

**NEW**

**LAB**

# COVID-19 Anti-S1 Total Ab

# COVID-19 Anti-NC Total Ab

**Serological tests for quantitative and qualitative detection of total antibodies against Spike RBD S1 protein or Nucleocapsid (NC) protein of SARS-CoV-2**



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# COVID-19 Anti-S1 Total Ab

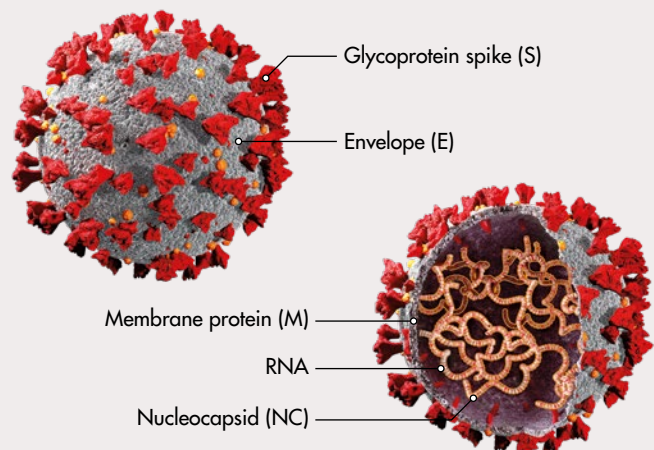
# COVID-19 Anti-NC Total Ab

## Serological tests for quantitative and qualitative detection of total antibodies against Spike RBD S1 protein or Nucleocapsid (NC) protein of SARS-CoV-2

COVID-19 is defined as the illness caused by the novel coronavirus, also known as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The common symptoms are fever, tiredness, dry cough and difficulties breathing. A severe acute respiratory distress Syndrome (ARDS) may develop and mortality rate depends on age, presence of chronic diseases, geographic location and season.

SARS-CoV-2 is an enveloped, single stranded RNA Virus of the Coronaviridae family. Coronaviruses encode 16 nonstructural proteins and 4 structural proteins: Spike (S), Envelope (E), Membrane (M) and Nucleocapsid (NC).

The COVID-19 Anti-S1 Total Ab and COVID-19 Anti-NC Total Ab assays are in vitro diagnostic tests for the detection of total antibodies (IgA, IgG and IgM) to SARS-CoV-2 in human serum versus specific protein of the virus, Spike RBD S1 or Nucleocapsid (NC), using immunoturbidimetric method. The assays can provide important information on the immunoresponse to SARS-CoV-2.



New needs have been raised since facing the SARS-CoV-2 pandemic: a quick evaluation of the immunological status of individuals and communities is crucial to understand what measures to adopt in order to avoid spreading of infections. Moreover, possible contacts must be traced, suspected patients must be evaluated quickly and immunity response after vaccination should be checked to verify effectiveness and allow recovered individuals to return to society.

The COVID-19 Anti-S1 Total Ab and COVID-19 Anti-NC Total Ab assays can provide fast high-throughput results useful to monitor the spread of the SARS-CoV-2 and help its management in local as well as large-scale situations. The two assays can be performed in the same assay run on one sample, allowing to obtain important information on the presence of different types of antibodies, thus on the nature of exposure to the virus, if positive to one, the other or both the antigens.

### Relevant hints from the simultaneous processing of the sample with the two assays:

COVID-19 Anti-S1 Total Ab	COVID-19 Anti-NC Total Ab	Type of antibodies	Exposure to the virus
+	+	Prevalence of: - Neutralizing antibodies - Non-neutralizing antibodies	Possible positivity due to past/present infection
+	-	Prevalence of: - Neutralizing antibodies	Possible positivity due to vaccination*
-	+	Prevalence of: - Non-neutralizing antibodies	Possible positivity due to past/present infection**
-	-	Absence of antibodies (or not detectable)	Possible absence of contact with the virus

