

DOI 10.24144/2077-6594.1.1.2021.227813
УДК 616.98:578.834.1]-093:001.891.5(437.6)

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Pilot mass rapid antigen testing for the diagnosis of a COVID-19 infection in Slovakia

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**Пілотне масове тестування швидкими тестами
для виявлення COVID-19 у Словаччині**
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**Пилотное массовое тестирование быстрыми тестами
для выявления COVID-19 в Словакии**
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Background

Tests for COVID-19 fall into two categories: diagnostic tests such as PCR and antigen assays, which detect parts of the SARS-CoV-2 virus, and antibody tests that sense molecules that people produce when they have been infected by the virus. Antibodies can take several days to develop after an infection and often stay in the blood for weeks after recovery, so antibody tests have limited use in diagnosis (Figure) [2].

Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection. Antigen tests are currently authorized to be performed on nasopharyngeal or nasal swab specimens placed directly into the assay's extraction buffer or reagent. The currently authorized antigen tests are not restricted to use on persons of a certain age. Antigen tests are relatively inexpensive, and most can be used at the point of care. Most of the currently authorized tests return results in approximately 15 minutes. Proper interpretation of both antigen test results and confirmatory testing when indicated is important for accurate clinical management of patients with suspected COVID-19, or for identification of infected persons when used for screening. Different types of COVID-19 test can detect the presence of the SARS-CoV-2 virus or the body's response to infection.

Infectious disease experts in Slovakia have urged the government to abandon plans to repeat nationwide testing of millions of people for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) amid warnings it would be a waste of resources and doubts over its effectiveness. The country made international headlines as, over the last weekend of October, Slovak authorities tested almost all the country's adult population for coronavirus. A total of 3.6 million people – out of an estimated 4 million target population – were tested that weekend with a countrywide positivity rate of 1.06%. Testing was repeated the following weekend in selected areas where the rate had been above 0.7%. The government turned to the plan as a way of trying to halt what it said at the time was an alarming acceleration in the virus spread with an

economically costly strict 3-week lockdown as the only alternative.

Since April 2020, 4 laboratories are performing the analysis of coronavirus SARS-CoV-2 within the Slovak Republic (based in Bratislava, Košice, Banská Bystrica and Trenčín).

In total, nine crews of emergency ambulances have been designated for collection of biological materials for testing in the Slovak Republic. Each region has one designated crew that can provide the collection of biological material (mucosal swabs) from patients at home who are suspected to have COVID-19. An infectologist trained crew personnel to collect material. The Ministry of Health designated the emergency ambulance stations for the collection of biological material.

After mobility restrictions and measures announced on March 24 and 27 were implemented, the effect of lower peak and slower onset of disease is more visible.

Anyone with symptoms or suspect of the disease can request testing via an electronic form.

From April 26 until further notice, COVID-19 samples may be taken in the households of an immobile patient through the ambulance service.

Samples collection will be performed in cases where the patient does not have the opportunity to travel by car to the mobile testing points and his condition does not require a medical examination or hospitalization.

The capacity of testing rapidly increased to approximately 4,000-5,000 tests per day [1].

Pilot mass rapid antigen testing in Slovakia

The process started with a pilot in 4 regions: Bardejov, Námestovo, Trstená and Dolný Kubín. These regions are in the northern part of Slovakia and were selected because they feature the highest infection rates in Slovakia. The pilot took place over the weekend of 23-25 of October and everybody between the ages of 10 to 65 years were invited to participate in the testing.

Even though testing was not mandatory, 10 days in quarantine has been requested from those who did not test. The tests were free of charge and the logistics of the whole program were delegated to the army. Each region set up several sampling points which opened at 7am and closed at 10pm. On average, 35 patients per hour were tested per station. A station

was staffed with 4 medically trained personnel (not necessarily doctors; also nurses and other health professionals), 3 administrative staff, a soldier and a police officer. Data was collected and processed by the army. While the tests were distributed by the army, protective gear was to be supplied by municipalities and the Ministry of Health [1,3].

- **PCR-based tests** can detect small amounts of viral genetic material, so a test can be positive long after a person stops being infectious.
- **Rapid antigen tests** detect the presence of viral proteins and can return positive results when a person is most infectious.
- **Antibody tests** detect the body's immune response to the virus and are not effective at the earliest phase of infection.

