On behalf of:

GENIUS Pharmaceutical AG

GENmonitor™

Evaluation of performance in the context of COVID-19 vaccination campaigns

Study abstract on the producer-related post-vaccination Covid-19-antibody detection performance of GEN***monitor***™ Ab Rapid Test

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PROFILE GENIUS PHARMACEUTICAL AG

Genius Pharmaceutical AG was founded 13 years ago out of a need to meet the growing demand for quality healthcare across countries and continents, and to provide solutions to the market-specific challenges of our customers, including organisations, companies and governments around the world.

Specialised in medical diagnostic testing, Genius Pharmaceutical AG produces and distributes high-quality pharmaceutical products for applications that make economic sense for our customers.

Our aim is to improve health care through unconventional thinking and action.

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POST-VACCINATION STUDIES WITH PFIZER BIONTECH

1. In April 2021, a study* was completed at the "Oncology Department of the Italian Cancer National Institute" using the COVID-19-SPIKE IgG (Neutralising Ab) Rapid Test** to verify that this test procedure (immunochromatography), respectively the mentioned assay, reliably detects seroconversion after vaccination with Pfizer BioNTech (detection of anti-Covid-19-Spike1/RBD-IgG antibodies = neutralising Ab).

   For this purpose, blood was collected from 66 subjects (study cohort) and analysed for neutralising antibodies against the ACE2-affine receptor binding domain (RBD) of the Covid-19-Spike1-Protein at a time interval of 22-35 days after the first vaccination (NB: subjects received the second booster vaccination 21 days after the first vaccination).

   In the evaluation summary of the test results, testing with the GEN***monitor***™ Rapid Test yielded in a qualitative antibody detection rate **(seroconversion rate) of 97%** related to the study cohort, indicating a very high detection reliability of the immune response of vaccinated individuals mediated via neutralising antibodies in the specified time interval after completion of the vaccination cycle (after second vaccination).

2. Another study* was completed at the Pharmacological Research Institute Mario Negri IRCCS in April 2021 on 55 subjects (study cohort).

   The study procedure differed from the previously described only with regard to time intervals between testing, i.e. the subjects were tested for neutralising antibodies 14 days after the first vaccination and 14 days after the second vaccination.

   Testing for neutralising antibodies using GEN***monitor***™ Rapid Test delivered the following measurement results:

   - 14 days after the first vaccination, a seroconversion rate of 31.1% was observed in the study cohort (NB: this positive test result, i.e. antibody detection of 31.1%, was found exclusively in subjects with a Covid infection(!) in the past, i.e. in those who had recovered).

   - 14 days after the second booster vaccination, the *entire* study cohort was tested positive for neutralising antibodies by GEN***monitor***™ Rapid Test, corresponding to a **seroconversion rate of 100%**.

POST-VACCINATION STUDIES WITH PFIZER BIONTECH - CONTINUED

3. A third study* was completed as a multi-center study in April 2021 at the following institutes:

   ◦ Instituto Nazionale dei Tumori, Mailand,

   ◦ Istituto di Ricerche Farmacologiche Mario Negri, Bergamo,

   ◦ Interuniversity Centre for Research on Influenza and other transmissible infections (CIRI-IT), Genua,

   namely on 234 subjects (study cohort) at different time points after vaccination, on days 7 / 14 / 21 / 28 / 35 after the first vaccination. NB: the second vaccination took place on the 21st day after the first vaccination.

   This protocol ensured that the development of seroconversion was also measured in the interval between first and second vaccination.

   A small number of subjects (5) had recovered from a Covid infection prior to recruitment into the study and had no detectable neutralising antibodies left in their blood at the time of study entry.

   The distribution of study volunteers across centers was as follows:

   ◦ National Centre of Cancer,
   Dept. of Haematology: 45 subjects

   ◦ Naitonal Centre for Cancer Diseases,
   Dept. Of Oncology: 66 subjects

   ◦ CIRI – IT: 73 subjects

   ◦ Institut Mario Negri: 50 subjects

   The result of this multi-center study demonstrated that the detection of neutralising antibodies 35 days after first vaccination (and thus 14 days after second vaccination) using GEN***monitor***™ Rapid Test is very reliable. The **consolidated seroconversion rate** measured with GEN***monitor***™ Rapid Test **across all 4 study** centres was **98.3%** two weeks after the complete vaccination cycle.

   One aspect of this study had already been shown in a comparable manner at the Mario Negri Institute (see above), namely that the seroconversion of vaccinated persons with previously overcome and cured Covid infection kicked in earlier and showed a steeper increase (100% seroconversion rate in this subgroup of the total cohort already 3 weeks after the first vaccination).

POST-VACCINATION STUDIES WITH MODERNA

1. A study* on the seroconversion rate measured with GEN***monitor***™ Rapid Test after vaccination with the Moderna vaccine was completed in June 2021 at the Institute Croce Verde di Teramo (Italy). Again, as shown in the other studies, qualitative detection testing for anti-Covid-19-Spike1/RBD-IgG antibodies was performed in 47 subjects 56 (+/- 4) days after the second vaccination (NB: which occurred 4 weeks after the first vaccination). The measurement of the **seroconversion rate** delivered a result of **95.74%.**

2. A second post-vaccination study* with the same question was started at PRIMA Lab SA in April 2021 and is still ongoing to recruit further subjects and include them in the current study. The study protocol requires blood sampling from 21 subjects, on day 0 and 7 after first vaccination, and on day 10 and 14 after second vaccination (NB: the second vaccination took place 27-28 days after first vaccination).

   The preliminary result of the measurement with GEN***monitor***™ Rapid Test two weeks after the second vaccination showed a **seroconversion rate of 95.2%** in relation to the total cohort.

POST-VACCINATION STUDY WITH ASTRA ZENECA

The study* was conducted at the Laboratorio Biologico dei Vigili del Fuoco (Milan) and was completed in June 2021. The study involved 68 subjects who were tested for seroconversion (at least) once with GEN***monitor***™ Rapid Test in the interval between the two vaccinations, and finally within the time frame of 10-14 days after the second vaccination had been given (NB: the vaccination interval between the first and second vaccination was 70 days).

The **seroconversion rate** after the complete vaccination cycle (i.e. 14 days after the second vaccination, and 84 days after the first vaccination, respectively) was **98.5%.**

* All original studies cited here were conducted at the institutes mentioned and can be made available on request. The studies referred to in the abstracts are listed here under:

Q8R318 Study Report - Italian National Cancer Institute (Milan, Italy), Interuniversity Center for Research on Influenza and other Transmissible infections (Genova, Italy), Pharmacological Research Institute Mario Negri (Bergamo, Italy) and PRIMA Lab SA (Balerna, Switzerland); May 2021. Q8R334 und Q8R335 Study Report. PRIMA Lab SA (Balerna, Switzerland); June 2021

** NB: The studies cited in this summary were initiated by the producer of the assay PRIMA COVID-19 SPIKE IgG Rapid Test (Covid-19 Neutralising Ab Rapid Test). This test is identical to the GEN***monitor***™ NEUTRALISING Ab RAPID TEST, hereafter referred to as the GEN***monitor***™ Rapid Test.

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