# FAQ COVID-19 antibody (serology) tests

# **Background and participation:**

# 1. What is the COVID-19 antibody study about?

Researchers at the Karolinska Institute (KI), KTH and SciLifeLab are working closely with the Public Health Agency of Sweden to contribute knowledge and analysis capacity concerning COVID-19. They are now scaling up their analysis capacity for antibody tests (also called serology tests, which shows if you have had COVID-19).

As part of this cooperation with the Public Health Agency, a study is now being performed that includes large scale analysis of both COVID-19 and the analysis of antibodies.

AstraZeneca has been invited to participate in one part of this study, which means that all AstraZeneca employees in Sweden, including those with fixed term contracts, will be offered the opportunity to be tested to see if they have developed antibodies (the other part of the KI study - virus tests via saliva samples - is not included for AstraZeneca employees). By participating, we are contributing to research within this important area.

Participation is completely voluntary and free of charge for our employees as AstraZeneca is covering the costs. The testing period will start on 10 June with the aim of performing as many tests as possible before the summer holidays. The initial study plan includes up to three tests over a period of time. We will get back with more specific information around this in due course. It is important for the study that you commit to the entire programme, as this will also be able to show how the COVID-19 antibodies develop or decrease over time, should an individual have had the infection.

#### 2. Who else will be participating in this COVID-19 antibody study?

The study will include personnel who work in essential services such as the healthcare and care sector, plus companies and workplaces that have been identified as essential for society, which includes AstraZeneca.

### 3. Do you need to have already been tested for the virus to participate?

There is no requirement on participants in the COVID-19 antibody study to have taken a virus test (PCR test) previously. AstraZeneca will continue to offer voluntary COVID-19 PCR virus assessments at its Södertälje and Gothenburg sites in parallel with the study, as the different tests complement each other.

### 4. Is this test offered instead of seeking medical attention if I do not feel well?

No, if you do not feel well, you should contact your healthcare provider as normal.

Please note that it is, at present, unclear the extent to which antibodies may protect you against becoming ill again and how long the antibodies will remain in your system. Therefore, until further scientific evidence is available, it is important that you continue to follow Public Health Agency recommendations and all applicable health and safety rules (social distancing, face masks, hand washing, etc.) when you are on our sites - even if you have been informed that you have antibodies.

# 5. What is the difference between the voluntary COVID-19 PCR Assessment offered to certain groups of AZ employees and this antibody test?

The voluntary COVID-19 PCR assessment can detect whether someone at that point in time <u>is</u> <u>carrying the virus</u> that causes COVID-19 and confirm whether they need to self-isolate.

The antibody test in this study detects if a person has developed antibodies, and thereby <u>has had COVID-19</u>.

### 6. Who is going to be tested?

The offer to participate is initially open only to all AstraZeneca employees in Sweden, including those with fixed term contracts. We are working on potential solutions that can make this test available also for consultants and on-site service providers at our sites (Sodexo, Caverion, etc.) and will come back with more information about this. It does not apply to relatives or other people outside of the company.

It is entirely voluntary and free of charge if you wish to participate, but you will need to have a Bank ID and access to a smartphone.

### 7. My mother is in a high risk group. Can she get tested as well?

No, the offer to participate initially only applies to AstraZeneca employees in Sweden and not to relatives or other people outside of the company. We are working on potential solutions that can make this test available also for consultants and on-site service providers at our sites (Sodexo, Caverion, etc.) and will come back with more information about this.

#### 8. What does it mean if my sample is negative?

The antibody test checks whether you have antibodies to SARS CoV 2 in your system, i.e. whether you have been infected and developed antibodies to the virus. If the test is negative, this means you do not have antibodies to the SARS CoV 2 virus in your blood - and therefore you have most probably not had COVID-19.

