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Original Paper

OBSERVATION OF AUTOMATED MANAGEMENT USE OF SELF-SAMPLING KITS

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In the current times of ever-growing prevalence of infectious diseases, it is requisite to explore ways to provide the safest and most effective medical care for our patients. The aim of this study is to explain how the issues raised by the SARS-CoV-2 pandemic were addressed by the E. Gulbis Laboratory in Latvia. The study looks back on the goal to introduce an automated and effective solution for the management of self-collected samples. The study is primarily aimed to formulate the conclusions about the data and use of automation in the self-sample kit collection. Results were collected from 18 automated (contactless) sample collection devices used by E. Gulbis Laboratory. Sixty-four thousand two hundred fifty-seven (64,257) saliva kits for SARS-CoV-2 PCR testing were employed. It was found that 3.92% of them were positive (SARS-CoV-2 virus RNA found in saliva sample). The average processing time in automated devices located in the capital city was 11.13 hours, in the suburbs — 15.52 hours, rest of the country — 17.60 hours. The average age of patients that choose an automatic device to hand in their saliva sample kits was 33.94 years. These results suggest that by using the automated device, patient contacts are decreased, and direct communication with medical staff is excluded, which reduces the risk of infection during processing. Automated devices make sample kit distribution available 24 hours. They save workforce resources in the laboratory that are already very limited, especially during a pandemic period.

Keywords: *patient collected samples, contactless, testing, laboratory, COVID-19.*

INTRODUCTION

During the closing of 2019, the world was shaken by the global novel coronavirus SARS-CoV-2 pandemic, which in turn caused a huge demand for mass screening of the population, using the gold standard rt-PCR method (Teymouri, 2021), to identify infected individuals and isolate them, with the ultimate goal to thwart the spread of the virus among the population. Until ultimately achieving collective immunity, the SARS-CoV-2 testing, identification and isolation of the affected people was deemed the most effective route to curtail the spread of the virus in the population, since no vaccination was possible at that time (Cohen and Kupferschmidt, 2020). The increased demand for testing caused a sudden shortage of resources in the medical sector, especially qualified medical personnel, who, in turn, would also be exposed to an ever-increasing workload, risking both overworking and the possibility of exposure to the virus (Smallwood, 2022).

In Latvia, with a population of approximately 1.8 million (Centrālā statistikas pārvalde, 2021), the first known infection case of SARS-CoV-2 was recorded on 2 March 2020 (Latvian Public Broadcasting, 2020). In order to alleviate the workload of the medical personnel and to minimise their risk of infection, while simultaneously increasing the capacity to conduct testing, in December of 2020, the first contactless equipment for collecting SARS-CoV-2 test samples was introduced, as reported by labs of Latvia. Originally, it was meant for testing the personnel of medical facilities only. An automated self-sample collection device resembling a vending machine at the Pauls Stradiņš Clinical University Hospital was the first for a nationwide rollout. The machine removed the need for two to five medical workers that would otherwise be needed to administer the SARS-CoV-2 nasopharyngeal swab tests and to register the sample, as well as lowered infection risk for healthcare workers (KIOSK, 2020).

The contactless equipment for collecting the SARS-CoV-2 saliva self-sample kits, made by Latvian engineers of E. Gulbis Laboratory in cooperation with JK Energo Ltd. and Latvijas Finieris Jsc., was a unique solution not found elsewhere in the world at that time and it continues to succeed in reducing the contact between the patients and the medical personnel. The automated technology facilitates effective identification of patients infected with SARS-CoV-2, all the while alleviating the workload of medical personnel and improving the logistics of the testing procedures (Labs of Latvia, 2020). At the time of writing, the year of 2022, the contactless analysis transfer/acceptance device works without halt in 18 locations across Latvia, five of them located in the nation's capital, Rīga, while the rest are scattered across the country (E. Gulbja Laboratorija, 2022) (Fig. 1). The original design of the devices purposefully served customers in strategic locations and during large events, for example, during the 2021 International Ice Hockey Federation World Championship (Fig. 2). By the end of 2021, a new design for contactless analysis transfer/acceptance devices was introduced, which were gradually deployed mostly in the nations capital city Riga (Fig. 3).

