COMD-19 rapid Antigen test in the ED

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Background

During the COVID-19 pandemic the gold standard for diagnosing a patient having SARS-COV-2 is the RT-PCR test. Due to costs, accessibility and time required for RT-PCR testing a demand for rapid point of care tests arose.

Methods

Bionote NowCheck COVID-19 Ag Test was used in the emergency department for five-months during the Alpha variant outbreak in Israel. The results were compared with a RT-PCR SARS-CoV-2 assay.

Results

Sensitivity was 63%, specificity was 100%, positive predictive value was 100% and negative predictive value was 93%. Significant Statistical differences were noted in the time from onset of symptoms to testing between the positive and negative antigen groups ,3.9 days with a SD of 5.6 and 5.6 days with a SD of 4 respectively (OR 0.93, CI 0.87-0.99, Pv 0.025) and in patients who presented without gastrointestinal symptoms (51, 32.3% and 107, 67.7% respectively, OR 0.48, CI 0.25-0.92, Pv 0.027). Mean Cycle Time in subjects with negative tests was 29.1 and 20.9 in subjects with positive tests (OR 0.71, CI 0.65-0.78, Pv<0.001).

Objective

To evaluate the sensitivity and specificity of the Bionote NowCheck COVID-19 Ag Test and to identify predictive factors for a false negative test in an emergency department setting.

