	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 1 of 19

# 1. Diagnostic specificity and Diagnostic Sensitivity

## 1.1 Summary:

The diagnostic specificity indicates the probability that the test gives a negative result in the absence of the target analyte. True negative indicates a specimen known to be negative for the target analyte and correctly classified by the test. False positive indicates a specimen known to be negative for the target analyte and misclassified by the test.

The diagnostic sensitivity indicates the probability that the test gives a positive result in the presence of the target analyte. True positive indicates a specimen known to be positive for the target marker and correctly classified by the test. False negative indicates a specimen known to be positive for the target marker and misclassified by the test.

102 COVID-19 positive specimens and 500 COVID-19 negative specimens confirmed by PCR and clinical Symptoms were used in clinical study. Commercial PCR served as the reference method for the GA CoV-2 Antigen Rapid Nasal . The result shows the GA CoV-2 Antigen Rapid Test has a high restive sensitivity and high relative specificity when tested with the 204 specimens.

## 1.2 Background:

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus in 2019 causes coronavirus disease COVID-19.[1] The new coronavirus is called 2019-nCoV or SARS-CoV-2. Due to the rapid spread of SARS-CoV-2, COVID-19 is now a pandemic affecting many countries globally. As of May 24th, there were 5.2 million confirmed cases worldwide and 337 000 reported deaths [2]. The clinical presentation of infection include respiratory symptoms, fever, and cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.[3]

## 1.3 Objective:

Do clinical studies of GA CoV-2 Antigen Rapid Nasal with the COVID-19 positive specimens and negative specimens which confirmed with PCR method.


## 1.4 Operation Method:

### Material:

GA CoV-2 Antigen Rapid Nasal

### Competitors:

Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio Tech Co., Ltd., a commercial SARS-COV-2 kit approved by CFDA, is used as the "gold standard" reagent.

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 2 of 19

## Methods:

102 samples of the novel coronavirus SARS-CoV-2 from medical institution and 500 samples of healthy people were included in the testing plan. A total of 602 samples were tested in the COVID-19 Antigen Rapid assay and the Novel Coronavirus (SARS-COV-2) real-time multiplex RT-PCR kit, and the clinical sensitivity, specificity and overall agreement between the 2 assays calculated.

## 1.5 Statistical analysis Method of test result:

This test adopt statistical analysis on pair enumeration data, and will record analysis in the form of fourfold table, see below:


Table 1: fourfold table for evaluating diagnostic test

		Comparison Test		
		positive	negative	
Test	positive	a	b	Y1
	negative	c	d	Y2
Total		C1	C2	N

$$\text{Positive conformity rate} = \frac{a}{(a+c)} * 100\%$$

$$\text{Negative conformity rate} = \frac{d}{(b+d)} * 100\%$$

$$\text{Total conformity rate} = \frac{(a+d)}{(a+b+c+d)} * 100\%$$

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 3 of 19

## 1.6 The results:

### Positive results:

NO.	days post symptom onset	RT-PCR		GA CoV-2 Antigen Rapid Nasal (Anterior Nasal Swab Specimen)
		Ct	Result	
Positive 1	10	35	+	+
Positive 2	2	23	+	+
Positive 3	7	33	+	+
Positive 4	9	28	+	+
Positive 5	11	37	+	+
Positive 6	14	36	+	+
Positive 7	15	35	+	+
Positive 8	16	36	+	+
Positive 9	15	39	+	+
Positive 10	16	37	+	-
Positive 11	13	37	+	+
Positive 12	15	35	+	+
Positive 13	16	36	+	+
Positive 14	9	38	+	+
Positive 15	7	31	+	+
Positive 16	8	28	+	+
Positive 17	14	39	+	+
Positive 18	15	38	+	+
Positive 19	17	35	+	+
Positive 20	16	39	+	+
Positive 21	10	36	+	+
Positive 22	13	34	+	+
Positive 23	15	37	+	+
Positive 24	16	38	+	+
Positive 25	9	28	+	+
Positive 26	14	35	+	+
Positive 27	17	39	+	+
Positive 28	15	36	+	+
Positive 29	11	33	+	+
Positive 30	8	35	+	+
Positive 31	2	24	+	+
Positive 32	3	24	+	+
Positive 33	11	30	+	+
Positive 34	5	39	+	-
Positive 35	4	23	+	+
Positive 36	6	25	+	+
Positive 37	13	36	+	+
Positive 38	7	24	+	+
Positive 39	9	39	+	-
Positive 40	4	27	+	+