Because of the obvious advantages of the contactless sample collection devices and systems, their use is now found elsewhere in the world as well. For example, 24/7 PCR saliva sample collection kits, which are mailed to the testing facilities after self-sampling, are available in Japan (Sakai and Swift, 2021). There are many similar systems or devices in the USA, for example, the self-administered tests found in vending machines at the San Diego university campus (SDSU News Team, 2021), or the automated kiosks with sample storage capability in the state of Georgia (Georgia Department of Public Health, 2022). Meanwhile, in the United Kingdom, in order to minimise human to human transmission of the SARS-CoV-2 a robotic arm has been handing out test tubes to drivers in cars for SARS-CoV-2 testing (Drives & Controls, 2020).

Solutions other than self-servicing, bulk collection and testing, and automation can be observed in the global fight against the virus. The pandemic saw the widespread use of protective gear and disposable coveralls, especially when performing testing and care of patients in proximity. However, close contact between medical personnel and patients still presents risk of transmission, as exemplified by one of the more common testing methods — nasopharyngeal swab test (World Heath Organization, 2021). In an attempt to eliminate such risk, the so-called throat swab robots and nasal swab robots became available on the market, albeit at a less than attractive price for widespread introduction. While these robots do boast an impressive artificial intelligence visual analysis system to recognise the features of the human face and track motion (GLOBALink, 2021), the lesser efficacy because of the inability to multitask (Farmer, 2020) and a somewhat mistrusting patient base (Torrent-Sellens, 2021) are also among reasons why these robots still remain an unplausible solution for systemic adoption (Xinhua, 2021).

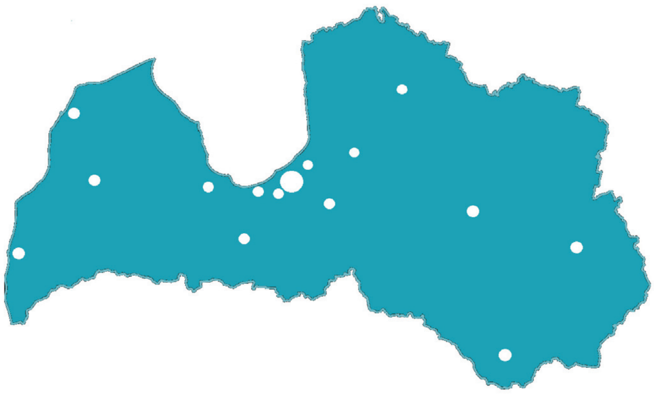

Fig. 1. Locations of the contactless analysis transfer/acceptance devices in Latvia

Fig. 2. Original design of the contactless analysis transfer/acceptance devices. Source: JK Energo Ltd.

Fig. 3. The new design of the contactless analysis transfer/acceptance devices

From patient-facing throat and nasal swab robots, and self-sample collection devices to automated testing devices speeding things along, it seems the use of robotics in a laboratory setting has escaped the realm of science fiction and stepped up to alleviate the workload of the human workforce, while performing more tasks (Cresswell, 2020). For example, while a laboratory specialist manually pipettes a mix for coronavirus testing, the *OT-2* robot can precisely fill 96 wells of fluid in 22 seconds (Baumgaertner, 2021). Another advantage the reliance on robotics brings, especially those with a closed loop functionality, is the elimination of human errors, such as cross-contamination of samples, input errors, etc. (Cresswell, 2020).

This publication set out to explain the methods for tackling the pressing situation induced by the SARS-CoV-2 pandemic, when simple and widely available testing was a requirement, all the while protecting valuable medical personnel from the risk of exposure and infection as priorities. This publication provides an insight into how the unfortunate circumstances of the pandemic accelerated the inevitable automation processes in medical laboratories and in patient care overall.

MATERIALS AND METHODS

The conducted research was based on data obtained in an accredited clinical laboratory, the E. Gulbis Laboratory (LVS ENISO 15189:2013, ISO/IEC 17025, Rīga, Latvia) (Latvijas Nacionālais akreditācijas Birojs, 2018), which provides laboratory services via contactless devices in 18 locations across Latvia.

Data collection was carried out using the E. Gulbis Laboratory information system, which tracks and stores anonymised clinical details about patients during laboratory visits, using MySQL database queries. Collected data graphical representation was made using MS Excel. Data does not have a *p*-value as there was no statistical hypothesis testing.

In total, sixty-four thousand two hundred fifty-seven (64 257) saliva SARS-CoV-2 PCR tests were collected in 18 automated (contactless) sample collection devices used by the E. Gulbis Laboratory in capital city Rīga as well as in the rest of the country.