Please note that it is, at present, unclear the extent to which antibodies may protect you against becoming ill again from the virus and how long the antibodies will remain in your system. To see how long antibodies remains in your system, follow-up samples will be taken. Therefore, until further scientific evidence is available, it is important that you continue to follow Public Health Agency recommendations and all applicable health and safety rules (social distancing, face masks, hand washing, etc.) when you are on our sites - even if you have been informed that you have antibodies.

# About the COVID-19 antibody (serology) test technology:

# 9. I have tested positive for the SARS CoV 2 virus from a PCR assessment for COVID-19. Do I need to provide blood samples to test for antibodies?

If you have tested positive for the virus, you will need to be fit and symptom-free for a minimum two days before you can take the antibody test. As antibodies take time to develop, we recommend you to wait at least 14 days from the time you had the first symptoms.

# 10. What happens if I have antibodies in my system? Does this mean I am immune and can do whatever I like?

No, we still do not have enough knowledge about immunity towards COVID-19 today, so you should continue to follow both Public Health Agency recommendations and the COVID-19 guidance that we have in place at our sites in Södertälje and Gothenburg.

#### 11. How does the antibody test work?

From your blood test a plasma fraction sample is prepared. The plasma is analysed to identify if you have antibodies against any of the SARS-CoV-2 proteins (antigens). If you have antibodies you will receive a response in the HOPE app: "positive – your blood test shows antibodies against COVID-19". If no antibodies are detected the response will be "negative – no antibodies was detected in your blood test".

The Royal Institute of Technology (KTH) has experience from the Human Protein Atlas and Secretome projects. Therefore, methods and routines are in place, to quickly design and produce proteins. Using this technology KTH has recently produced a large number of variants of SARS-CoV-2 virus proteins. These proteins (antigens) are then coupled to individually color-coded beads and applied in a highly multiplex format (see figures below). The plasma sample is mixed with antigen coated beads. Then labelled anti-antibodies are added and react with your antibodies. The complex can then be identified and measured. The bead-based multiplex assay has high specificity and selectivity.

The serology (plasma test) assay is evaluated based on the analyses of 154 positive samples (defined as PCR-positive individuals with mild to severe symptoms sampled more than 14 days after onset) and 321 negative samples (defined as samples collected 2019 and earlier, including confirmed infections with non-SARS-CoV-2 corona viruses). Based on these control samples, the method was calculated to have 99.4% sensitivity and 99.1% specificity. See image of COVID-19 antibody test analysis principles.

If you want to learn more about the Swedish Covid-19 research have a look at <u>The Swedish COVID-19</u> <u>Data Portal</u> operated by the SciLifeLab Data Centre.

#### 12. How can we know that the antibody test is reliable?

The antibody analysis uses a panel of SARS-Cov2 proteins. This new platform has been validated by the Karolinska University Laboratory and the test has shown to have a sensitivity and specificity of almost 100%. Blood samples need to be taken from your arm for this test.

#### 13. Why have we chosen these tests? Aren't there many different analysis laboratories?

These are among the tests that the Public Health Agency of Sweden has chosen to use when scaling up, and by participating, we are contributing to research within this important area and supporting the scaling up of analysis capacity.

# 14. I understand that AstraZeneca R&D is developing its own COVID-19 antibody (serology) test – what is the status of this?

Yes, AstraZeneca serology assessments will be introduced to our sites across UK and US. In Sweden, however, we have taken the opportunity to take part in a national KI/KTH/SciLifeLab initiative, which will give employees access to large scale serology testing whilst contributing to scientific research in this area.

# 15. Why are we using these resources on AstraZeneca employees instead of on people who work in healthcare, care homes, etc.?

The study is part of the scaling up of analysis capacity that is being done, also including care home residents, care homes / health care personnel and others. In addition, the study contributes to the further development of the test itself, informs the Public Health Agency about the previous spread of the disease and how levels of antibodies develop over time. AstraZeneca came into consideration for this partly because we are an essential business, and because we have a large number of employees that can rapidly add statistical value to the study.

# About booking a time:

### 16. When will I be asked to provide a sample?

The first step in the process starts with you getting an invitation by email to participate in the study. The initial study plan includes up to three tests over a period of time. We will get back with more specific information around this in due course.