DIAGNOSTIC SPECIFICITY  
&  
DIAGNOSTIC SENSITIVITY

22.03.2021 GA CoV-2 Antigen Rapid  
Nasal\_DIAGNOSTIC SPECIFICITY &  
DIAGNOSTIC SENSITIVITY\_V01


**GA CoV-2 Antigen Rapid Nasal**

Valid from: 08.06.2020


Version 01

Page 4 of 19

Positive 41	1	35	+	-
Positive 42	2	21	+	+
Positive 43	3	25	+	+
Positive 44	2	23	+	+
Positive 45	5	24	+	+
Positive 46	6	28	+	+
Positive 47	13	35	+	+
Positive 48	6	27	+	+
Positive 49	3	18	+	+
Positive 50	10	37	+	+
Positive 51	5	25	+	+
Positive 52	4	24	+	+
Positive 53	2	18	+	+
Positive 54	9	35	+	+
Positive 55	5	26	+	+
Positive 56	11	37	+	+
Positive 57	2	23	+	+
Positive 58	6	26	+	+
Positive 59	13	29	+	+
Positive 60	12	30	+	+
Positive 61	7	29	+	+
Positive 62	11	31	+	+
Positive 63	9	35	+	+
Positive 64	5	27	+	+
Positive 65	6	34	+	+
Positive 66	4	23	+	+
Positive 67	7	30	+	+
Positive 68	10	35	+	+
Positive 69	4	30	+	+
Positive 70	5	29	+	+
Positive 71	7	29	+	+
Positive 72	5	25	+	+
Positive 73	6	24	+	+
Positive 74	4	25	+	+
Positive 75	4	22	+	+
Positive 76	5	28	+	+
Positive 77	3	23	+	+
Positive 78	2	23	+	+
Positive 79	1	23	+	+
Positive 80	7	32	+	+
Positive 81	6	28	+	+
Positive 82	5	30	+	+
Positive 83	2	21	+	+
Positive 84	3	19	+	+
Positive 85	3	25	+	+


	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 5 of 19

Positive 86	5	22	+	+
Positive 87	6	28	+	+
Positive 88	4	25	+	+
Positive 89	7	31	+	+
Positive 90	6	23	+	+
Positive 91	1	25	+	+
Positive 92	5	28	+	+
Positive 93	3	24	+	+
Positive 94	2	25	+	+
Positive 95	5	32	+	+
Positive 96	6	27	+	+
Positive 97	7	29	+	+
Positive 98	5	24	+	+
Positive 99	4	27	+	+
Positive 100	7	26	+	+
Positive 101	6	25	+	+
Positive 102	3	21	+	+


	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 6 of 19

**Negative results:**

NO.	RT-PCR	GA CoV-2 Antigen Rapid Nasal (Anterior Nasal Swab Specimen)
Negative 1#	-	-
Negative 2#	-	-
Negative 3#	-	-
Negative 4#	-	-
Negative 5#	-	-
Negative 6#	-	-
Negative 7#	-	-
Negative 8#	-	-
Negative 9#	-	-
Negative 10#	-	-
Negative 11#	-	-
Negative 12#	-	-
Negative 13#	-	-
Negative 14#	-	-
Negative 15#	-	-
Negative 16#	-	-
Negative 17#	-	-
Negative 18#	-	-
Negative 19#	-	-
Negative 20#	-	-
Negative 21#	-	-
Negative 22#	-	-
Negative 23#	-	-
Negative 24#	-	-
Negative 25#	-	-
Negative 26#	-	-
Negative 27#	-	-
Negative 28#	-	-
Negative 29#	-	-
Negative 30#	-	-
Negative 31#	-	-
Negative 32#	-	-
Negative 33#	-	-
Negative 34#	-	-
Negative 35#	-	-
Negative 36#	-	-
Negative 37#	-	-
Negative 38#	-	-
Negative 39#	-	-
Negative 40#	-	-
Negative 41#	-	-
Negative 42#	-	-


