Usability of a novel Mouthwash sampling Kit for SARS-CoV-2 Antigen Measurements

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Comparison of samples taken at the site and samples taken at home and shipped to the site

Final Report

Study No.PRO-USA-001

System investigated: LEAD Horizon Corona Test Kit
(LEAD Horizon GmbH, Vienna, Austria)

Date: 10th November 2021

I. STUDY SUMMARY

Title:	Usability of a novel Mouthwash sampling Kit for SARS-CoV-2 antigen measurements – Comparison of samples taken at the site and samples taken at home and shipped to the site
Indication:	Collection of mouth rinse samples at home for SARS-CoV-2 RT-PCR antigen measurements
Study Objectives:	<u>Primary objective:</u> Usability and robustness of mouth rinse sample collection using the LEAD Horizon Corona Test Sampling Kit for the RT-PCR measurement of SARS-CoV-2 Antigen. <u>Secondary objective:</u> Accuracy of the mouth rinse collection solution for RT-PCR measurement of SARS-CoV-2 antigen in comparison to a standard reference method performed with nasal swabs. Comparison of mouth rinse samples taken at the study site with mouth rinse samples taken at home and following shipment per standard mail in the subsequent RT-PCR measurement of SARS-CoV-2 antigen.
Efficacy Variables:	RT-PCR measurements of SARS-Cov-2 antigen with EURORealtime SARS-Test
Safety Variables:	Adverse Events.
Study Duration:	Duration of the study for one volunteer/patient: one visit at the study site with approx. 30 min and further 30 min at home. Duration of the whole study: 3 months
Study activities	1. The subjects signed informed consent 2. The subjects underwent a nasal swab sample collection by a health care professional. 3. The subjects received a LEAD Horizon Corona Test Sampling Kit and collected a mouth rinse sample according to the IFU of the Kit. A Health care professional observed the subject and documented possible difficulties or problems (=site MR sample). 4. The subject received a second LEAD Horizon Corona Test Sampling Kit for home use at least 2 h later. The second collected sample was sent by standard mail back to the study site (=home MR sample).

5. Both mouth rinse samples collected at home and at the study site were stored until measurement at 4°C-8°C and then measured by RT-PCR. The results were compared for consistency with the reference RT-PCR performed with the nasal swab sample.

Results:

A total of 210 participants were enrolled in the study of which 52 had flu-like or Covid-like symptoms (122 male, 88 female, age: 38±12 yrs., range: 18 – 70 years). A subgroup of 30 subjects provided an additional positive sample by splitting the samples and by spiking one of each with inactivated virus at the site (reference nasal swab and both mouth rinse samples). Reference PCR-measurements revealed 31 positive patients by detectable amounts of SARS-CoV-2 virus antigen in the RT-PCR (= total of 61 positive and 179 negative samples).

All subjects performed the study per protocol and there were no adverse events reported. All positive nasal swab reference samples were found to be positive also in the site and in the home samples (61/61, sensitivity: 100 % for both, site and home MR samples). From the 179 negative site samples, all were tested negative with the site MS sample, and 177 were tested negative in the home MS sample. In two cases, the home MR sample tested positive (one questionable case: CT:35.4 and one case with a CT of 33.2; 177/179; specificity: site MR sample: 100 %; home MR sample: 98.9 %).

Conclusions:

In this direct head-to-head comparison, the home sampling kit from LEAD Horizon was demonstrated to provide a robust and reliable procedure to obtain valid PCR samples both at the site and during home use. Based on the results of the comparison testing of the mouth wash sampling method with the approved nasal swab sampling method, the accuracy of the mouth wash sampling was shown and the method was validated for the use in RT-PCR measurement of SARS-CoV-2 Antigen. All participants performed the mouth rinse sampling in accordance with the instructions for use by themselves without any major difficulties. With an agreement of 99.2 % (238/240), the method is suitable e.g. for safe and effective PCR community screening.

II. SIGNATURE PAGE

It is here with confirmed that this laboratory study was performed in compliance with the rules and regulations of ISO quality management requirements.

