

# SARS-CoV-2 assay development in a bioanalysis laboratory

EBF open symposium November 2020

**Else Marie Agger**

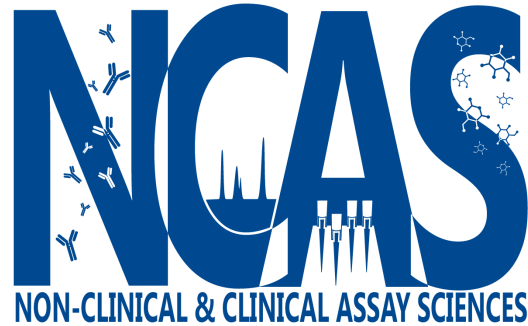
**November 2020**

# Private contributors during Covid-19 crisis



Antibody testing

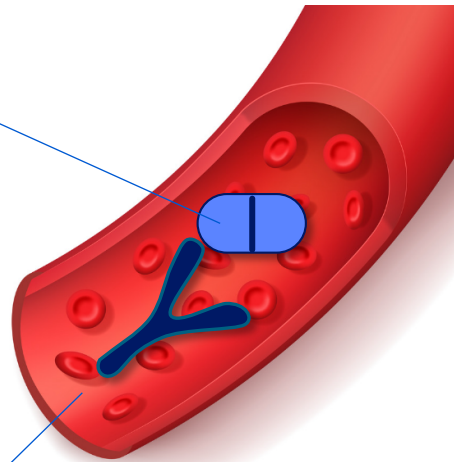
# Non-clinical and Clinical Assay Sciences (NCAS)



**Bioanalysis**

**Biomarkers**

**Immunogenicity Assessment**



**Support non-clinical studies**

A dark blue rounded rectangle containing white icons of a pig, a mouse, a rabbit, a dog, and a monkey. Below the icons, the text 'Support non-clinical studies' is written in white.

**Support clinical trials**

A dark blue rounded rectangle containing white icons of a female and a male human figure. Below the icons, the text 'Support clinical trials' is written in white.