E. Gulbis Laboratory collected data about SARS-CoV-2 saliva sample kit collection in automated devices, average processing time between sample collections, and result reception by the patient, proportions of positive tests, the age distribution of patients who used automated collection devices, and the ratio of sample kits that were collected outside of regular working hours (20:00–08:00).

The patient experience was as follows: (1) The patient completes authorisation (logs in) using the hospital or laboratory webpage, after which, a code is sent to their mobile device. (2) After receiving the code, the patient can receive a testing kit at the automated device and submit their sample for testing. (3) After collecting a bulk of samples, a courier is dispatched to collect the samples and transport them to a laboratory. (4) Finally, after the completing the laboratory analyses of the sample, the patient receives the test results via e-mail or in the laboratory webpage (Figs. 4 and 5).

RESULTS

In Latvia, in December of 2021, the number of infected reached more than 277,000 (Trading Economics, 2022), and the number of tests surpassed 5.5 million (Statista, 2022), a

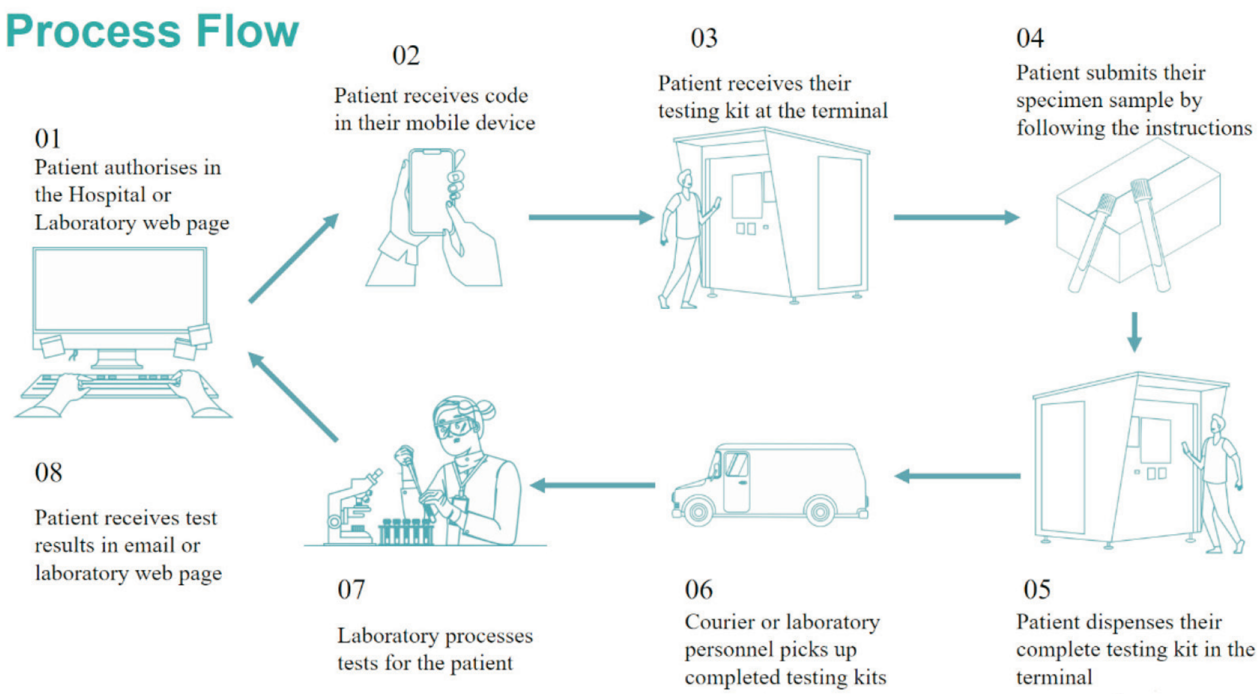

Fig. 4. Process flow of the contactless analysis transfer/acceptance devices

Fig. 5. QR code for video demostration on contactless analysis transfer/acceptance device technology

part of those being the SARS-CoV-2 saliva sample kits collected by automated (contactless) sample collection devices. In a span of a year from 1 January 2021 until 31 December 2021 a total of 64,257 saliva kits for SARS-CoV-2 rt-PCR were processed in the automated (contactless) sample collection devices used by E. Gulbis Laboratory.