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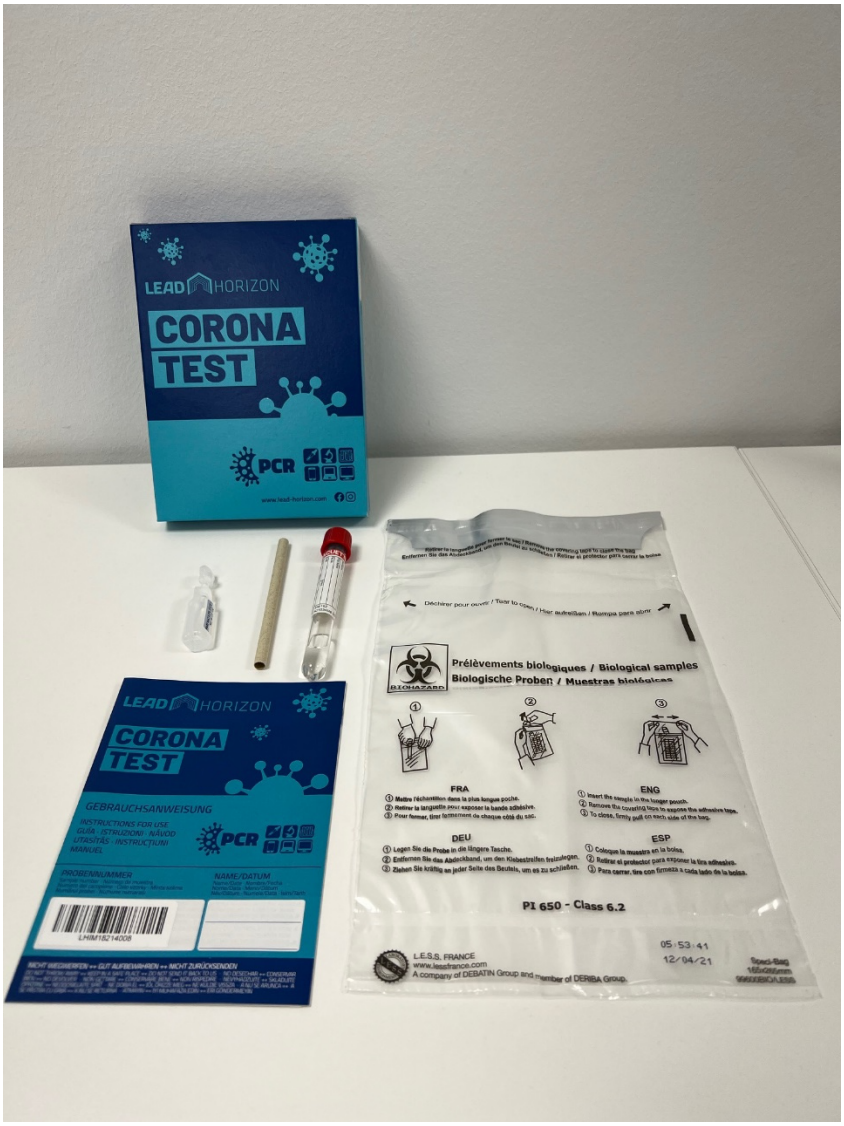
1. INTRODUCTION

1.1 Study Rationale

The SARS-CoV-2 virus has spread rapidly from its place of first detection and description (Wuhan, China) to become a global pandemic disease in Spring 2020. While aggressive measures have been taken to limit the spread of the virus in many countries, there is a clear need to understand the status of a given population with respect to infection rate, incidence and prevalence of new infections, mortality, and the immune status of the surviving population. This challenge can only be achieved with frequent and consequent testing, which requires access to several methods for screening and confirmation of a viral contact.

For this purpose, a system for laboratory-based analysis of self-collected pharyngeal lavage samples for SARS-CoV-2 mRNA using RT-PCR was developed.The system combines low-contact sampling, independent of medical testing facilities, with laboratory-based analysis using RT-PCR (see Figure 1.).

Figure 1.: Picture of the components of the LEAD Horizon Mouth Rinse Home Sampling Kit



Due to the transmission of SARS-CoV-2 via aerosols, there is a high risk of infection in contacts without mouth-nose protection, especially indoors. There is an increased risk of infection especially when performing rapid tests or swabs for PCR analysis. By taking mouth rinse samples independently and at home, this risk is completely eliminated. To ensure correct sample collection, the LEAD Horizon system offers the possibility to film the sample collection and to identify oneself at the end via passport. This way, the correct sampling can be ensured and a certificate of the result can be issued. Otherwise, only the PCR result can be transmitted.