	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 7 of 19

Negative 43#	-	-
Negative 44#	-	-
Negative 45#	-	-
Negative 46#	-	-
Negative 47#	-	-
Negative 48#	-	-
Negative 49#	-	-
Negative 50#	-	-
Negative 51#	-	-
Negative 52#	-	-
Negative 53#	-	+
Negative 54#	-	-
Negative 55#	-	-
Negative 56#	-	-
Negative 57#	-	-
Negative 58#	-	-
Negative 59#	-	-
Negative 60#	-	-
Negative 61#	-	-
Negative 62#	-	-
Negative 63#	-	-
Negative 64#	-	-
Negative 65#	-	-
Negative 66#	-	-
Negative 67#	-	-
Negative 68#	-	-
Negative 69#	-	-
Negative 70#	-	-
Negative 71#	-	-
Negative 72#	-	-
Negative 73#	-	-
Negative 74#	-	-
Negative 75#	-	-
Negative 76#	-	-
Negative 77#	-	-
Negative 78#	-	-
Negative 79#	-	-
Negative 80#	-	-
Negative 81#	-	-
Negative 82#	-	-
Negative 83#	-	-
Negative 84#	-	-
Negative 85#	-	-
Negative 86#	-	-
Negative 87#	-	-


	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 8 of 19

Negative 88#	-	-
Negative 89#	-	-
Negative 90#	-	-
Negative 91#	-	-
Negative 92#	-	-
Negative 93#	-	-
Negative 94#	-	-
Negative 95#	-	-
Negative 96#	-	-
Negative 97#	-	-
Negative 98#	-	-
Negative 99#	-	-
Negative 100#	-	-
Negative 101#	-	-
Negative 102#	-	-
Negative 103#	-	-
Negative 104#	-	-
Negative 105#	-	-
Negative 106#	-	-
Negative 107#	-	-
Negative 108#	-	-
Negative 109#	-	-
Negative 110#	-	-
Negative 111#	-	-
Negative 112#	-	-
Negative 113#	-	-
Negative 114#	-	-
Negative 115#	-	-
Negative 116#	-	-
Negative 117#	-	-
Negative 118#	-	-
Negative 119#	-	-
Negative 120#	-	-
Negative 121#	-	-
Negative 122#	-	-
Negative 123#	-	-
Negative 124#	-	-
Negative 125#	-	-
Negative 126#	-	-
Negative 127#	-	-
Negative 128#	-	-
Negative 129#	-	-
Negative 130#	-	-
Negative 131#	-	-
Negative 132#	-	-




	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 9 of 19


Negative 133#	-	-
Negative 134#	-	-
Negative 135#	-	-
Negative 136#	-	-
Negative 137#	-	-
Negative 138#	-	-
Negative 139#	-	-
Negative 140#	-	-
Negative 141#	-	-
Negative 142#	-	-
Negative 143#	-	-
Negative 144#	-	-
Negative 145#	-	-
Negative 146#	-	-
Negative 147#	-	-
Negative 148#	-	-
Negative 149#	-	-
Negative 150#	-	-
Negative 151#	-	-
Negative 152#	-	-
Negative 153#	-	-
Negative 154#	-	-
Negative 155#	-	+
Negative 156#	-	-
Negative 157#	-	-
Negative 158#	-	-
Negative 159#	-	-
Negative 160#	-	-
Negative 161#	-	-
Negative 162#	-	-
Negative 163#	-	-
Negative 164#	-	-
Negative 165#	-	-
Negative 166#	-	-
Negative 167#	-	-
Negative 168#	-	-
Negative 169#	-	-
Negative 170#	-	-
Negative 171#	-	-
Negative 172#	-	-
Negative 173#	-	-
Negative 174#	-	-
Negative 175#	-	-
Negative 176#	-	-
Negative 177#	-	-