In January 2021, the saliva samples collected by automated systems or devices made up 6% of all saliva samples collected. In February, March, and April of the same year, this proportion shrank due to increased testing overall. By comparison, in March 2021 104,316 saliva tests were conducted in total, whereas in June of 2021, the total amount of tests was roughly halved, with a total of 50,032 tests conducted. However, in June of 2021, the saliva samples collected by the automated systems or devices made up 12% of the total samples collected.

Proportionally the highest amount of saliva samples collected by automated systems or devices was reached in July 2021, these tests making up almost 33% of the total number of samples collected, although, this is explained by the second lowest number of samples collected overall that month.

In the months that followed, the number of samples collected increased. In August 2021, 111,927 samples were collected, whereas in September 2021, 225,020) samples were collected in total.

During this time the samples collected by automated systems or devices remained steady, with 17,443 samples collected in August and 16,251 samples collected in September of that year. This is partially explained by considering the then state mandated obligatory screening of pupils in schools using the SARS-CoV-2 rt-PCR saliva sample test method, where only non-automated methods were used for testing (LV portāls, 2021). Thus, the proportion of the number of samples collected by automated systems or devices made up 16% in August of 2021, and only 7% in September, far from the 33% recorded in July of 2021.

After the peak in September of 2021, the overall amount of saliva samples collected for testing steadily decreased, with 221,610 samples collected overall in October of that year, 117,083 samples collected overall in November, and 134,749 samples collected overall in December. The proportion of samples collected in automated systems or devices decreased with the trend, making up 10% in the beginning of October, and only 4% in November and December (Figs. 6 and 7).

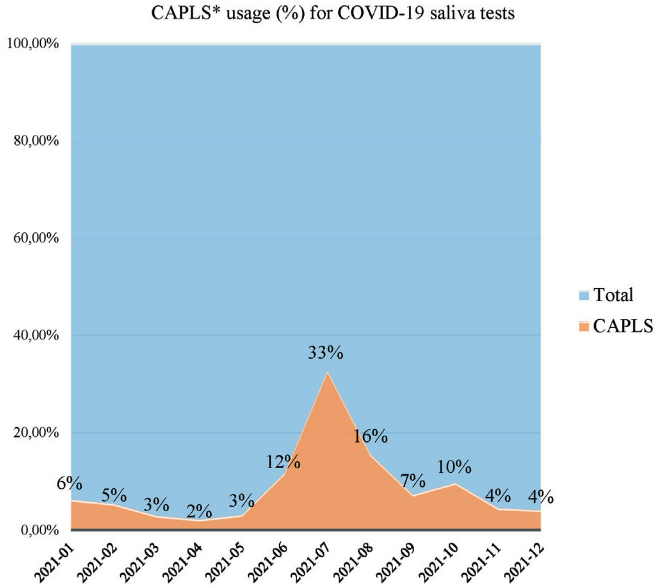

Fig. 6. SARS-CoV-2 saliva sample automated device usage (%) compared to total amount of SARS-CoV-2 saliva sample tests conducted each month. CAPLS, Contactless Access Point for Lab Samples.

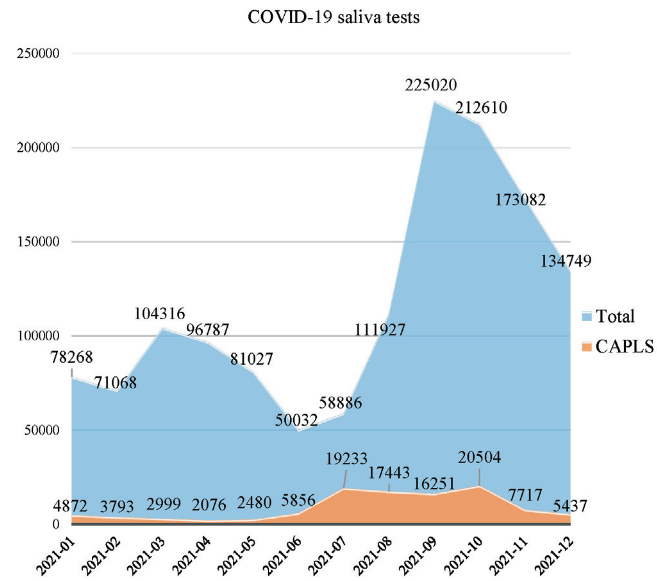

Fig. 7. Number of SARS-CoV-2 saliva samples collected by automated devices compared to total amount of SARS-CoV-2 saliva sample tests conducted each month.