1.4 Study Design

This is a prospective cross-sectional single-center study consisting of 1 study visit. A total of 480 samples from 210 subjects with unknown SARS-CoV-2 infection status were collected. Each subject provided a nasal swab sample at the site (reference sample) prior to a mouth rinse sample at the site first (site MR sample), and a second sample was collected at home (home MR sample) at least 2 hours after the site sampling procedure. Of these, 30 sampling tubes were aliquoted and one sample was additionally spiked with 2µL (1.77 x 10^5 cp/µL) of heat-inactivated SARS-CoV-2 virus (reference sample as well as both site MR sample and home MR sample) prior to the sampling procedures. In case of the spiked samples, the initiation of the mail shipment was handled by a health care professional.

The site MR samples were stored until arrival of the home samples via mail. While the nasal swab reference sample was measured immediately after collection, both MR samples were measured in parallel by means of the reference PCR method after arrival of the home sample at the site (EuroRealTime SARS-CoV-2).

2. METHODS

2.1 Investigational Device, Reference and Laboratory Instruments

2.1.1 Investigational Device

LEAD Horizon Corona Test Kit with sampling instructions (LEAD Horizon GmbH, Vienna, Austria)

2.1.2 Laboratory Instruments

- Block Heater (Digital Dry Bath/Block Heater with 2 blocks; Thermo Scientific)
- Clean bench category II (Safeguard Pro 600; HMC Europe)
- Mini plate centrifuge (NG040; Nippon Genetics Europe GmbH)
- RT-PCR device (QuantStudio 3; Applied Biosystems)

2.2 Subjects and samples

Samples were collected on day 0 from 210 subjects participating in the community testing program. Sampling was done at the site (nasal swab as well as site MR sample) and at home (home sample) according to the manufacturer's instructions. Additional samples were spiked with virus material and were prepared at the site. In this case, the mail shipment was initiated by a health care professional, who shipped them from his home 30 km away from the site.

2.3 Laboratory protocol

2.3.1 Sampling Procedures

The nasal swabs were taken by trained site staff. Mouth rinse sampling at the site and at home was carried out by the participants using the LEAD Horizon Mouth Rinse Sampling Kit (LEAD Horizon GmbH, Vienna, Austria) according to the manufacturer's instructions.

2.3.2 Viral RNA Extraction Procedures

For each measurement, 20 µL were taken from the sample and the viral RNA was extracted using Quick Extract protocol.

2.3.3 Measurement Procedures

RT-PCR was performed using the EURORealTime-SARS-CoV-2 (EUROIMMUN Medizinische Labordiagnostika AG) test kit according to the manufacturer's instructions.

2.3.4 Number of measurements for the comparison

The reference RT-PCR was done with 240 nasal swab samples. A total of 480 measurements were performed with 240 site MR samples and 240 home MR samples.

2.4 Ethical and Regulatory aspects

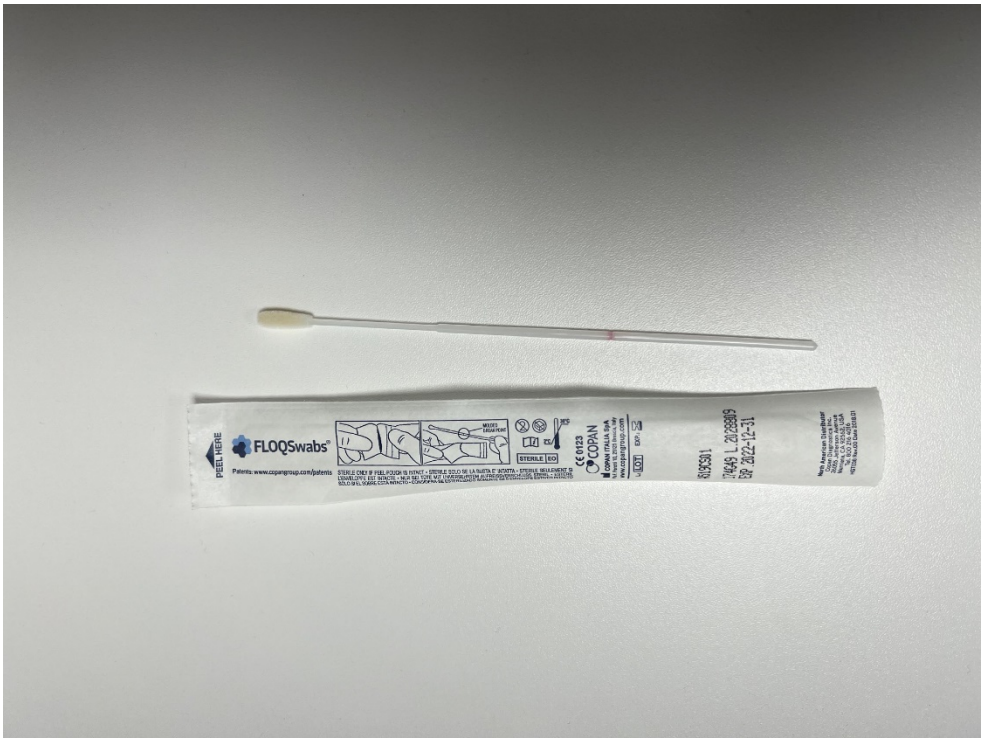
The clinical study protocol was approved by the responsible ethics committee on May 15th, 2021.
The study was carried out in accordance with the following references:

