Figure 1. Flow of participants through study
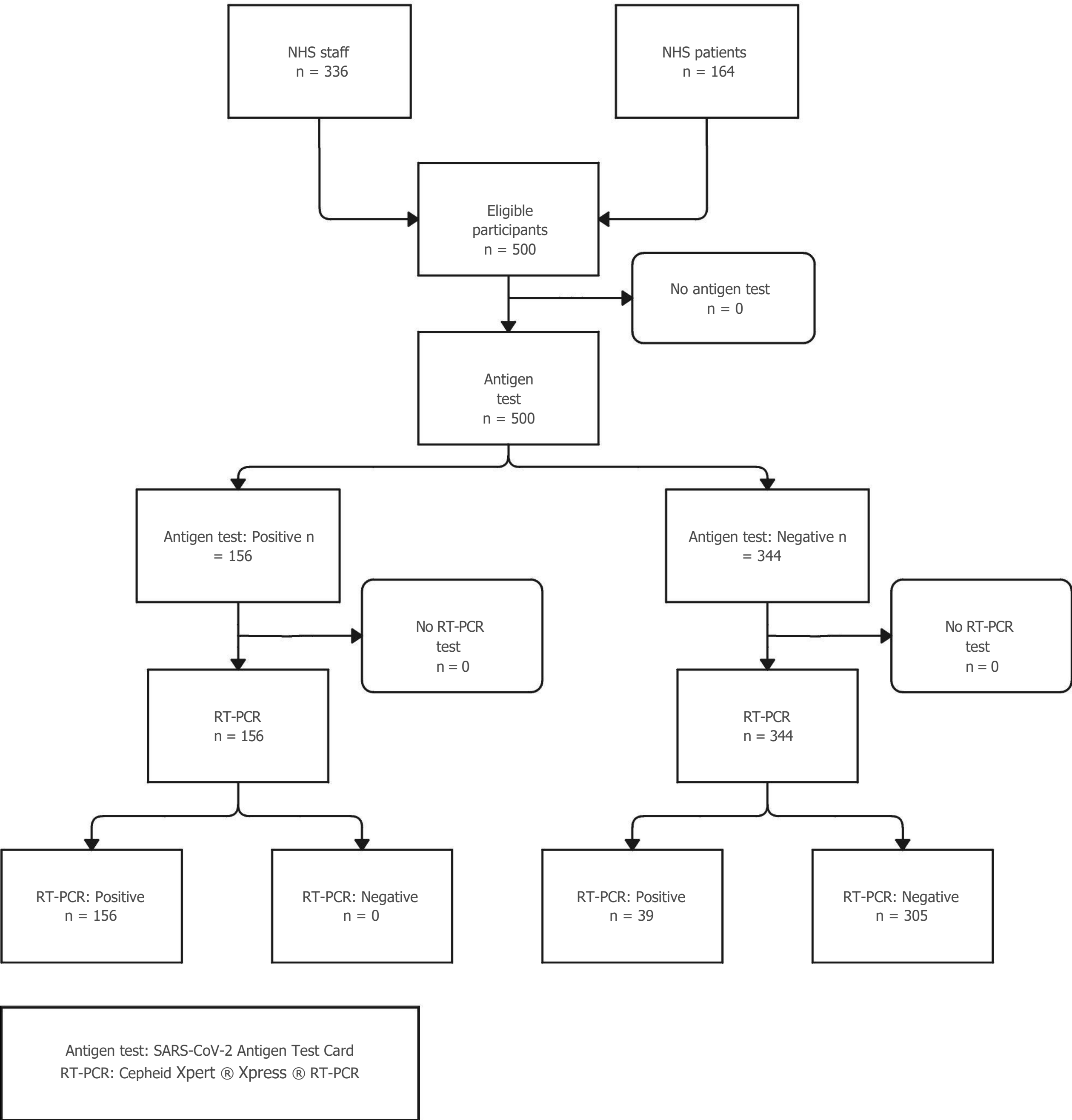

NHS staff
n = 336

NHS patients
n = 164

Eligible
participants
n = 500

No antigen test
n = 0

Antigen
test
n = 500

Antigen test: Positive n = 156

Antigen test: Negative n = 344

No RT-PCR
test
n = 0

No RT-PCR
test
n = 0

RT-PCR
n = 156

RT-PCR
n = 344

RT-PCR: Positive
n = 156

RT-PCR: Negative
n = 0

RT-PCR: Positive
n = 39

RT-PCR: Negative
n = 305

Antigen test: SARS-CoV-2 Antigen Test Card
RT-PCR: Cepheid Xpert ® Xpress ® RT-PCR

