/a
11	М	POS	33	26.48	POS	ASx												n/a
11	М	POS	29.63	20.77	POS	ASx												n/a
12	F	POS	17.77	23.91	POS	Asx												n/a
12	F	POS	19.38	21.69	POS	ASx												n/a
12	М	POS	28.13	24.42	POS	ASx												n/a
12	М	POS	26.13	21.43	POS	ASx												n/a
13	F	POS	21.41	26.51	POS	ASx												n/a
13	М	POS	15.02	23.09	POS	ASx										 		n/a
13	М	POS	18.81	22.28	POS	ASx												n/a
14	М	POS	23	23.72	POS	ASx												n/a
14	F	POS	34.35	25.54	POS	ASx												n/a
14	F	POS	25.82	24.55	POS	ASx												n/a
15	М	POS	23.74	20.75	POS	ASx												n/a
15	М	POS	32.1	22.45	POS	ASx												n/a
15	F	POS	21.48	22.93	POS	ASx												n/a
15	M	POS	24.18	22.59	POS	ASx												n/a
15	M	POS	16.09	23.35	POS	ASx												n/a
15	F	POS	21.04	23.6	POS	ASx												n/a
15	F	POS	20.9	23.6	POS	ASx												n/a
15	F	POS	30.4	25.71	POS	ASx												n/a
16	М	POS	16.99	21.01	POS	ASx												n/a
16	F	POS	18.29	23.6	POS	ASx												n/a
17	F	POS	19.81	21.22	POS	ASx												n/a
17	F	POS	18.1	22.44	POS	ASx												n/a
17	F	POS	17.2	24.71	POS	ASx												n/a
17	F	POS	24.45	24.72	POS	ASx												n/a
17	F	POS	21.3	26.47	POS	ASx												n/a
18	F	POS	35.73	23.96	POS	ASx												n/a
12	F	POS	27.2	22.72	NEG	Sx				Y		Y						0
12	F	POS	35.74	25.98	NEG	Sx		Υ					Υ					1
14	F	POS	31.43	27.78	NEG	Sx	Y	Y	Υ	Υ	Y	Υ	Y	Υ				4
15	F	POS	34.2	27.7	NEG	Sx	Y						Y					1
1	М	POS	13.91	19.02	POS	Sx	Y						Υ					6
1	М	POS	15.21	25.39	POS	Sx						Υ	Y	Y				1
7	F	POS	26.84	26.63	POS	Sx		Y										2
9	М	POS	32.74	22.38	POS	Sx			Y	Υ		Υ	Υ				Υ	1
9	F	POS	14.62	22.48	POS	Sx		Y		Y	Y	<u> </u>	Y				-	2
10	F	POS	26.34	25.6	POS	Sx	Y	<del>-                                    </del>		<u> </u>	<u> </u>		<del></del>			 Y		2
10	F	POS	20.87	26.76	POS	Sx				Y				Y	Y	<u> </u>		1
11	M	POS			POS	Sx	Y	Y	Y				Y	Y	'	Y	Y	2
			16.5	25.98				Y	Y	-			Y			1	ľ	
11	М	POS	27.67	20.53	POS	Sx	Y							Y				4
12	М	POS	26.22	26.25	POS	Sx	Y	Y	Y	Υ		Y	Υ	Y	Y			5
14	F	POS	12.21	23.05	POS	Sx	Y	Y	Y	Y	Y			Y	Y			3
14	F	POS	21.13	22.5	POS	Sx	Y	Y	Υ	Υ								2
14	F	POS	20.34	22.95	POS	Sx	Y		Y	Υ		Y		Y				2
14	М	POS	17.74	23.27	POS	Sx	Y	Y	Y			Y		Y	Y			7
16	F	POS	26.61	25.71	POS	Sx	Υ	Υ		Υ	Y		Υ				Υ	6
17	F	POS	21.69	26.48	POS	Sx		Y			Y			Y			Y	4
17	F	POS	25.69	23.37	POS	Sx	Y	Y	Y	-	<u> </u>	Y	-	<u> </u>	<b> </b>		Y	0
18	F	POS	24.75	27.03	POS	Sx	Y	<del>-</del> '	<del>- '-</del>	-		<del>- '</del>	-		<b> </b>	 -	- '	1
18	M	POS						- v			L				ļ			
			14.9	21.68	POS	Sx	L	Y		Y	Y			L				1
18	F	POS	30.63	22.9	POS	Sx	Y			Y			Y	Y				1
18	F	POS	23.55	20.27	POS	Sx	Υ		Υ	Υ		Υ	Υ	Υ	Υ		Υ	4
18	М	POS	15.69	21.66	POS	Sx		Υ		Υ			Υ	Y				1
2	F	POS	27.65	25.53	POS	Sx7+		Y		Υ				Y		Y		15
18	F	POS	26.79	27.71	POS	Sx7+		Y		Y			Y	Y			Y	11

F, female; M, male; POS, positive; Ct, cycle threshold; N2, SARS-CoV-2 target; RP, host control target; ASx, asymptomatic; Sx, symptomatic; n/a, not applicable

# Distribution of positive and negative BinaxNOW and RT-PCR results across clinical subgroups

Asymptomati	c (Childre	n: ≤18 yo)	
		RT-PCR	
BinaxNOW Ag	Positive	Negative	Total
Positive	70	7	77
Negative	37	715	752
Total (12.9% prevalence)	107	722	829

Asympto	matic (Adu	lts: >18 yo)	
		RT-PCR	
BinaxNOW Ag	Positive	Negative	Total
Positive	40	4	44
Negative	17	913	930
Total (5.9% prevalence)	57	917	974