- The Declaration of Helsinki (1996)
- International ICH-GCP Guidelines
- EN ISO 13485
- EN 13612
- EN 62366-1:2015
- Pfützner Science and Health Institute Standard Operation Procedures

3. MATERIALS

COMPONENT NAME	MATERIAL	PCS
LEAD Horizon Self-sampling kit	Lot No.: 0002; Expiry Date: 02.12.2021 Lot No.: A21034M8/MSK, Expiry Date: 13.12.2021	210 each
Greiner Storage Buffer	Lot No. A20054NU Expiry Date: 02/12/2021 (for PCR-Reference)	240
EURORealTime-SARS-CoV-2 test kit	Lot. No. I210907AR, Expiry Date 28.03.2022 (single determination)	720
Lucigen Reagent	Lot No.: 24363	50 mL

Figure 2.: The COPAN FLOQ Swabs were used to obtain the reference nasal swab sample



4. DATA ANALYSIS

To assess agreement between the reference PCR results with the nasal swab samples, and the paired mouth rinse samples, the CT-values of the site sample and the home sample were compared. The evaluation of the individual PCR runs was carried out with the Quant Studio Design & Analysis Software v1.5.1.

Curves without a sigmoidal slope, curves with a linear slope or sigmoidal curves whose Ct-values were >36 were evaluated as negative. Only curves with a sigmoid curve and a Ct-value <36 were evaluated as positive. Samples without a valid internal control were evaluated as invalid.

In order to pass this robustness test, the paired mouth rinse samples had to deliver the same qualitative result in 98% of the measurements in comparison to the reference PCR method.

5. RESULTS

The study was conducted in compliance with all applicable regulations. All participants signed informed consent prior to any study procedures. All 210 participants (122 male, 88 female, age: 38±12 years, range: 18-70 years) conducted the study per protocol. No adverse or serious adverse events were reported in this trial. The mean shipment duration of the home samples to arrive at the site by regular mail was 1.37±0.67 days. The results of the RT-PCR Tests are provided in the following Table 1.

Table 1.: Results of the individual PCR tests with site samples and home samples (No Amp = no amplification)

No.	SARS-CoV-2		sample	site sample result			home sample result		shipment	Arrival	shipment		Reference Result		Agreement
	symptoms	Sample ID	date	qualitative	Ct-value	PCR date	qualitative	Ct-value	date	date	duration	PCR date	Ct-value	qualitative	
1	no	001A	19.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
2	no	002A	19.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
3	no	003A	19.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
4	no	004A	19.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
5	no	005A	19.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
6	no	006A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
7	yes	007A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
8	no	008A	23.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
9	no	009A	27.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
10	no	010A	27.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
11	yes	011A	22.08.2021	Negative	No Amp	02.09.2021	Positive	33,159/24,71	24.08.2021	25.08.2021	1	02.09.2021	No AMP	negative	no
12	no	012A	22.08.2021	Negative	No Amp	02.09.2021	Negative	38,274	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
13	no	013A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
14	no	014A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
15	no	015A	22.08.2021	Negative	No Amp	02.09.2021	Negative	37,652	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
16	no	016A	24.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
17	no	017A	21.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
18	no	018A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	38,32	negative	yes
19	no	019A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
20	yes	020A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
21	yes	021A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
22	no	022A	22.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
23	no	023A	24.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
24	no	024A	24.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
25	no	025A	23.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
26	no	026A	23.08.2021	Negative	No Amp	02.09.2021	Negative	No Amp	24.08.2021	25.08.2021	1	02.09.2021	No Amp	negative	yes
27	no	027A	31.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
28	no	028A	31.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
29	no	029A	31.08.2021	Negative	38,084	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
30	no	030A	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
31	no	031	30.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
32	no	032	30.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
33	no	033	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
34	no	034	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
35	no	035	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
36	no	036	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
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39	no	039	26.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
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41	no	041	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
42	no	042	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
43	no	043	26.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
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45	no	045	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
46	no	046	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
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49	no	049	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
50	no	050	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
51	no	051	30.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
52	no	052	30.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
53	no	053	30.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
54	no	054	30.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
55	no	055	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
56	no	056	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
57	no	057	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
58	no	058	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
59	no	059	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
60	no	060	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes

