INFECTIOUS DISEASES

VERIFY THE IMMUNE STATUS OF VACCINATED INDIVIDUALS WITH

LIAISON® SARS-CoV-2 TrimericS IgG

FOR OUTSIDE
THE US
AND CANADA ONLY

DiaSorin

The Diagnostic Specialist

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A HIGH-QUALITY TOOL TO VERIFY IMMUNE RESPONSES OF VACCINATED INDIVIDUALS

DiaSorin has developed a cost-effective, automated, high-throughput SARS-CoV-2 serology testing solution to support Public Health Systems in confirming the efficacy of their vaccination strategy.

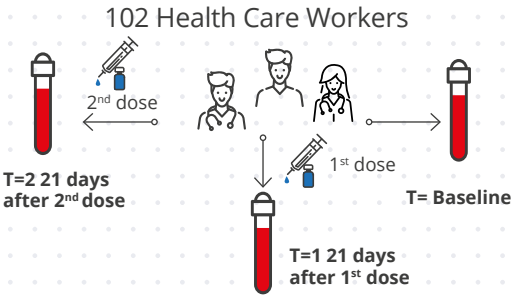
Used as follow-up, or as part of a long-term vaccination monitoring strategy, the highly-effective **LIAISON® SARS-CoV-2 TrimericS IgG** assay enables the reliable detection of Trimeric S spike protein IgG antibodies, which are the body's natural defense response against SARS-CoV-2.

To this end, a recent study was conducted in Alessandria (Italy) to support the Italian national vaccine program, which began in SS Antonio e Biagio Hospital in Alessandria December 2020. The aim was to evaluate pre- and post-vaccination samples. A total of 102 sets of samples were collected from apparently healthy adults that were SARS-CoV-2 IgG negative at the time of vaccine and who received the full course (2 injections) of the Pfizer-BioNTech vaccine (COMIRNATY®).

Samples were collected as follows:

- **(time0)** at first vaccine dose (baseline);
- **(time1)** 21 days after the first vaccine dose;
- **(time2)** 21 days after the second vaccine dose. The serum samples were tested with the LIAISON® SARS-CoV-2 TrimericS IgG to verify the presence of Trimeric S spike assay protein IgG antibodies and therefore the effectiveness of the vaccine, reaching a sensitivity of 99% (21 days after the first injection) and 100% (21 days after the second injection).

STUDY DESIGN



IMMUNE RESPONSE IN VACCINE RECIPIENTS

	Time 0 at first dose	Time 1 at 21 days after 1st dose	Time 2 at 21 days after 2nd dose
Negative	102	1	0
Positive	0	101	102
Sensitivity	-	99.0%	100%
Wilson 95% CI	-	94.7% - 99.8%	96.3% - 100%

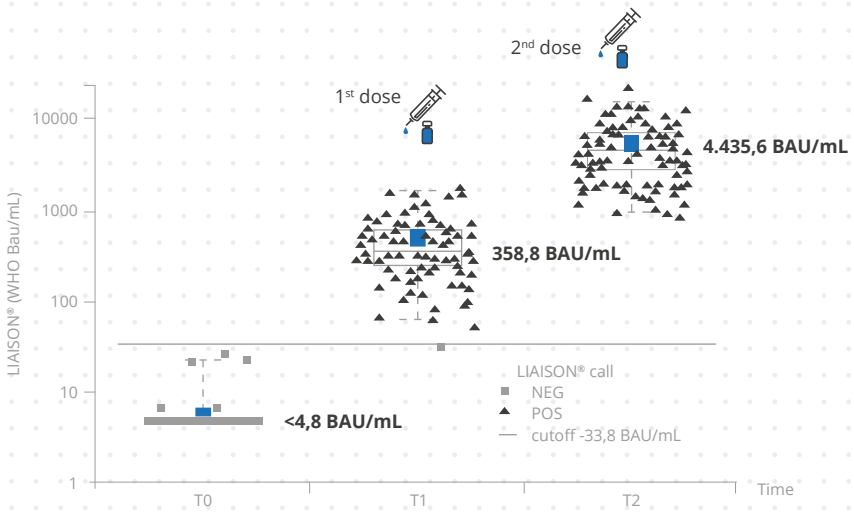
The immunity threshold (immune cutoff) that protects from SARS-CoV-2 infection has not been established.

ANTIBODY LEVELS (BAU/mL) ON VACCINES COHORT (N=102) AT EACH TIME POINT

	Time0 at 1st dose	Time 1 at 21 days after 1st dose	Time 2 at 21 days after 2nd dose
Number of subjects	102	102	102
Median (*BAU/mL)	<4.8	358.8	4435.6
2.5th percentile (BAU/mL)	<4.8	64.9	966.1
97.5th percentile (BAU/mL)	21.0	1604.8	15,236.4

*BAU/mL Binding Antibodies Unit/mL

ANTIBODY LEVELS (BAU/mL) - BOX PLOTS WITH MINIMA, MAXIMA, MEDIAN LINE AND DATA POINTS



Product availability subject to required regulatory approvals

M0870004414 05/21