Owing to the automated devices, patients had the ability to submit saliva tests and samples in different locations across Latvia, but the speed of receiving the results was not consistent. Results were delivered the fastest in the city of Rīga, with the average time between sample submission and receiving the results being 11.13 hours. The average in suburban territories was 15.52 hours, with rural territories receiving the results slowest — in 17.60 hours on average (Fig. 8). The difference is mostly explained by the transportation time needed — the furthest automated device sites being approximately 220 kilometers away from the main laboratory facility in the capital city Rīga.

The age of the patient was in direct correlation with the decision to choose the automated services. Patients older than 38 were less likely to use the automated services than those younger (Fig. 9).

Of these 64 257 SARS-CoV-2 saliva sample kits collected by automated sample collection devices from 1 January 2021 until 31 December 2021, 3.92% were found to be positive (SARS-CoV-2 virus RNA found in saliva sample) (Fig. 10).

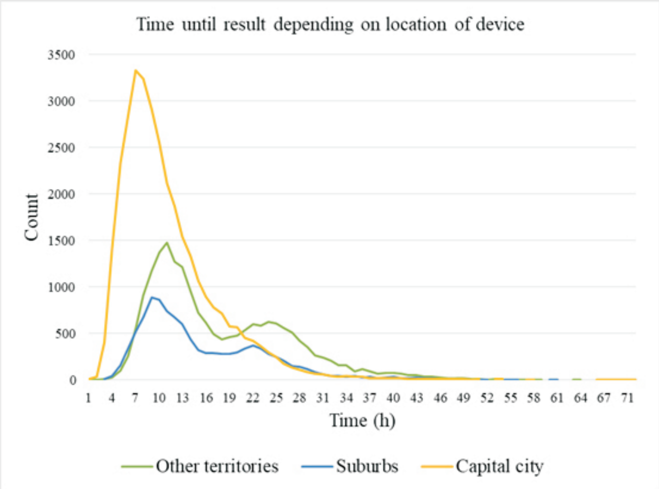

Fig. 8. Time (hours) until result depending on location of device. 95% of tests were executed and patients received their results in less than 28 hours since handing the sample in the contactless device.

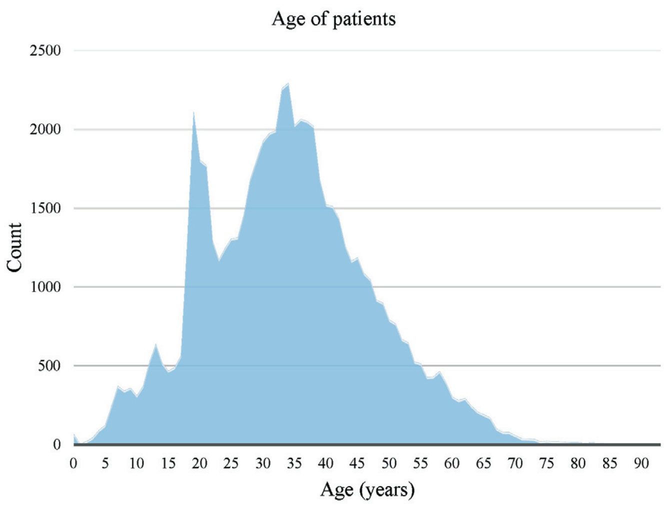

Fig. 9. Distribution of patient age (years) by SARS-CoV-2 saliva sample count collected by automated devices.

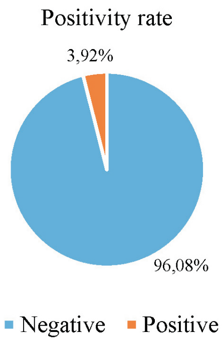

Fig. 10. Positivity rate – SARS-CoV-2 virus RNA found in saliva samples (%) collected by automated devices.

DISCUSSION

This study primarily addresses the need for further development in automatisation in the laboratory and hospital environment. After introducing contactless equipment for collecting SARS-CoV-2 test samples, this turned a new page of endless possibilities in optimising laboratory work and focused resources to work on innovation.

Now these automated sample collection devices are equipped to handle even more various tests — starting from the pioneering SARS-CoV-2 saliva sample test kits, now patients can easily make use of preventative and diagnostic measures including various faecal tests such as faecal analysis — coprogram, occult blood, intestinal parasites (rt-PCR), *G. Lamblia* antigen, *H. pylori* antigen, calprotectin, as well as basic urine tests — test strip and microscopy, sexually transmitted infection panel (rt-PCR), alfa-amylase, microalbuminuria, DPD, *Ureaplasma* and *Microplasma* culture with antibiotic susceptibility and microflora urine culture. The newest additions are the easy-to-perform *H. pylori* breath test and high-risk human papillomavirus DNA test with extended typing, which are paving the way for safe and patient-friendly preventative screening.