Table 1 (continued)

61	no	061	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
62	no	062	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
63	no	063	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
64	no	064	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	03.09.2021	2	06.09.2021	No Amp	negative	yes
65	no	065	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
66	yes	066	27.08.2021	Negative	No Amp	06.09.2021	Positive	35,389	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	no
67	no	067	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
68	no	068	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
69	no	069	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
70	no	070	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
71	no	071	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
72	no	072	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
73	no	073	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
74	no	074	27.08.2021	Negative	No Amp	06.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	06.09.2021	No Amp	negative	yes
75	no	075	01.09.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
76	no	076	01.09.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
77	no	077	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
78	no	078	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
79	no	079	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
80	no	080	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
81	no	081	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
82	no	082	30.08.2021	Negative	38,093	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
83	no	083	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
84	no	084	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
85	no	085	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
86	no	086	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
87	no	087	30.08.2021	Negative	38,382	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
88	no	088	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
89	no	089	30.08.2021	Negative	No Amp	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
90	no	090	30.08.2021	Negative	38,298	08.09.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.09.2021	No Amp	negative	yes
91	no	001B	19.08.2021	Positive	32,14	02.09.2021	Positive	30,09	24.08.2021	25.08.2021	1	02.09.2021	28,34	positive	yes
92	no	002B	19.08.2021	Positive	30,79	02.09.2021	Positive	29,63	24.08.2021	25.08.2021	1	02.09.2021	27,54	positive	yes
93	no	003B	19.08.2021	Positive	30,12	02.09.2021	Positive	28,73	24.08.2021	25.08.2021	1	02.09.2021	28,91	positive	yes
94	no	004B	19.08.2021	Positive	31,60	02.09.2021	Positive	30,76	24.08.2021	25.08.2021	1	02.09.2021	30,23	positive	yes
95	no	005B	19.08.2021	Positive	31,52	02.09.2021	Positive	31,20	24.08.2021	25.08.2021	1	02.09.2021	30,85	positive	yes
96	no	006B	22.08.2021	Positive	30,81	02.09.2021	Positive	29,98	24.08.2021	25.08.2021	1	02.09.2021	29,56	positive	yes
97	no	007B	22.08.2021	Positive	31,29	02.09.2021	Positive	29,90	24.08.2021	25.08.2021	1	02.09.2021	29,68	positive	yes
98	no	008B	23.08.2021	Positive	30,31	02.09.2021	Positive	29,83	24.08.2021	25.08.2021	1	02.09.2021	29,54	positive	yes
99	no	009B	27.08.2021	Positive	32,25	02.09.2021	Positive	31,10	24.08.2021	25.08.2021	1	02.09.2021	30,97	positive	yes
100	no	010B	27.08.2021	Positive	32,21	08.09.2021	Positive	30,41	01.09.2021	02.09.2021	1	08.09.2021	30,41	positive	yes
101	no	011B	22.08.2021	Positive	32,01	02.09.2021	Positive	29,79	24.08.2021	25.08.2021	1	02.09.2021	28,34	positive	yes
102	no	012B	22.08.2021	Positive	32,32	02.09.2021	Positive	29,54	24.08.2021	25.08.2021	1	02.09.2021	29,38	positive	yes
103	no	013B	22.08.2021	Positive	31,72	02.09.2021	Positive	29,80	24.08.2021	25.08.2021	1	02.09.2021	30,81	positive	yes
104	no	014B	22.08.2021	Positive	32,03	02.09.2021	Positive	30,41	24.08.2021	25.08.2021	1	02.09.2021	30,87	positive	yes
105	no	015B	22.08.2021	Positive	31,57	02.09.2021	Positive	31,11	24.08.2021	25.08.2021	1	02.09.2021	31,44	positive	yes
