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Performance of Rapid Diagnostic Testing at Days 4-6 from Diagnosis: Implications for Discharge from Isolation on a University Campus

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BACKGROUND

- Omicron rapidly replaced delta as the predominant strain causing COVID-19 related illness in the United States (US) in December 2021.
- That same month, the US CDC reduced the recommended isolation period from 10 to 5 days for asymptomatic individuals or those with resolving symptoms.
- We sought to evaluate the performance of a SARS-CoV-2 antigen rapid diagnostic test (RDT) in predicting persistent potential for transmission at the end of a five-day isolation period among young, fully vaccinated individuals in a university community.

METHODS AND MATERIALS

- A subgroup of participants enrolled in a longitudinal COVID-19 cohort were asked to self-perform RDTs on days 4 to 6 from diagnostic test date in addition to a separate self-collected anterior nasal swab used for culture and RT-PCR, and a daily symptom screen (15 COVID-19 symptom questions on a 4-point scale).
- We calculated the daily and overall sensitivity and specificity of the RDTs in comparison to SARS-CoV-2 culture result.
- We also compared the N1 cycle threshold (CT) values and symptom score on each day of the study by RDT results.

TABLE 1: Demographics

Variables	Total (N= 24)
Age, Mean (SD)	20 (2)
Sex, N (%)	
Male	6 (25.0%)
Female	18 (75.0%)
Race, N (%)	
White	18 (75.0%)
Black	1 (4.2%)
Asian	4 (16.7%)
Multiracial	1 (4.2%)
Vaccination Status, N (%)	
Fully Vaccinated, not boosted	7 (29.2%)
Fully Vaccinated, boosted	17 (70.8%)
Vaccine Type, N (%)	
Pfizer	19 (79.2%)
Moderna	3 (12.5%)
Janssen	1 (4.2%)
Other	1 (4.2%)

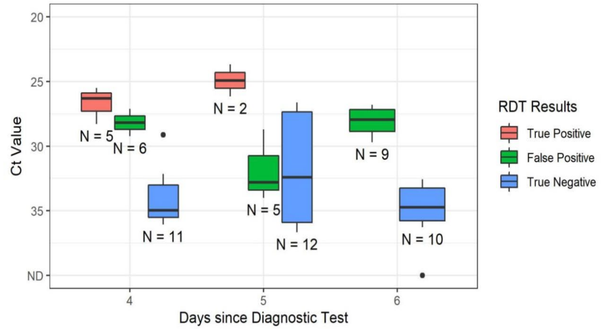
TABLE 2: Patterns of RDT Results

All Positive	8
All Negative	10
Positive Positive Negative	1
Negative Negative Positive	1
Positive Negative Positive	1
Missing Data	3

TABLE 3: Sensitivity and Specificity of RDT (Culture is gold standard)

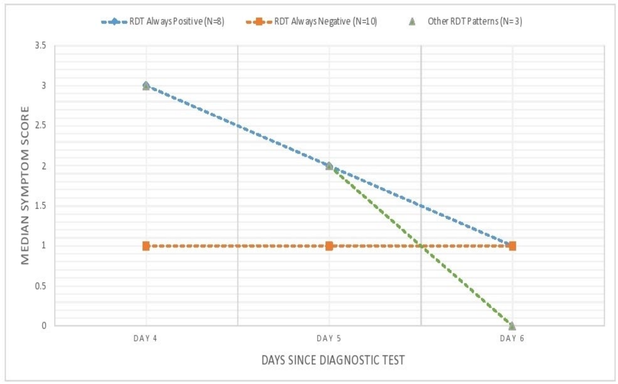
Days since Diagnostic Test	N	True Positive (TP)	True Negative (TN)	False Positive (FP)	False Negative (FN)	Sensitivity	Specificity
Day 4	22	5	11	6	0	1	0.65
Day 5	19	2	12	5	0	1	0.71
Day 6	19	0	10	9	0	NA	0.53
Overall	60	7	33	20	0	1	0.62

Figure 1: Box plots of CT values for each day of the study stratified by RDT results (N=24)



	Day 4-True Positive	Day 4-False Positive	Day 4-True Negative	Day 5-True Positive	Day 5-False Positive	Day 5-True Negative	Day 6-False Positive	Day 6-True Negative
Median	26.3	28.18	34.95	24.92	32.79	32.42	27.94	34.72

Figure 2: Line graph of the median symptom score for each day stratified by pattern of RDT results (N=28).



RESULTS

- Of the 24 participants, the mean age was 20 years, all had completed their primary COVID-19 vaccine series, and 17 (70.8%) had received a booster vaccine
- Compared to culture, sensitivity and specificity of the RDTs were 100% and 62% respectively.
- Compared to participants with negative RDTs, median CT values were lower in those with positive RDTs on each day of the study.
- Participants who had positive RDTs on all three days had higher symptom scores than those without.

CONCLUSION

- RDTs have a high sensitivity in detecting culture positive SARS-CoV-2 on Days 4 to 6 from initial diagnostic test.
- However, the **high false positive rate of 38%** means that over a third of culture negative individuals will stay in isolation longer than necessary if RDTs are used in test to release from isolation protocols.
- Viral loads (CT values) and symptom scores were higher for participants with persistently positive RDT result.
- An approach that uses a **combination** of RDTs, CT values and symptom score may prove useful in guiding isolation duration.

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