

CLINITEST Rapid COVID-19 Antigen Test

New Specimen Collection Claims and Updated Performance Data

Siemens Healthineers announced that the CLINITEST® Rapid COVID-19 Antigen Test has received CE Mark for anterior nasal swab specimen collection and updated performance data. Demonstrated performance data for anterior nasal and nasopharyngeal specimens is as follows:

Table 1: CLINITEST Rapid COVID-19 Antigen Test (Nasopharyngeal Swab) vs PCR

		PCR (Nasopharyngeal)		
		Positive	Negative	Total Results
CLINITEST Rapid COVID-19 Antigen Test (Nasopharyngeal Swab)	Positive	117	3	120
	Negative	2	743	745
	Total	119	746	865
		Relative Sensitivity 98.32%	Relative Specificity 99.60%	Accuracy 99.42%

Table 2: CLINITEST Rapid COVID-19 Antigen Test (Nasal Swab) vs PCR

		PCR (Nasopharyngeal)		
		Positive	Negative	Total Results
CLINITEST Rapid COVID-19 Antigen Test (Nasal Swab)	Positive	106	0	106
	Negative	3	128	131
	Total	109	128	237
		Relative Sensitivity 97.25%	Relative Specificity 100%	Accuracy 98.73%

Please note that there are no changes to the product or contents of the kit, and the same swab can be used for anterior nasal and nasopharyngeal specimen collection.

The updated data will be reflected beginning with version 5 of the instructions for use (IFU). The version number can be located in the bottom right corner of the IFU below the Revision Date. The last two digits indicate the version-- for example, version 5 is indicated as B21986-05.

It is expected that kits with an updated IFU will be manufactured starting in early February 2021. If you have product containing a printed IFU below version 5, you can access the updated version at www.siemens-healthineers.com/clinitest-covid-antigen or by contacting your Siemens Healthineers representative.

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