Table 1. Participant characteristics (n=500)

Characteristics	All participants n=500
Gender, n (%)	
Male	158 (31.6)
Female	342 (68.4)
Age (years)	
Mean (SD)	51.4 (20.5)
Range	18 - 98
Age < 65, n (%)	370 (74.0)
Age ≥ 65, n (%)	130 (26.0)
Participant role, n (%)	
NHS staff	336 (67.2)
NHS patients	164 (32.8)
Symptoms	
Symptomatic	179 (35.8)
Asymptomatic	321 (64.2)
Ct values of RT-PCR positive samples, n (%)	195 (39.0)
Ct < 25	102 (52.3)
Ct 25 - 35	77 (39.5)
Ct > 35	16 (8.2)
SARS-CoV-2 Omicron sub-variants	195 (39.0)
BA.1	22 (11.3)
BA.2	67 (34.4)
BA.5	57 (29.2)
No lineage	49 (25.1)

Table 3: Primary outcome measure - overall diagnostic performance of the MP Biomedicals antigen test

	NUMBER (%)	SENSITIVITY % (95% CI)	SPECIFICITY % (95% CI)	ACCURACY % (95% CI)
TOTAL	**500**	**80.0** **(73.7 to 85.5)**	**100** **(98.8 to 100)**	**92.2** **(89.5 to 94.4)**

	NUMBER (%)	SENSITIVITY % (95% CI)	SPECIFICITY % (95% CI)	ACCURACY % (95% CI)

Table 4: Secondary outcome measures - diagnostic performance of the MP Biomedicals antigen test in various categories

GENDER				
MALES	158 (31.6)	85.3 (76.5 to 91.7)	100 (94.3 to 100)	91.1 (85.6 to 95.1)
FEMALES	342 (68.4)	75.0 (65.3 to 83.1)	100 (98.5 to 100)	92.7 (89.4 to 95.2)
AGE				
AGE < 65 years	370 (74.0)	72.0 (61.8 to 80.9)	100 (98.7 to 100)	93.0 (89.9 to 95.4)
AGE ≥ 65 years	130 (26.0)	87.3 (79.2 to 93.0)	100 (87.7 to 100)	90.0 (83.5 to 94.6)
PARTICIPANT ROLE				
NHS STAFF	336 (67.2)	70.0 (56.8 to 81.2)	100 (98.7 to 100)	94.6 (91.7 to 96.8)
NHS PATIENTS	164 (32.8)	84.4 (77.2 to 90.1)	100 (88.1 to 100)	87.2 (81.1 to 91.9)
Ct VALUES				
PCR POSITIVES:	195			
CT < 25	102 (52.3)	98.0 (93.1 to 99.8)	-	-
CT 25 – 35	77 (39.5)	68.8 (57.3 to 78.9)	-	-
CT > 35	16 (8.2)	18.8 (4.1 to 45.7)	-	-
SYMPTOMATIC VS ASYMPTOMATIC				
SYMPTOMATIC	**179**	**82.2 (74.1 to 88.6)**	**100 (94.1 to 100)**	**88.3 (82.6 to 92.6)**
Days 0-3	132 (73.7)	80.0 (69.9 to 87.9)	100 (92.5 to 100)	87.1 (80.2 to 92.3)
Days 4-7	35 (19.6)	100 (85.8 to 100)	100 (71.5 to 100)	100 (90.0 to 100)
Days 8-10	12 (6.7)	55.6 (21.2 to 86.3)	100 (29.2 to 100)	66.7 (34.9 to 90.1)
Days 0-7	167 (93.3)	84.4 (76.2 to 90.6)	100 (93.8 to 100)	89.8 (84.2 to 94.0)
ASYMPTOMATIC	**321**	**76.6 (65.6 to 85.5)**	**100 (98.5 to 100)**	**94.4 (91.3 to 96.6)**
SARS-CoV-2 Omicron sub-variants				
BA.1	22 (11.3)	72.7 (49.8 to 89.3)	-	-
BA.2	67 (34.4)	86.6 (76.6 to 93.7)	-	-
BA.5	57 (29.2)	91.2 (80.7 to 97.1)	-	-
No lineage	49 (25.1)	-	-	-

There were no adverse events associated with this study.