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 10 of 19


Negative 178#	-	-
Negative 179#	-	-
Negative 180#	-	-
Negative 181#	-	-
Negative 182#	-	-
Negative 183#	-	-
Negative 184#	-	-
Negative 185#	-	-
Negative 186#	-	-
Negative 187#	-	-
Negative 188#	-	-
Negative 189#	-	-
Negative 190#	-	-
Negative 191#	-	-
Negative 192#	-	-
Negative 193#	-	-
Negative 194#	-	+
Negative 195#	-	-
Negative 196#	-	-
Negative 197#	-	-
Negative 198#	-	-
Negative 199#	-	-
Negative 200#	-	-
Negative 201#	-	-
Negative 202#	-	-
Negative 203#	-	-
Negative 204#	-	-
Negative 205#	-	-
Negative 206#	-	-
Negative 207#	-	-
Negative 208#	-	-
Negative 209#	-	-
Negative 210#	-	-
Negative 211#	-	-
Negative 212#	-	-
Negative 213#	-	-
Negative 214#	-	-
Negative 215#	-	-
Negative 216#	-	-
Negative 217#	-	-
Negative 218#	-	-
Negative 219#	-	-
Negative 220#	-	-
Negative 221#	-	-
Negative 222#	-	-

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 11 of 19


Negative 223#	-	-
Negative 224#	-	-
Negative 225#	-	-
Negative 226#	-	-
Negative 227#	-	-
Negative 228#	-	-
Negative 229#	-	-
Negative 230#	-	-
Negative 231#	-	-
Negative 232#	-	-
Negative 233#	-	-
Negative 234#	-	-
Negative 235#	-	-
Negative 236#	-	-
Negative 237#	-	-
Negative 238#	-	-
Negative 239#	-	-
Negative 240#	-	-
Negative 241#	-	-
Negative 242#	-	-
Negative 243#	-	-
Negative 244#	-	-
Negative 245#	-	-
Negative 246#	-	-
Negative 247#	-	-
Negative 248#	-	-
Negative 249#	-	-
Negative 250#	-	-
Negative 251#	-	-
Negative 252#	-	-
Negative 253#	-	-
Negative 254#	-	-
Negative 255#	-	-
Negative 256#	-	-
Negative 257#	-	-
Negative 258#	-	-
Negative 259#	-	-
Negative 260#	-	-
Negative 261#	-	-
Negative 262#	-	-
Negative 263#	-	-
Negative 264#	-	-
Negative 265#	-	-
Negative 266#	-	-
Negative 267#	-	-

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 12 of 19


Negative 268#	-	-
Negative 269#	-	-
Negative 270#	-	-
Negative 271#	-	-
Negative 272#	-	-
Negative 273#	-	-
Negative 274#	-	-
Negative 275#	-	-
Negative 276#	-	-
Negative 277#	-	-
Negative 278#	-	-
Negative 279#	-	-
Negative 280#	-	-
Negative 281#	-	-
Negative 282#	-	-
Negative 283#	-	-
Negative 284#	-	-
Negative 285#	-	-
Negative 286#	-	-
Negative 287#	-	-
Negative 288#	-	-
Negative 289#	-	-
Negative 290#	-	-
Negative 291#	-	-
Negative 292#	-	-
Negative 293#	-	-
Negative 294#	-	-
Negative 295#	-	-
Negative 296#	-	-
Negative 297#	-	-
Negative 298#	-	-
Negative 299#	-	-
Negative 300#	-	-
Negative 301#	-	-
Negative 302#	-	-
Negative 303#	-	-
Negative 304#	-	-
Negative 305#	-	-
Negative 306#	-	-
Negative 307#	-	-
Negative 308#	-	-
Negative 309#	-	-
Negative 310#	-	-
Negative 311#	-	-
Negative 312#	-	-