#### 17. I want to take part in the study. How do I register?

The process starts with you getting an invitation by email to participate in the study. To take part, you will need to download the HOPE App (app instructions will be provided in your invite email), log

in to the app and register via your Bank ID and a password. The app will then provide you with further information, link to book a sample appointment, confirmation of your sample appointments, and then the results of your sample test.

Please have patience with the booking process at Previa and Feelgood as there is a risk of slowdown if many access at the same time. To decrease the risk of overloading the systems, we will be inviting you to the test in groups. Once you have received an invitation with detailed instructions, you are good to go.

# 18. Where will the blood samples be taken?

The blood sample for the antibody analysis needs to be taken in specific rooms at our sites in Gothenburg and Södertälje, or at certain Feelgood/Previa locations in Gothenburg/Stockholm/Södertälje (see maps at the end of the Q&A). You should go there at the time specified according to your booking in the app. In case you need to leave scheduled work to take the test, please inform your line manager.

It is very important that you bring your smartphone (with the HOPE App installed) with you to the testing appointment as you need to be able to scan the QR-code that you receive after the blood sample has been taken. You also need to bring valid identification and mobil BankID. It is also important that you have had something to eat and drink before the appointment.

# 19. I am working from home and am afraid of coming on site, but would still like to take part in the study, is this possible?

The blood samples will be taken in line with safe and secure procedures by Previa for employees in Södertälje and by Feelgood for employees in Gothenburg and you can choose to come to specific rooms at our sites in Gothenburg and Södertälje, or to certain Feelgood/Previa locations in Gothenburg/Stockholm/Södertälje. The information is available in the app.

#### 20. I am sick at the moment. Can I still provide a sample?

You need to be fit and symptom-free before you can take the antibody test. We recommend that you wait for at least 2 days after you become symptom-free before taking part. As antibodies take time to develop, we recommend you to wait at least 14 days from the time you had the first symptoms.

# **About the HOPE App:**

# 21. How do I download the app and log in?

You will receive instructions on how to do this in your invite email.

### 22. I do not have a BankID, can I get help for this?

You will need to contact your bank to obtain a Bank ID. You need this to log in to the app.

#### 23. The app is in Swedish. I don't understand Swedish. What should I do?

We hope to be able to offer a version in English by the end of the test period. Until then, please ask a colleague for help if you need guidance.

#### 24. Which company is behind the app?

The HOPE App has been developed, maintained and supported by a Swedish company, ADDI Medical. Their employees are based in Sweden and they have an office in Danderyd, Stockholm.

# 25. Why do I have to use an app?

The HOPE App is being used to process the information flow between the people behind the study, the people taking part in the investigation, the sample-taking unit and the analysis labs. The app is necessary to manage the logistics between the different parties in a secure way.

It is very important that you bring your smartphone (with the HOPE App installed) with you to the testing appointment as you need to be able to scan the QR-code that you receive after the blood sample has been taken. You also need to bring valid identification and mobile BankID.

**26.** Can I take part in the study without using the app? No.

# Processing of personal and health data:

# 27. How will my personal and health data be processed in the HOPE App?

Please see the user terms and conditions for the Hope App for how your personal data will be used in the app. How your data will then be used depends on what you consent to in the app, for example, whether or not you agree to be contacted for subsequent research studies, etc.

**28.** Who can access the information on the status of antibody levels in my blood? AstraZeneca will not be given access to any individual test results or any personal data from the study, and you will not be required to inform your line manager or SHE representative of your test results. This information is purely for your own personal use.

AstraZeneca will only be given aggregated and anonymised data for three groups (Gothenburg, Snäckviken, Gärtuna) with subgroups depending on whether you have been working on site or from home. Such data can be of value for our future operations planning.

### Finding the locations for taking the blood samples - maps:

Södertälje/Stockholm: Link to information on Previa test clinic locations

Gothenburg: Link to information on Feelgood test clinic locations