\* If absence of Anti-NC antibodies is confirmed

\*\* If presence of Anti-NC antibodies is confirmed after retesting

## Results from the two assays can provide several useful information:

- To verify **immune response** after vaccination
- To monitor population **infection level**
- To identify potential **current infections** and **asymptomatic patients**

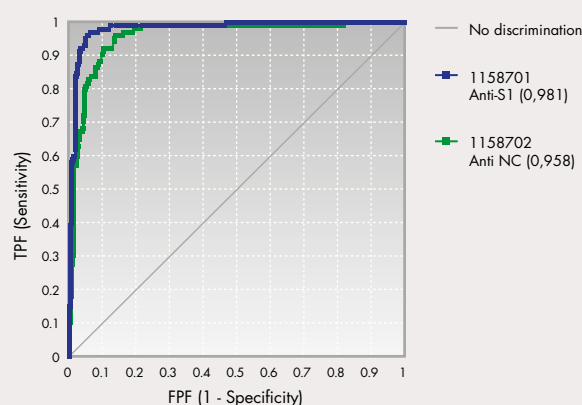
### Benefits of the kits:

- The quick solution for evaluating immunity status of patients
- High throughput testing on fully automated systems
- Applicable on most common clinical chemistry analyzers
- Ideal solution for screening of community and population
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability
- Better precision and repeatability than rapid card tests
- Perfectly matched liquid-stable reagents, calibrator and controls
- Very good correlation with PCR results
- Avoid interference due to Biotin and HAMA
- Environmental sustainable product from ISO 14001:2015 certified company

### Comparison to alternative immunological method:

A total of 479 (105 positive and 374 negative) patient samples have been tested with the COVID-19 anti-S1 Total Ab and the COVID-19 anti-NC Total Ab kits and compared to the results of an automated commercial available method for the detection of total antibodies to SARS-CoV-2.

Clinical concordance	COVID-19 Anti-S1 Total Ab	COVID-19 Anti-NC Total Ab
Area Under ROC Curve (AUC)	98.1% (95% CI: 96.8% - 99.3%)	95.8% (95% CI: 93.8% - 97.9%)



Name	COVID-19 Anti-S1 Total Ab	COVID-19 Anti-NC Total Ab
Target	Spike RBD S1 (S1) viral protein of the SARS-CoV-2	Nucleocapsid (NC) viral protein of the SARS-CoV-2
Quality control	COVID-19 Total Ab Controls REF 1158703 (sold separately)	
Sample	Human serum	
Platforms	SENTiFIT® 270 Analyzer	
Time to first result	About 10 minutes	
Throughput	Up to 270 tests/h - 2000 tests/working shift	
Reagent on board stability	28 days	
Calibration stability	14 days	
Specificity	Cross reactivity has been evaluated in 90 samples* IgG positive to several viruses and in 60 samples* IgG positive to CMV. Specificity vs. other virus: 100% Specificity vs. CMV: 100%	Specificity vs. other virus: 99% Specificity vs. CMV: 100%

\*All samples were obtained before December 2019

# COVID-19 Anti-S1 Total Ab

# COVID-19 Anti-NC Total Ab

Available on fully automated **SENTiFIT<sup>®</sup> 270** Analyzer



Ref. 1158701

**COVID-19 Anti-S1 Total Ab**

200 tests



Ref. 1158702

**COVID-19 Anti-NC Total Ab**

200 tests



Ref. 1158703

**COVID-19 Total Ab Controls**

2 x (1 x 1) mL

Ref.	Description	Kit size
1158701	COVID-19 Anti-S1 Total Ab Immuno-turbidimetric test for the quantitative and qualitative detection of human total antibodies against Spike RBD S1 protein of SARS-CoV-2 in human serum	200 tests
1158702	COVID-19 Anti-NC Total Ab Immuno-turbidimetric test for the quantitative and qualitative detection of human total antibodies against Nucleocapsid protein of SARS-CoV-2 in human serum	200 tests
1158703	COVID-19 Total Ab Controls Set of COVID-19 total antibodies negative and positive controls	2 x (1 x 1) mL

**SENTINEL** DIAGNOSTICS is member of IFCC Task force on COVID-19

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