**Develop and validate state-of-the-art assays**

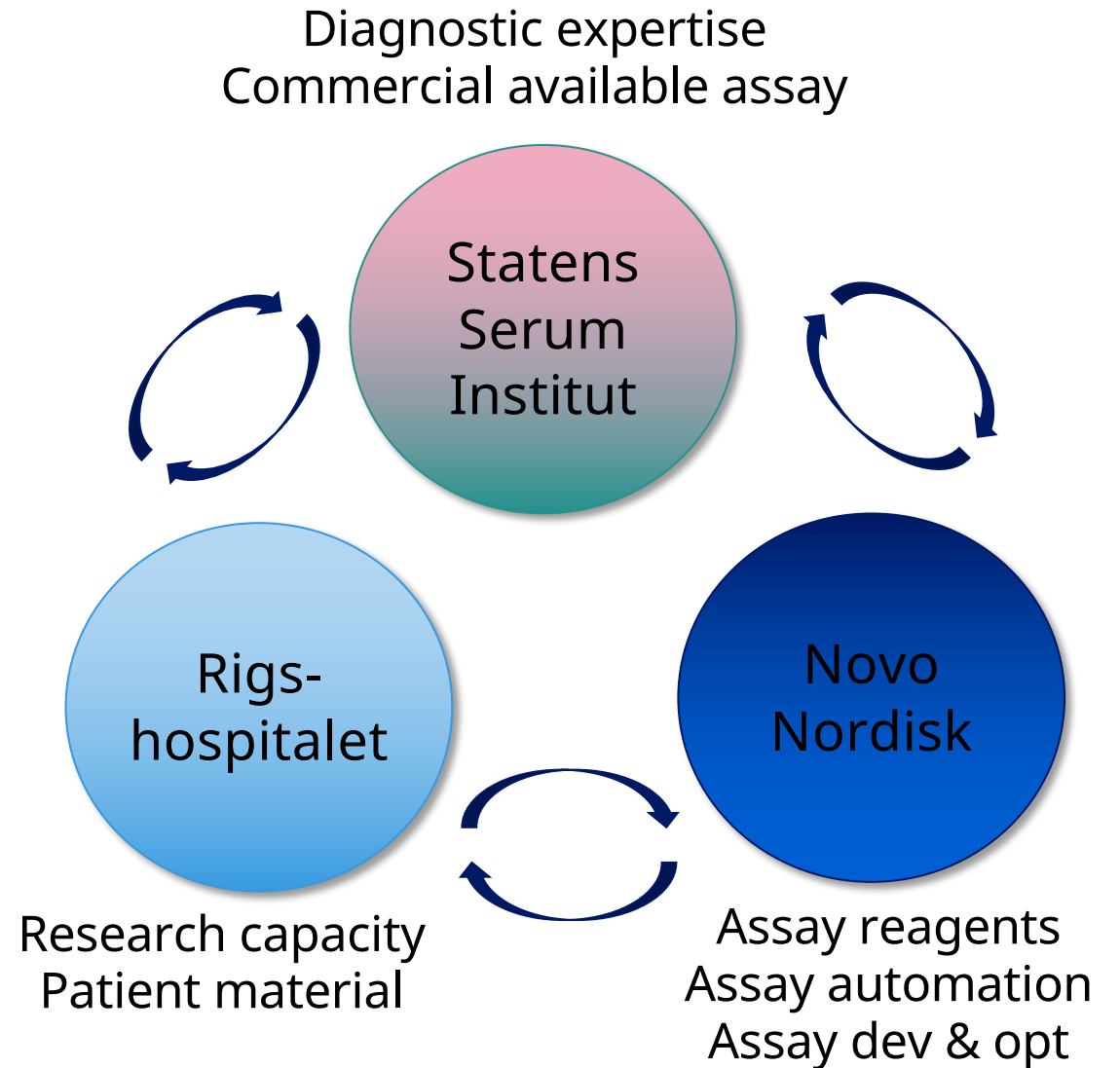
**Sample analyse**

**Correlate data to non-clinical and clinical findings**

A large blue rounded rectangle containing three white icons: a flask and beaker, a rack of test tubes, and a line graph. Below each icon is a corresponding text label in white.