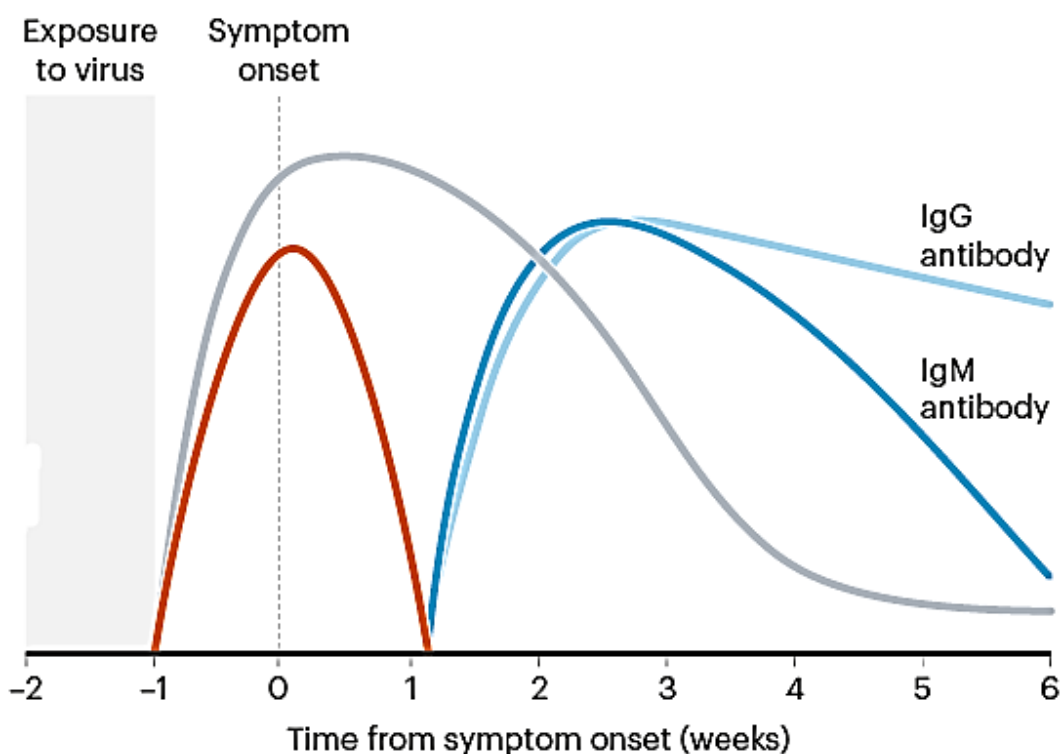


Fig. Probability of coronavirus detection

(Source: G. Guglielmi, 'The explosion of new coronavirus tests that could help to end the pandemic', *Nature*, 16 September 2020, based on data from N. Sethuraman et al., 'Interpreting Diagnostic Tests for SARS-COV-2', *Journal of the American Medical Association*, Vol. 323(22), pp. 2249-2251)

Results

Out of the total of 139,969 tests taken at the pilot test sampling points, the highest number, 48,320, was carried out in Bardejov. A total of 1,569 people had positive antigen tests (translating into a rate of 3.25%).

The most critical situation was in the Tvrdošín district, where 4.85% were tested positively (followed by the district of Námestovo – 4.77%; and the lowest rate in Dolný Kubín – 3.12%, 916 persons).

Based on the inhabitants of Orava and Bardejov, with a total of 155,000 people, the real participation rate was roughly

91%. However, this figure included people who came from other regions, so “real” attendance was expected to be lower. Most people in Orava and Bardejov came to the collection points to test on Friday, a total of 61,905 people. On Saturday, 59,613 people took the test at sampling points and on Sunday 18,451 inhabitants.

However, despite public pressure, no validation of the antigen rapid tests was conducted. Yet at the same time, Czech hospitals conduct these validations and sensitivity in laboratory conditions was 63–67%, specificity 98.5–100%. In field use, these numbers were expected to decrease below 50% for

sensitivity. Without the validation, experts warned that pilot test results could be potentially misleading [1,4].

First round of mass testing

Despite several public statements of leading experts, including the president, not to extend mass testing to all regions, the prime minister pushed his idea during the weekend of 31 October – 1 November 2020.

Despite the logistical success of the pilot testing, the army did not have sufficient resources to cover the process and hence the government shifted significant burden of responsibilities to municipalities that had been not prepared for such tasks and expressed their concerns. Testing stations were open only on Saturday and Sunday.

