

Research design and methodology

# Falck COVID-19 antibody study



**FALCK**

# Scientific research project with NVK-approved methodology

## About the Falck COVID-19 antibody study

- The Falck COVID-19 antibody study is a **scientific research project** launched by Falck amidst the global outbreak of the COVID-19 virus
- The **methodology has been approved** by the Danish National Committee on health research ethics (NVK)

## About the National Committee

- The Committee consists of 13 members appointed by the minister for health and prevention
- The purpose of the committee is to ensure the rights, safety and wellbeing of trial subjects participating in biomedical research projects
- The NVK's approval acts as a safeguard – certifying that research projects that are created for the development of new, valuable knowledge are carried out in a responsible manner



# The aim is to carefully assess the prevalence of COVID-19 in Falck

## Primary research objective

Assess the **prevalence** of COVID-19 antibodies **among Falck employees** over a period of 6 months

## Secondary objectives

Compare prevalence of COVID-19 antibodies **across different exposure groups** as well as **geographical variation** within Denmark and Sweden

## Limitations

The test **measures existence of COVID-19 antibodies** in the blood which might not appear until the illness has run its course – as a result, the test indicates whether someone has had COVID-19 but **cannot determine active illness or developed immunity**



# The study tracks prevalence of antibodies in ~4,000 employees

## Research design

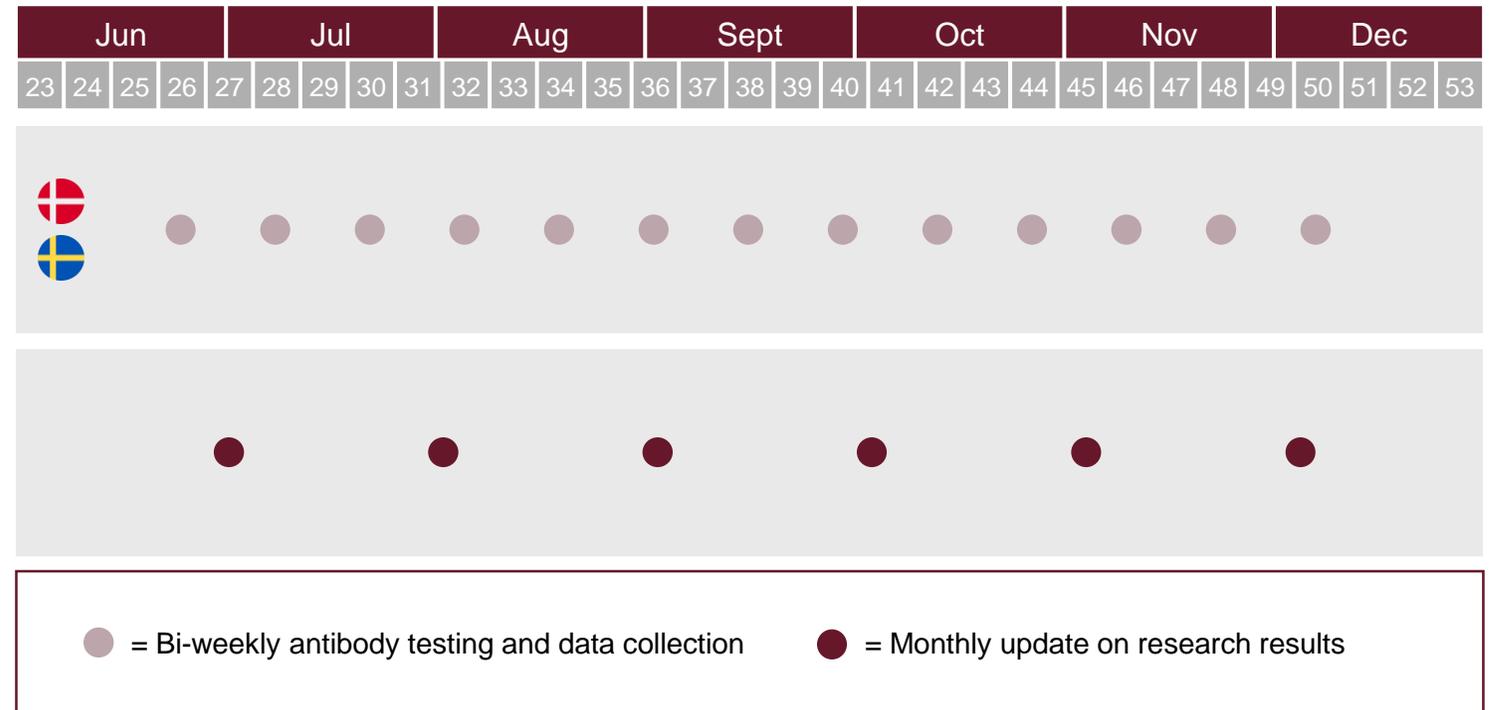
 Large-scale, multicentre, observational study over 6 months