The results of this study could be used to pinpoint the potential patient base not only for SARS-CoV-2 saliva sample tests, but also clinical analysis of all types. Considering that younger patients were more likely to use the automated services than older patients, this technology could be used as an alternative to in-office cervical screening with high-risk human papillomavirus DNA tests in regions where having an in-person appointment would be challenging due to physician shortages. These automated sample collection devices could be used more widely in faecal ocult blood screening tests as well. Taking into account the sharp drop in automated sample collection device use in patients older than 38, solutions need to be found on how to improve experience for patients of older generation in order to make the automated sample collection device use as a screening tool more accessible.

Since these contactless analysis transfer/acceptance devices are a novelty, there is none other research done on their efficacy in the medical field. For this reason data for comparative analysis is not available.

CONCLUSIONS

This study shows that the E. Gulbis Laboratory is on the advent of automatisation in the medical sector and elsewhere. At the time when World Health Organisation guidelines stipulated social distancing as a measure to combat the growing SARS-CoV-2 infection rates, there was no better way to improve screening than to make it something that could be easily and quickly done in the privacy of one's own home. At the time of grave need, this technology helped to promote accessibility by opening new testing points and bringing the medical care closer to patient at any hour of the day.

It helped to increase the volume of tests done each day and in that curb the spread of the pandemic. While many regions were experiencing shortages in qualified personnel for sample collection and administration and battled the growing workload of hospital and laboratory specialists, the technology did all that at a push of a few buttons. With limiting people's contacts by bringing the testing process to an open-air location, it produced the possibility for reduced risk of infection. In the future this technology could bring everyday laboratory testing closer to patients in remote areas where access to health care is scarce.

All that was made possible with remote communications, monitoring and control systems integrated in the laboratory or hospital information system. New obstacles were set forth by the SARS-CoV-2 pandemic that needed new 21st century solutions to be introduced, but it also meant new opportunities for the laboratory to acquire experience and evolve.

ETHICS

The study protocol of using saliva as testing samples for SARS-CoV-2 detection by RT-PCR was approved by the Ethics Committee of Pauls Stradiņš Clinical University Hospital (record No 300720-18L).

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AUTOMATIZĒTĀS PĀRVALDĪBAS NOVĒRTĒJUMS BEZKONTAKTA TESTU IEVIEŠANĀ

Pētījuma mērķis bija analītiski izskaidrot, kādus risinājumus piedāvāja E. Gulbja laboratorija, saskaroties ar SARS-CoV-2 pandēmijas izraisītajām problēmām Latvijā. Analizējot sasniegto, pētnieki atskatās uz pandēmijas laikā izvirzīto mērķi — ieviest automatizētu un efektīvu risinājumu bezkontakta nodoto testu paraugu pārvaldībai, kā arī sniedz pārskatu par automatizācijas datiem. Pētījuma dati iegūti, apkopojot astoņpadsmit E. Gulbja laboratorijā izmantoto automatizēto analīžu nodošanas iekārtu rezultātus. Automatizētajās analīžu nodošanas iekārtās tika veikta 64 257 siekalu komplektu SARS-CoV-2 PCR testēšana. No kopējā paraugu skaita 3,92% bija pozitīvi, t.i., siekalu paraugā konstatēts SARS-CoV-2 vīrusa RNS. Vidējais testu izpildes laiks Rīgā izvietotajās automatizētajās ierīcēs bija 11,13 stundas, Rīgas apkaimēs — 15,52 stundas, pārējā valstī — 17,60 stundas. Vidējais pacientu vecums, kuri izvēlējās izmantot automatizētās analīžu nodošanas iekārtas bija 33,94 gadi. Izmantojot automatizētās analīžu nodošanas iekārtas, mazinājās pacientu savstarpējie kontakti, kā arī tika izslēgta tieša saskarsme ar medicīnas personālu, kas, savukārt, samazināja infekciju izplatības risku. Automatizētās analīžu nodošanas iekārtas nodrošināja iespēju nodot testējamo materiālu 24 stundas diennnaktī, un tika ietaupīti pandēmijas laikā ierobežotie laboratorijas darbaspēka resursi.