106	no	016B	24.08.2021	Positive	30,28	08.09.2021	Positive	29,85	01.09.2021	02.09.2021	1	08.09.2021	30,12	positive	yes
107	no	017B	21.08.2021	Positive	31,67	02.09.2021	Positive	31,63	24.08.2021	25.08.2021	1	02.09.2021	31,07	positive	yes
108	no	018B	22.08.2021	Positive	31,19	02.09.2021	Positive	28,90	24.08.2021	25.08.2021	1	02.09.2021	30,32	positive	yes
109	no	019B	22.08.2021	Positive	31,71	02.09.2021	Positive	30,53	24.08.2021	25.08.2021	1	02.09.2021	30,39	positive	yes
110	no	020B	22.08.2021	Positive	31,50	02.09.2021	Positive	29,48	24.08.2021	25.08.2021	1	02.09.2021	28,88	positive	yes
111	no	021B	22.08.2021	Positive	31,99	02.09.2021	Positive	31,20	24.08.2021	25.08.2021	1	02.09.2021	31,57	positive	yes
112	no	022B	22.08.2021	Positive	30,47	02.09.2021	Positive	28,94	24.08.2021	25.08.2021	1	02.09.2021	28,21	positive	yes
113	no	023B	24.08.2021	Positive	30,58	08.09.2021	Positive	29,21	01.09.2021	02.09.2021	1	08.09.2021	29,56	positive	yes
114	no	024B	24.08.2021	Positive	29,80	08.09.2021	Positive	28,64	01.09.2021	02.09.2021	1	08.09.2021	28,11	positive	yes
115	no	025B	23.08.2021	Positive	30,93	02.09.2021	Positive	31,55	24.08.2021	25.08.2021	1	02.09.2021	28,45	positive	yes
116	no	026B	23.08.2021	Positive	31,48	02.09.2021	Positive	30,54	24.08.2021	25.08.2021	1	02.09.2021	29,94	positive	yes
117	no	027B	31.08.2021	Positive	30,83	08.09.2021	Positive	30,40	01.09.2021	02.09.2021	1	08.09.2021	28,57	positive	yes
118	no	028B	31.08.2021	Positive	31,32	08.09.2021	Positive	29,64	01.09.2021	02.09.2021	1	08.09.2021	28,02	positive	yes
119	no	029B	31.08.2021	Positive	28,95	09.09.2021	Positive	30,71	01.09.2021	02.09.2021	1	08.09.2021	26,86	positive	yes
120	no	030B	30.08.2021	Positive	31,12	08.09.2021	Positive	30,39	01.09.2021	02.09.2021	1	08.09.2021	30,55	positive	yes
121	yes	091	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	02.11.2021	1	08.11.2021	No Amp	negative	yes
122	yes	092	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	04.11.2021	3	08.11.2021	No Amp	negative	yes
123	yes	093	30.08.2021	Positive	31,24	08.11.2021	Positive	30,93	01.11.2021	02.11.2021	1	08.11.2021	28,95	positive	yes
124	yes	094	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	02.11.2021	1	08.11.2021	No Amp	negative	yes
125	yes	095	30.08.2021	Positive	29,45	08.11.2021	Positive	29,98	01.11.2021	03.11.2021	2	08.11.2021	27,84	positive	yes
126	yes	096	30.08.2021	Positive	26,20	08.11.2021	Positive	25,3	01.11.2021	03.11.2021	2	08.11.2021	24,33	positive	yes
127	yse	097	30.08.2021	Positive	32,12	08.11.2021	Positive	31,94	01.11.2021	03.11.2021	2	08.11.2021	30,72	positive	yes
128	yes	098	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	02.11.2021	1	08.11.2021	No Amp	negative	yes
129	yes	099	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	02.11.2021	1	08.11.2021	No Amp	negative	yes
130	yes	100	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	03.11.2021	2	08.11.2021	No Amp	negative	yes
131	yes	101	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	03.11.2021	2	08.11.2021	No Amp	negative	yes
132	yes	102	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	04.11.2021	3	08.11.2021	No Amp	negative	yes
133	yes	103	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	04.11.2021	3	08.11.2021	No Amp	negative	yes
134	yes	104	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	03.11.2021	2	08.11.2021	No Amp	negative	yes
135	yes	105	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	02.11.2021	1	08.11.2021	No Amp	negative	yes
136	yes	106	30.08.2021	Positive	26,23	08.11.2021	Positive	27,34	01.11.2021	02.11.2021	1	08.11.2021	26,22	positive	yes
137	yes	107	30.08.2021	Positive	30,67	08.11.2021	Positive	30,85	01.11.2021	02.11.2021	1	08.11.2021	29,41	positive	yes
138	yes	108	30.08.2021	Positive	27,19	08.11.2021	Positive	26,62	01.11.2021	02.11.2021	1	08.11.2021	25,98	positive	yes
139	yes	109	30.08.2021	Positive	32,64	08.11.2021	Positive	33,91	01.11.2021	02.11.2021	1	08.11.2021	32,01	positive	yes
140	yes	110	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.11.2021	02.11.2021	1	08.11.2021	No Amp	negative	yes