Variables Negative N (%) Positive N (%) OR (95% Cl) p Age (years) 54.0 (21.0) 54.5 (22.3) 1.00 (0.99-1.01) 0.872 ED decision		A			
Variables Negative N(%) Positive N(%) OR (95% CI) p N(%) N(%) N(%) 0R (95% CI) p Age (years) 54.0 (21.0) 54.5 (22.3) 1.00 (0.99-1.01) 0.872 ED decision	Variables	Antigen Negetive Desitive			
N (%) N (%) N (%) Age (years) 54.0 (21.0) 54.5 (22.3) 1.00 (0.99-1.01) 0.872 ED decision	variables	Negative	Positive	OR (95% CI)	р
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Discharge 41 (37.6) 68 (62.4) 1.09 (0.62-1.91) 0.777 Admission 35 (35.7) 63 (54.3) Ref. Exposure to verified covid-19 patient	ED decision				-
Admission 35 (35.7) 63 (54.3) Ref. Exposure to verified covid-19 patient	Discharge	41 (37.6)	68 (62.4)	1.09 (0.62-1.91)	0.777
Exposure to verified covid-19 patient No 69 (37.3) 116 (62.7) 1.50 (0.56-4.05) 0.423 Yes 6 (28.6) 15 (71.4) Ref. 0.025 Time from onset of symptoms 5.6 (5.6) 3.9 (4.0) 0.93 (0.87-0.99) 0.025 Chest X-ray findings	Admission	35 (35.7)	63 (54.3)	Ref.	
No 69 (37.3) 116 (62.7) 1.50 (0.56-4.05) 0.423 Yes 6 (28.6) 15 (71.4) Ref. 0.025 Time from onset of symptoms 5.6 (5.6) 3.9 (4.0) 0.93 (0.87-0.99) 0.025 Chest X-ray findings	Exposure to verified covid-19 patient				
Yes 6 (28.6) 15 (71.4) Ref. Time from onset of symptoms 5.6 (5.6) 3.9 (4.0) 0.93 (0.87-0.99) 0.025 Chest X-ray findings	No	69 (37.3)	116 (62.7)	1.50 (0.56-4.05)	0.423
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Yes	6 (28.6)	15 (71.4)	Ref.	
Chest X-ray findings Image: Chest X-ray findings Pneumonia 30 (44.8) 37 (55.2) 0.47 (0.24-0.90) 0.065 Interstitialchanges 11 (40.7) 16 (59.3) 0.55 (0.23-1.34) Within normal limits 27 (27.6) 71 (72.4) Ref. Fever 71 (72.4) Ref. 0.55 (0.23-1.34) 0.55 (0.23-1.34) 0.51 (5.5) 0.689 (0.51 (5.5) 0.689 (0.51 (5.7)) 0.331 (0.59 (0.51 (5.2)) 0.331 (0.59 (0.51 (5.6)) 0.77 (0.42 (5.2)) 0.331 (0.59 (0.51 (5.6)) 0.77 (0.42 (5.4) (1.5) (0.59 (5.6)) 0.77 (0.42 (5.4) (1.5) (0.59 (5.6)) 0.77 (0.42 (5.4) (1.5) (0.59 (5.6)) 0.59 (0.51	Time from onset of symptoms	5.6 (5.6)	3.9 (4.0)	0.93 (0.87-0.99)	0.025
Pneumonia 30 (44.8) 37 (55.2) 0.47 (0.24-0.90) 0.065 interstitialchanges 11 (40.7) 16 (59.3) 0.55 (0.23-1.34) 0.47 (0.24-0.90) 0.065 Within normal limits 27 (27.6) 71 (72.4) Ref. 0.47 (0.24-0.90) 0.689 Fever	Chest X-ray findings				
Interstitialchanges 11 (40.7) 16 (59.3) 0.55 (0.23-1.34) Within normal limits 27 (27.6) 71 (72.4) Ref. Fever 71 (72.4) Ref. <38.0 C'	Pneumonia	30 (44.8)	37 (55.2)	0.47 (0.24-0.90)	0.065
Within normal limits 27 (27.6) 71 (72.4) Ref. Fever	Interstitial changes	11 (40.7)	16 (59.3)	0.55 (0.23-1.34)	
Fever Fever <38.0 C'	Within normal limits	27 (27.6)	71 (72.4)	Ref.	
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≥ 38.0 C' 37 (37.8) 61 (62.2) Ref. Pulse 98.1 (24.0) 94.7 (22.8) 0.99 (0.98-1.01) 0.314 Oxygen Saturation 94.5 (5.8) 95.1 (5.1) 1.02 (0.97-1.08) 0.439 General 0 0 33 (39.8) 50 (60.2) 1.28 (0.72-2.28) 0.394 Yes 43 (34.4) 82 (65.6) Ref. 0.394 Upper Respiratory Symptoms 0 69 (37.7) 114 (62.3) 1.57 (0.62-3.95) 0.338 Yes 7 (28.0) 18 (72.0) Ref. 0 0 SymptomsRespiratory Lower 7 24 (32.4) 50 (67.6) 0.77 (0.42-1.41) 0.398 Yes 52 (38.8) 82 (61.2) Ref. 0 0 9 SymptomsRespiratory Lower 0 50 (67.6) 0.77 (0.42-1.41) 0.398 0.398 0 0 9 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0<	<38.0 C°	39 (35.7)	71 (64.5)	0.89 (0.51-1.57)	0.689
Pulse 98.1 (24.0) 94.7 (22.8) 0.99 (0.98-1.01) 0.314 Oxygen Saturation 94.5 (5.8) 95.1 (5.1) 1.02 (0.97-1.08) 0.439 General	≥ 38.0 C°	37 (37.8)	61 (62.2)	Ref.	
Oxygen Saturation 94.5 (5.8) 95.1 (5.1) 1.02 (0.97-1.08) 0.439 General	Pulse	98.1 (24.0)	94.7 (22.8)	0.99 (0.98-1.01)	0.314
General General No 33 (39.8) 50 (60.2) 1.28 (0.72-2.28) 0.394 Yes 43 (34.4) 82 (65.6) Ref. 0.394 Upper Respiratory Symptoms 69 (37.7) 114 (62.3) 1.57 (0.62-3.95) 0.338 Yes 7 (28.0) 18 (72.0) Ref. 0.394 SymptomsRespiratory Lower 7 114 (62.3) 1.57 (0.62-3.95) 0.338 Yes 7 (28.0) 18 (72.0) Ref. 0.398 Yes 50 (67.6) 0.77 (0.42-1.41) 0.398 Yes 52 (38.8) 82 (61.2) Ref. 0.398 Gastrointestinal Symptoms 90 51 (32.3) 107 (67.7) 0.48 (0.25-0.92) 0.027	Oxygen Saturation	94.5 (5.8)	95.1 (5.1)	1.02 (0.97-1.08)	0.439
No 33 (39.8) 50 (60.2) 1.28 (0.72-2.28) 0.394 Yes 43 (34.4) 82 (65.6) Ref. 0.394 Upper Respiratory Symptoms	General				
Yes 43 (34.4) 82 (65.6) Ref. Upper Respiratory Symptoms	No	33 (39.8)	50 (60.2)	1.28 (0.72-2.28)	0.394
Upper Respiratory Symptoms 69 (37.7) 114 (62.3) 1.57 (0.62-3.95) 0.338 Yes 7 (28.0) 18 (72.0) Ref. 0.338 SymptomsRespiratory Lower	Yes	43 (34.4)	82 (65.6)	Ref.	
No 69 (37.7) 114 (62.3) 1.57 (0.62-3.95) 0.338 Yes 7 (28.0) 18 (72.0) Ref. 0.338 SymptomsRespiratory Lower	Upper Respiratory Symptoms				
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SymptomsRespiratory Lower 24 (32.4) 50 (67.6) 0.77 (0.42-1.41) 0.398 Yes 52 (38.8) 82 (61.2) Ref. 52 (38.8) 52 (38.8) 52 (38.8) 52 (51.2) 0.277 (0.42-1.41) 0.398 Gastrointestinal Symptoms 51 (32.3) 107 (67.7) 0.48 (0.25-0.92) 0.027	Yes	7 (28.0)	18 (72.0)	Ref.	
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Yes 52 (38.8) 82 (61.2) Ref. Gastrointestinal Symptoms	No	24 (32.4)	50 (67.6)	0.77 (0.42-1.41)	0.398
Gastrointestinal Symptoms 0.48 (0.25-0.92) 0.027 No 51 (32.3) 107 (67.7) 0.48 (0.25-0.92) 0.027	Yes	52 (38.8)	82 (61.2)	Ref.	
No 51 (32.3) 107 (67.7) 0.48 (0.25-0.92) 0.027	Gastrointestinal Symptoms				
	No	51 (32.3)	107 (67.7)	0.48 (0.25-0.92)	0.027
Yes 25 (50.0) 25 (50.0) Ref.	Yes	25 (50.0)	25 (50.0)	Ref.	



Conclusion

This rapid antigen test is highly specific but lacks sensitivity. It's lacked sensitivity exclude it from being a wide screening test and it has a time limit of about a week to detect a positive subject. Positive tests correlates with lower Cycle Time thus a higher viral load in the individual.