A total of 3,625,332 people participated in the mass testing (or 91%). Of these, 38,359, or 1.06%, were tested positively. However, considering the concerns about the specificity of tests, only 23–25,000 are expected to be actually

positive. The lowest share of positive tests was in the Revúca district, at 0.27%. It was followed by the district of Banská Štiavnica (0.28%) and Rožňava (0.29%).

The highest share of positive tests was recorded in Čadca (3.22%), followed by the district of Stará Ľubovňa (2.8%) and the district of Púchov (2.65%). Attendance varied from 48–76%, depending on region and commuting patterns [1].

Conclusions

In conclusion, the combination of nationwide restrictions and mass testing with quarantining of household contacts of test positives rapidly reduced the prevalence of infectious residents in Slovakia. While impossible to disentangle the precise contribution of control measures and mass testing, the latter is likely to have had a substantial effect in curbing the pandemic in Slovakia and may provide a key tool in the containment of SARS-CoV-2.

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Дата надходження рукопису до редакції: 14.01.2021 р.

The author explains pilot testing for Covid-19 infection in Slovakia using rapid antigen tests. Mass testing campaigns are an alternative way to identify infectious individuals and allow targeting of interventions without much added burden to those uninfected. However, they have been limited until recently by the dependence on Polymerase Chain Reaction (PCR) for the diagnosis of a SARS-CoV-2 infection. While laboratory capacities have been upscaled in record time, PCR testing remains expensive and can seldom achieve a turnaround time of less than one day. In comparison, recently developed rapid antigen tests are cheap and can be quickly produced in large quantities offering results on site in 15-30 mins without the need for a laboratory. They are less sensitive in detecting infections with low viral load but have been found to detect the vast majority of infectious infections, and hence may make mass testing a viable part of the portfolio of nonpharmaceutical interventions.

Key words: Covid-19, SARS-CoV-2 virus, rapid antigen test, Slovakia, diagnostic.

Автор пояснює пілотне тестування на інфекцію Covid-19 в Словаччині за допомогою експрес-тестів на антигени. Кампанії масового тестування є альтернативним способом виявлення заразних людей і дозволяють проводити цільові втручання без особливого додаткового тягаря для тих, хто не заразився. Однак до недавнього часу вони були обмежені залежністю від полімеразної ланцюгової реакції (ПЛР) для діагностики інфекції SARS-CoV-2. Незважаючи на те, що лабораторні можливості були збільшені в рекордно короткі терміни, тестування ПЛР залишається дорогим і рідко може досягати часу виконання менше одного дня. Для порівняння, недавно розроблені експрес-тести на антигени дешеві і можуть бути швидко зроблені у великих кількостях, пропонуючи результати на місці за 15-30 хвилин без необхідності звернення в лабораторію. Вони менш чутливі при виявленні інфекцій з низьким вірусним навантаженням, але були ефективні в переважній більшості випадків виявлення інфекційних агентів і, отже, можуть зробити масове тестування життєздатною частиною нефармацевтичних втручань.

Ключові слова: Covid-19, вірус SARS-CoV-2, швидкий тест на антиген, Словаччина, діагностичний.

Автор объясняет пилотное тестирование на инфекцию Covid-19 в Словакии с помощью экспресс-тестов на антигены. Кампании массового тестирования являются альтернативным способом выявления заразных людей и позволяют проводить целевые вмешательства без особого дополнительного бремени для тех, кто не заразился. Однако до недавнего времени они были ограничены зависимостью от полимеразной цепной реакции (ПЦР) для диагностики инфекции SARS-CoV-2. Несмотря на то, что лабораторные возможности были увеличены в рекордно короткие сроки, тестирование ПЦР остается дорогостоящим и редко может достигать времени выполнения менее одного дня. Для сравнения, недавно разработанные экспресс-тесты на антигены дешевы и могут быть быстро произведены в больших количествах, предлагая результаты на месте за 15-30 минут без необходимости в лаборатории. Они менее чувствительны при обнаружении инфекций с низкой вирусной нагрузкой, но были обнаружены в подавляющем большинстве случаев выявления инфекционных инфекций и, следовательно, могут сделать массовое тестирование жизнеспособной частью нефармацевтических вмешательств.

Ключевые слова: Covid-19, вирус SARS-CoV-2, быстрый тест на антиген, Словакия, диагностический.

Відомості про автора

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