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 13 of 19


Negative 313#	-	-
Negative 314#	-	-
Negative 315#	-	-
Negative 316#	-	-
Negative 317#	-	-
Negative 318#	-	-
Negative 319#	-	-
Negative 320#	-	-
Negative 321#	-	-
Negative 322#	-	-
Negative 323#	-	-
Negative 324#	-	-
Negative 325#	-	-
Negative 326#	-	-
Negative 327#	-	-
Negative 328#	-	-
Negative 329#	-	-
Negative 330#	-	-
Negative 331#	-	-
Negative 332#	-	-
Negative 333#	-	-
Negative 334#	-	-
Negative 335#	-	-
Negative 336#	-	-
Negative 337#	-	-
Negative 338#	-	-
Negative 339#	-	-
Negative 340#	-	-
Negative 341#	-	-
Negative 342#	-	-
Negative 343#	-	-
Negative 344#	-	-
Negative 345#	-	-
Negative 346#	-	-
Negative 347#	-	-
Negative 348#	-	-
Negative 349#	-	-
Negative 350#	-	-
Negative 351#	-	-
Negative 352#	-	-
Negative 353#	-	-
Negative 354#	-	-
Negative 355#	-	-
Negative 356#	-	-
Negative 357#	-	-

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 14 of 19

Negative 358#	-	-
Negative 359#	-	-
Negative 360#	-	-
Negative 361#	-	-
Negative 362#	-	-
Negative 363#	-	-
Negative 364#	-	-
Negative 365#	-	-
Negative 366#	-	-
Negative 367#	-	-
Negative 368#	-	-
Negative 369#	-	-
Negative 370#	-	-
Negative 371#	-	-
Negative 372#	-	-
Negative 373#	-	-
Negative 374#	-	-
Negative 375#	-	-
Negative 376#	-	-
Negative 377#	-	-
Negative 378#	-	-
Negative 379#	-	-
Negative 380#	-	-
Negative 381#	-	-
Negative 382#	-	-
Negative 383#	-	-
Negative 384#	-	-
Negative 385#	-	-
Negative 386#	-	-
Negative 387#	-	-
Negative 388#	-	-
Negative 389#	-	-
Negative 390#	-	-
Negative 391#	-	-
Negative 392#	-	-
Negative 393#	-	-
Negative 394#	-	-
Negative 395#	-	-
Negative 396#	-	-
Negative 397#	-	-
Negative 398#	-	-
Negative 399#	-	-
Negative 400#	-	-
Negative 401#	-	-
Negative 402#	-	-


	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 15 of 19

Negative 403#	-	-
Negative 404#	-	-
Negative 405#	-	-
Negative 406#	-	-
Negative 407#	-	-
Negative 408#	-	-
Negative 409#	-	-
Negative 410#	-	-
Negative 411#	-	-
Negative 412#	-	-
Negative 413#	-	-
Negative 414#	-	-
Negative 415#	-	-
Negative 416#	-	-
Negative 417#	-	-
Negative 418#	-	-
Negative 419#	-	-
Negative 420#	-	-
Negative 421#	-	-
Negative 422#	-	-
Negative 423#	-	-
Negative 424#	-	-
Negative 425#	-	-
Negative 426#	-	-
Negative 427#	-	-
Negative 428#	-	-
Negative 429#	-	-
Negative 430#	-	-
Negative 431#	-	-
Negative 432#	-	-
Negative 433#	-	-
Negative 434#	-	-
Negative 435#	-	-
Negative 436#	-	-
Negative 437#	-	-
Negative 438#	-	+
Negative 439#	-	-
Negative 440#	-	-
Negative 441#	-	-
Negative 442#	-	-
Negative 443#	-	-
Negative 444#	-	-
Negative 445#	-	-
Negative 446#	-	-
Negative 447#	-	-