Symptomatic ≤7	days (Chile	dren: ≤18 yo	<b>)</b>
		RT-PCR	
BinaxNOW Ag	Positive	Negative	Total
Positive	22	0	22
Negative	4	65	69
Total (28.6% prevalence)	26	65	91

Symptomati	c ≤7 days (A	Adults: >18 yo	)
		RT-PCR	
BinaxNOW Ag	Positive	Negative	Total
Positive	82	0	82
Negative	3	270	273
Total (23.9% prevalence)	85	270	355

Symptomatic	(Children	: >7 days)	
		RT-PCR	
BinaxNOW Ag	Positive	Negative	Total
Positive	2	0	2
Negative	0	6	6
Total (25% Prevalence)	2	6	8

Symptor	natic (Adult	s: >7 days)	
		RT-PCR	
BinaxNOW Ag	Positive	Negative	Total
Positive	10	1	11
Negative	5	35	40
Total (29.4% prevalence)	15	36	51

Predictive value of the Abbott BinaxNOW for detection of SARS-CoV-2 in samples from adult and pediatric (≤18) patients, with varying prevalence, based on observed sensitivity/specificity in each subgroup.

		P	revalence	
	20%	10%	5%	1%
PPV				
Adult, Sx ≤7D	100%	100%	100%	100%
Adult, ASx	97.65% (93.91-	94.87% (87.27-	89.75% (76.45-	62.68% (38.39-
	99.12)	98.03)	95.93)	81.91)
Pediatric, Sx ≤7D	100%	100%	100%	100%
Pediatric, ASx	93.41% (88.32-	86.30% (77.06-	74.91% (61.41-	36.42% (23.40-
	96.38)	92.20)	84.85)	51.80)
NPV				
Adult, Sx ≤7D	99.17% (98.38-	99.63% (99.27-	99.82% (99.65-	99.97% (99.93-
	99.58)	99.81)	99.91)	99.98)
Adult, ASx	93.15% (90.11-	96.83% (95.35-	98.47% (97.74-	99.70% (99.56-
	95.30)	97.85)	98.97)	99.80)
Pediatric, Sx ≤7D	96.30% (95.20-	98.32% (97.81-	99.20% (98.95-	99.84% (99.80-
	97.15)	98.71)	99.39)	99.88)
Pediatric, ASx	91.89% (89.95-	96.23% (95.27-	98.18% (97.70-	99.64% (99.55-
	93.49)	97.00)	98.55)	99.72)

PPV and NPV were calculated using the sensitivity and specificity observed in each subgroup for a hypothetical population of 1000 individuals per subgroup, with varying prevalence. PPV, positive predictive value; NPV, negative predictive value; Sx, symptomatic; ASx, asymptomatic; D, days

# Performance of the Abbott BinaxNOW versus RT-PCR with varied Ct value cutoffs

	All Ct Values					Ct valu	es ≤ 35			Ct val	ues ≤ 30			Ct valu	es ≤ 25	
	N	TP (+/+)	FN (+/-)	Sens	N	TP (+/+)	FN (+/-)	Sens	N	TP (+/+)	FN (+/-)	Sens	N	TP (+/+)	FN (+/-)	Sens
Combined All	292	226	66	77.4%	276	224	52	81.2%	214	205	9	95.8%	150	149	1	99.3%
All Children (Sx, ASx)	135	94	41	69.6%	125	92	33	73.6%	92	83	9	90.2%	62	61	1	98.4%
All Adult (Sx, ASx)	157	132	25	84.1%	151	132	19	87.4%	122	122	0	100.0%	88	88	0	100%
Sx (≤7D) Children	26	22	4	84.6%	25	22	3	88.0%	21	20	1	95.2%	14	14	0	100%
Sx (≤7D) Adult	85	82	3	96.5%	85	82	3	96.5%	76	76	0	100.0%	59	59	0	100%
ASx Children	107	70	37	65.4%	98	68	30	69.4%	69	61	8	88.4%	48	47	1	97.9%
ASx Adult	57	40	17	70.2%	51	40	11	78.4%	37	37	0	100.0%	24	24	0	100%

Ct, cycle threshold; TP, true positive (RT-PCR positive/BinaxNOW positive); FN, false negative (RT-PCR positive/BinaxNOW negative); Sens, sensitivity; Sx, symptomatic; ASx, asymptomatic; D, days; Ped, pediatric

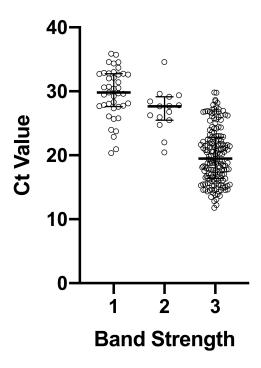
# Impact of temperature on BinaxNOW performance in individuals $\leq$ 7 days post symptom onset

BinaxNOW result	RT-PCR result					
	Temperature range: ≥59°F			Temperature range: 46-58.5°F		
	Positive	Negative	Total	Positive	Negative	Total
Positive	104	0	104	6	1	7
Negative	7	335	342	3	20	23
Total	111	335	446	9	21	30
Sensitivity	(104/111) 93.7%			(6/9) 66.7%		
Specificity	(335/335) 100.0%			(20/21) 95.2%		

The manufacturer recommends that tests be run at temperatures ≥ 59°F. Ag, antigen; Sx, symptoms

# **Supplementary Figure 1**

# Correlation of Cycle Threshold with BinaxNOW band strength



Band strength (1= faint, n = 41; 2 = medium, n = 15; 3 = strong, n = 170) as interpreted by the first reader for the 226 true positive BinaxNOW tests correlated clearly with Ct value, with median Cts of 29.7 (27.6-32.7), 27.7 (25.5-29.1), and 19.5 (16.4-22.8), respectively.