Table 1 (continued)

141	yes	111	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.11.2021	No Amp	negative	yes
142	yes	112	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.11.2021	No Amp	negative	yes
143	yes	113	30.08.2021	Positive	32,63	08.11.2021	Positive	30,96	01.09.2021	02.09.2021	1	08.11.2021	29,77	positive	yes
144	yes	114	30.08.2021	Positive	31,77	08.11.2021	Positive	30,56	01.09.2021	02.09.2021	1	08.11.2021	28,96	positive	yes
145	no	115	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	02.09.2021	1	08.11.2021	No Amp	negative	yes
146	no	116	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
147	no	117	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
148	no	118	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
149	no	119	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
150	yes	120	30.08.2021	Positive	30,82	08.11.2021	Positive	31,04	01.09.2021	03.09.2021	2	08.11.2021	30,06	positive	yes
151	yes	121	30.08.2021	Positive	29,73	08.11.2021	Positive	30,77	01.09.2021	03.09.2021	2	08.11.2021	30,08	positive	yes
152	yes	122	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
153	yes	123	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
154	yes	124	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	positive	yes
155	yes	125	30.08.2021	Positive	30,68	08.11.2021	Positive	29,61	01.09.2021	03.09.2021	2	08.11.2021	28,53	positive	yes
156	no	126	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
157	no	127	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
158	no	128	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
159	no	129	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
160	yes	130	30.08.2021	Positive	33,21	08.11.2021	Positive	32,89	01.09.2021	03.09.2021	2	08.11.2021	30,99	positive	yes
161	yes	131	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
162	no	132	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
163	no	133	30.08.2021	Negative	38,24	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
164	no	134	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
165	no	135	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
166	no	136	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	03.09.2021	2	08.11.2021	No Amp	negative	yes
167	yes	137	30.08.2021	Positive	31,37	08.11.2021	Positive	30,85	01.09.2021	06.09.2021	5	08.11.2021	29,99	positive	yes
168	yes	138	30.08.2021	Positive	30,34	08.11.2021	Positive	29,01	01.09.2021	06.09.2021	5	08.11.2021	28,78	positive	yes
169	yes	139	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
170	yes	140	30.08.2021	Positive	30,18	08.11.2021	Positive	30,42	01.09.2021	06.09.2021	5	08.11.2021	28,78	positive	yes
171	no	141	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
172	no	142	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
173	no	143	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
174	no	144	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
175	no	145	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
176	yes	146	30.08.2021	Positive	27,51	08.11.2021	Positive	27,96	01.09.2021	06.09.2021	5	08.11.2021	26,81	positive	yes
177	yes	147	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
178	yes	148	30.08.2021	Negative	38,21	08.11.2021	Negative	37,66	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
179	yes	149	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
180	yes	150	30.08.2021	Positive	29,39	08.11.2021	Positive	29,44	01.09.2021	06.09.2021	5	08.11.2021	28,88	positive	yes
181	no	151	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
182	no	152	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
183	no	153	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
184	no	154	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
185	no	155	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
186	yes	156	30.08.2021	Positive	34,22	08.11.2021	Positive	34,03	01.09.2021	06.09.2021	5	08.11.2021	32,78	positive	yes
187	no	157	30.08.2021	Positive	27,52	08.11.2021	Positive	26,77	01.09.2021	06.09.2021	5	08.11.2021	26,98	positive	yes
188	no	158	30.08.2021	Positive	28,53	08.11.2021	Positive	28,89	01.09.2021	06.09.2021	5	08.11.2021	28,17	positive	yes
189	yes	159	30.08.2021	Positive	30,05	08.11.2021	Positive	30,31	01.09.2021	06.09.2021	5	08.11.2021	28,49	positive	yes
190	yes	160	30.08.2021	Positive	28,67	08.11.2021	Positive	28,38	01.09.2021	06.09.2021	5	08.11.2021	27,53	positive	yes
191	yes	161	30.08.2021	Positive	32,00	08.11.2021	Positive	31,72	01.09.2021	06.09.2021	5	08.11.2021	30,99	positive	yes
192	no	162	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
193	no	163	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
194	no	164	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
195	no	165	30.08.2021	Positive	32,47	08.11.2021	Positive	31,93	01.09.2021	06.09.2021	5	08.11.2021	30,77	positive	yes
196	no	166	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
197	yes	167	30.08.2021	Positive	31,45	08.11.2021	Positive	30,99	01.09.2021	06.09.2021	5	08.11.2021	29,54	positive	yes
198	no	168	30.08.2021	Positive	30,63	08.11.2021	Positive	30,47	01.09.2021	06.09.2021	5	08.11.2021	29,89	positive	yes
199	no	169	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
200	no	170	30.08.2021	Negative	38,01	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
201	no	171	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
202	no	172	30.08.2021	Negative	No Amp	08.11.2021	Negative	37,22	01.09.2021	06.09.2021	5	08.11.2021	37,22	negative	yes
203	no	173	30.08.2021	Positive	28,81	08.11.2021	Positive	29,31	01.09.2021	06.09.2021	5	08.11.2021	27,66	positive	yes
204	yes	174	30.08.2021	Positive	32,58	08.11.2021	Positive	32,83	01.09.2021	06.09.2021	5	08.11.2021	29,93	positive	yes
205	no	175	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
206	no	176	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
207	no	177	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
208	no	178	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
209	yes	179	30.08.2021	Positive	27,48	08.11.2021	Positive	27,33	01.09.2021	06.09.2021	5	08.11.2021	26,47	positive	yes
210	no	180	30.08.2021	Negative	No Amp	08.11.2021	Negative	No Amp	01.09.2021	06.09.2021	5	08.11.2021	No Amp	negative	yes
211	no	181	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
212	no	182	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
213	no	183	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
214	no	184	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
215	no	185	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
216	no	186	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
217	no	187	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
218	no	188	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
219	no	189	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
220	no	190	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
221	no	191	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
222	no	192	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
223	no	193	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
224	no	194	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
225	no	195	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes