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 16 of 19

Negative 448#	-	-
Negative 449#	-	-
Negative 450#	-	-
Negative 451#	-	-
Negative 452#	-	-
Negative 453#	-	-
Negative 454#	-	-
Negative 455#	-	-
Negative 456#	-	-
Negative 457#	-	-
Negative 458#	-	-
Negative 459#	-	-
Negative 460#	-	-
Negative 461#	-	-
Negative 462#	-	-
Negative 463#	-	-
Negative 464#	-	-
Negative 465#	-	-
Negative 466#	-	-
Negative 467#	-	-
Negative 468#	-	-
Negative 469#	-	-
Negative 470#	-	-
Negative 471#	-	-
Negative 472#	-	-
Negative 473#	-	-
Negative 474#	-	-
Negative 475#	-	-
Negative 476#	-	-
Negative 477#	-	-
Negative 478#	-	-
Negative 479#	-	-
Negative 480#	-	-
Negative 481#	-	-
Negative 482#	-	-
Negative 483#	-	-
Negative 484#	-	-
Negative 485#	-	-
Negative 486#	-	-
Negative 487#	-	-
Negative 488#	-	-
Negative 489#	-	-
Negative 490#	-	-
Negative 491#	-	-
Negative 492#	-	-




	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 17 of 19

Negative 493#	-	-
Negative 494#	-	-
Negative 495#	-	-
Negative 496#	-	-
Negative 497#	-	-
Negative 498#	-	-
Negative 499#	-	-
Negative 500#	-	-

## 1.7 The results:

GA CoV-2 Antigen Rapid Nasal		Comparison Test (RT-PCR)		Total
		positive	negative	
Covid-19 Antigen	positive	98	4	102
	negative	4	496	500
Total		102	500	602
Relative Sensitivity		96.1% 95% CI:(90.26%~98.92%)		
Relative Specificity		99,2% 95%CI : (97.96%-99.78%)		
Accuracy		98.7% ; 95%CI : (97.40%-99.42%)		


	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 18 of 19

### 1.8 GA CoV-2 Antigen Rapid Nasal Positive Results by time from symptom onset:

Days post symptom onset	Number of samples	PCR positive	GA CoV-2 Antigen Rapid Nasal
≤3	20	20	19/20=95.0%
4~7	43	43	42/43=97.7%
8~14	26	26	25/26=96.2%
> 14	13	13	12/13=92.3%
Total	102	102	98/102=96.1% 95% CI: (90.26%~98.92%)

The performance of GA CoV-2 Antigen Rapid Nasal with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the GA CoV-2 Antigen Rapid Nasal is higher with samples of a Ct count <35. GA CoV-2 Antigen Rapid Nasal performance against the Comparator Method – by Cycle Threshold Counts.

GA CoV-2 Antigen Rapid Nasal	RT-PCR(Positive by Ct Category)	
	Positive(Ct < 35)	Positive(Ct ≥ 35)
Positive	70	28
Negative	0	4
Total	70	32
Positive Agreement (95% CI)	100.0%(94.87%~100.00%)	87.5%(71.01%~96.49%)

	DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY	22.03.2021 GA CoV-2 Antigen Rapid Nasal_DIAGNOSTIC SPECIFICITY & DIAGNOSTIC SENSITIVITY_V01
	GA CoV-2 Antigen Rapid Nasal	Valid from: 08.06.2020
		Version 01
		Page 19 of 19

## 1.9 Conclusion:

The overall clinical performance of the GA CoV-2 Antigen Rapid Nasal was comparable with the data obtained in the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR assay and supports the use of the GA Generic Assays GmbH assay in the detection of SARS-CoV-2.