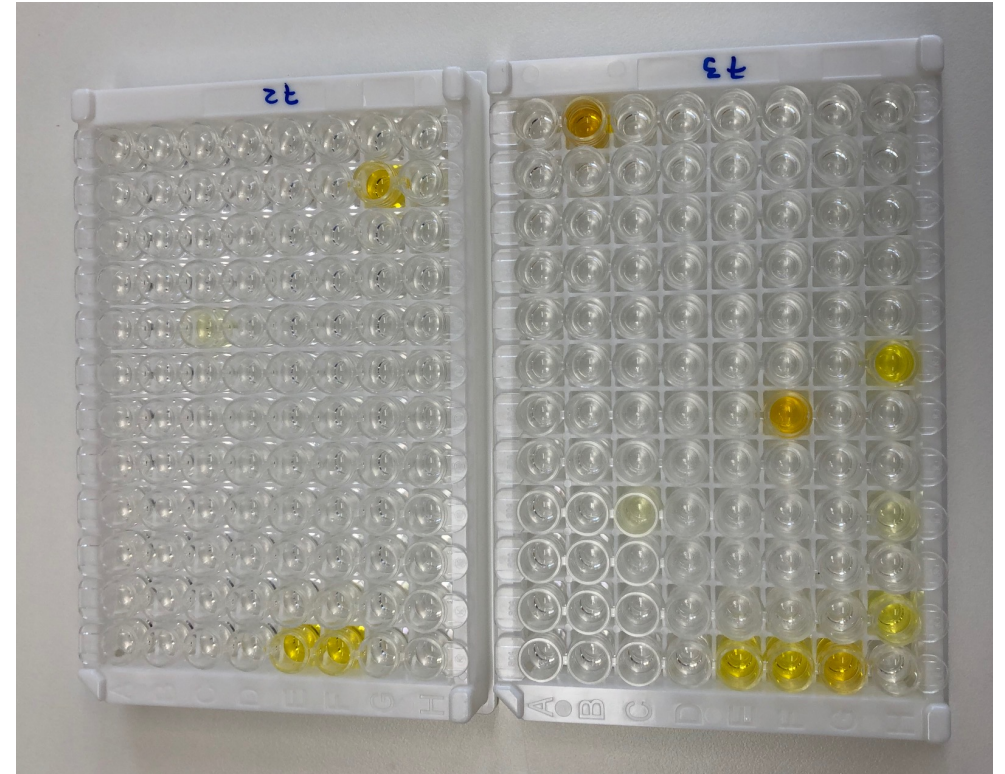
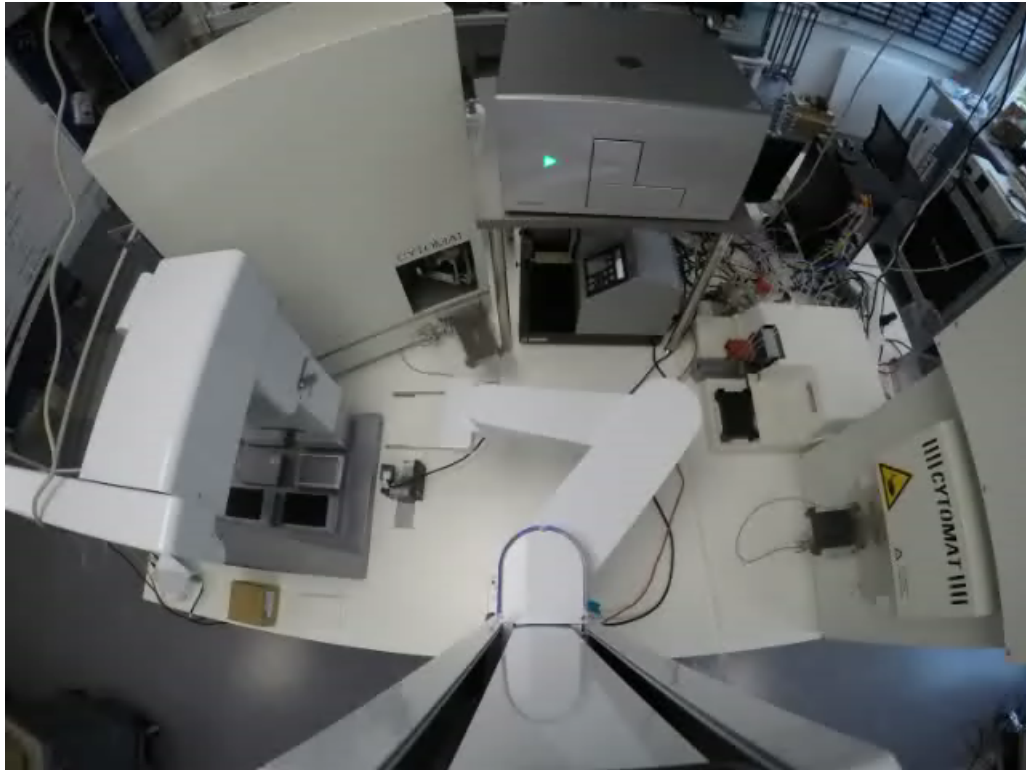
# Public-private partnership

- How many develop antibodies?
- Are asymptomatic antibody positives?
- Which antigens to use?
- Can we discriminate to other Corona virus?
- How good are commercial tests?
- Can we get hold on commercial tests?
- Etc.....