Table 1 (continued)

225	no	195	02.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	02.09.2021	06.09.2021	4	08.11.2021	No Amp	negative	yes
226	no	196	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
227	no	197	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
228	no	198	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
229	no	199	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
230	no	200	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
231	no	201	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
232	no	202	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
233	no	203	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
234	no	204	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
235	no	205	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
236	no	206	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
237	no	207	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
238	no	208	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
239	no	209	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes
240	no	210	03.09.2021	Negative	No Amp	08.11.2021	Negative	No Amp	03.09.2021	06.09.2021	3	08.11.2021	No Amp	negative	yes

A total of 210 participants were enrolled in the study, of which 52 had flu-like or Covid-like symptoms. A subgroup of 30 subjects provided an additional positive sample set (samples 91 to 120 in the Table, split-samples from the original sample) by artificially splitting the samples and by spiking the reference nasal swab sample and the two mouth rinse samples with inactivated virus at the site (prior to shipment of the home MR sample). By reference PCR-measurement, an additional group of 31 patients was found to be positive by detectable amounts of SARS-CoV-2 virus antigen in the nasal swab RT-PCR, resulting in a total of 61 positive and 179 negative samples.

All positive nasal swab reference samples were found to be also positive in the site MR and in the home MR samples (61/61, sensitivity: 100 % for both mouth rinse samples).

From the 179 negative reference PCR samples, all were confirmed with the site MR sample and 177 were tested negative in the MR home sample. In two cases, the home MR sample tested positive (one questionable case: CT of 35.4 and one case with a CT of 33.2; 177/179; specificity: 98.9 %). It cannot be ruled out that these “wrong positive” samples provide even a more precise information, as they A. were collected at a slightly later timepoint, and B. were both obtained from participants with flu-like symptoms.

In any case, the theoretical consequences of the positive findings (i.e. quarantine) would not compromise the intention of frequent PCR-testing, which is protection of the community by isolation of infected subjects.

6. SUMMARY AND CONCLUSIONS

In this study, we investigated the suitability and reliability of a mouth rinse sampling kit for site and home use for the consecutive valid detection of SARS-CoV-2 antigen by RT-PCR, after shipment of the sample. All subjects performed the study per protocol and there were no adverse events reported. In this direct head-to-head comparison, both the site MR samples and the samples obtained with the home sampling kit from LEAD Horizon were demonstrated to provide a robust and reliable procedure to obtain valid PCR samples. The shipment process did not compromise the sample stability and integrity.

In conclusion, with an agreement of 99.2 % (238/240), the mouth rinse collection kit is a suitable and reliable alternative to sample collection with nasal swabs at the laboratory. Both, mouth rinse sampling at the site and at home can be used e.g. for safe and effective PCR community screening.