 Research cohort of ~4,000 Danish and Swedish employees

 Bi-weekly testing, data collection and registration

 100% voluntary participation

## Timeline



# Collaboration with key partners ensures test & research validity

**Henrik Ullum**

**Professor and Chief Consultant**

- Department of Clinical Immunology at Rigshospitalet
- Professor at Institute for Clinical Medicine, University of Copenhagen
- Head of the Biobank and the Virology Section



**Kaspar Karmark Iversen**

**Professor and Chief Consultant**

- Department of Clinical Medicine, Herlev-Gentofte Hospital



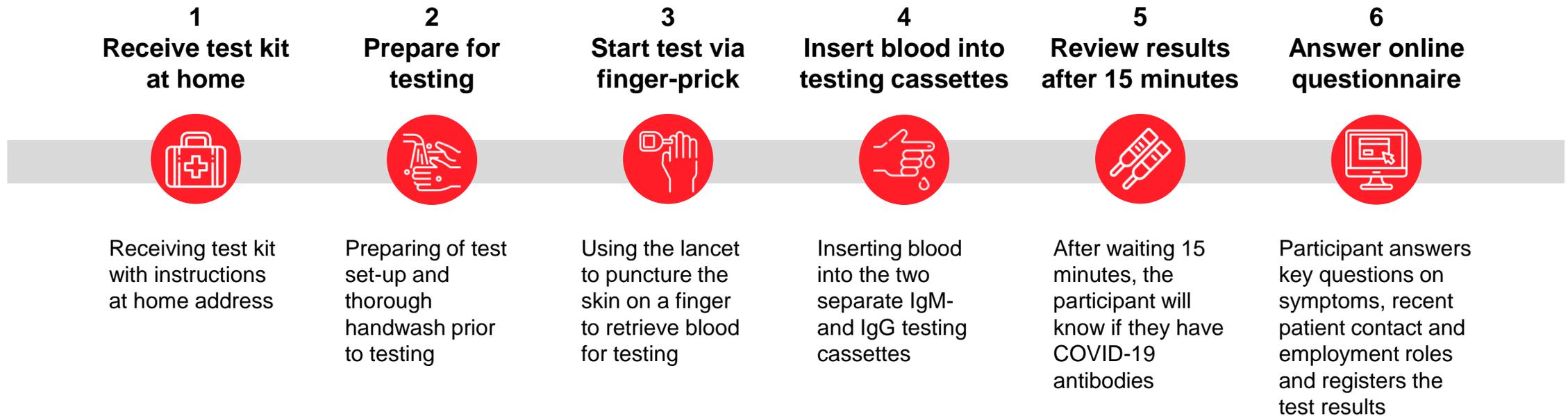
## Test validation

- The used LivZon test was validated in collaboration with Blodbanken, Region Hovedstaden
- Test performance is close to 100% accuracy in terms of sensitivity (~93%) and specificity (~97%)
- This means the test is highly unlikely to give a false-negative or false-positive result

## Health authority approval

- Test kits are approved under European CE-act indicating conformity with EU health, safety and environmental protection standards
- Test supplier is ISO-certified (ISO 13485:2012; ISO 9001:2008)

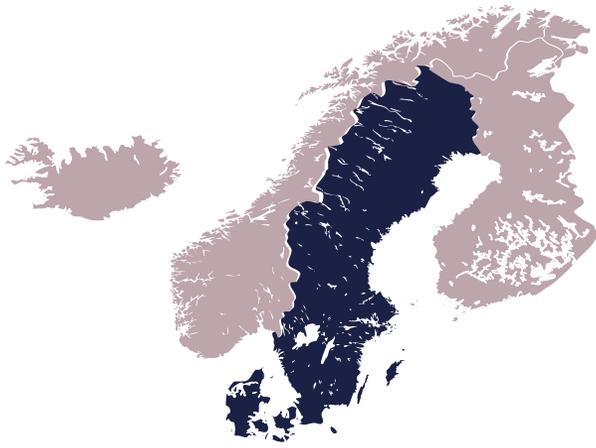
# Point-of-care test kits allow for testing while staying safe at home



# Participants are grouped along different sets of criteria...

## Two countries

- ~2,500 employees from Denmark
- ~1,500 employees from Sweden



## Key demographic indicators

- Age
- Gender
- Home postal code
- Primary and secondary



## Different levels of exposure

- Level of patient contact through employment roles



High – Ambulance staff with frequent patient interaction



Medium – Healthcare staff with direct physical contact with clients



Low – Roadside assistance and other field staff



Low – Office-based staff



Unknown – Firefighters who might have roles outside of Falck

# ...and comparing the results could deliver valuable insights

**How can we improve our understanding of the dynamics of the COVID-19 virus and similar viral infections?**



### **Prevalence of COVID-19 among Falck employees**

What percentage of Falck employees currently have COVID-19 antibodies in their blood? How does that number develop over time? And how does it differ across the two countries?



### **Insights on groups with higher risk of infection**

What risk of infection with COVID-19 is associated with having higher levels of exposure through interactions with patients, clients, colleagues or similar?



### **Data and knowledge on the COVID-19 infection**

For persons with a positive test result, how long are antibodies detected in the blood? What are key insights from monitoring further test results of people who have had COVID-19?