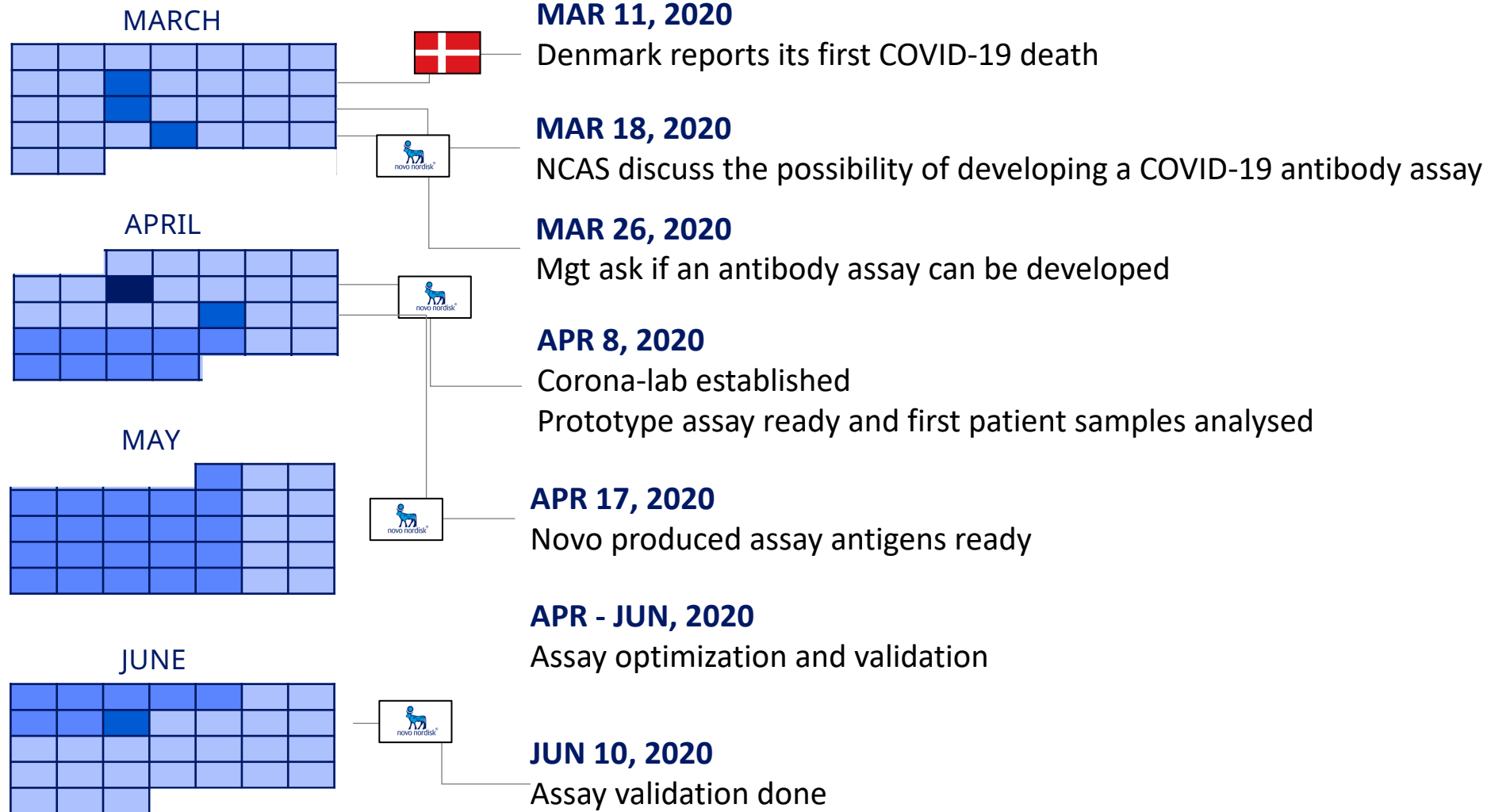




# Building a robot for Statens Serum Institut

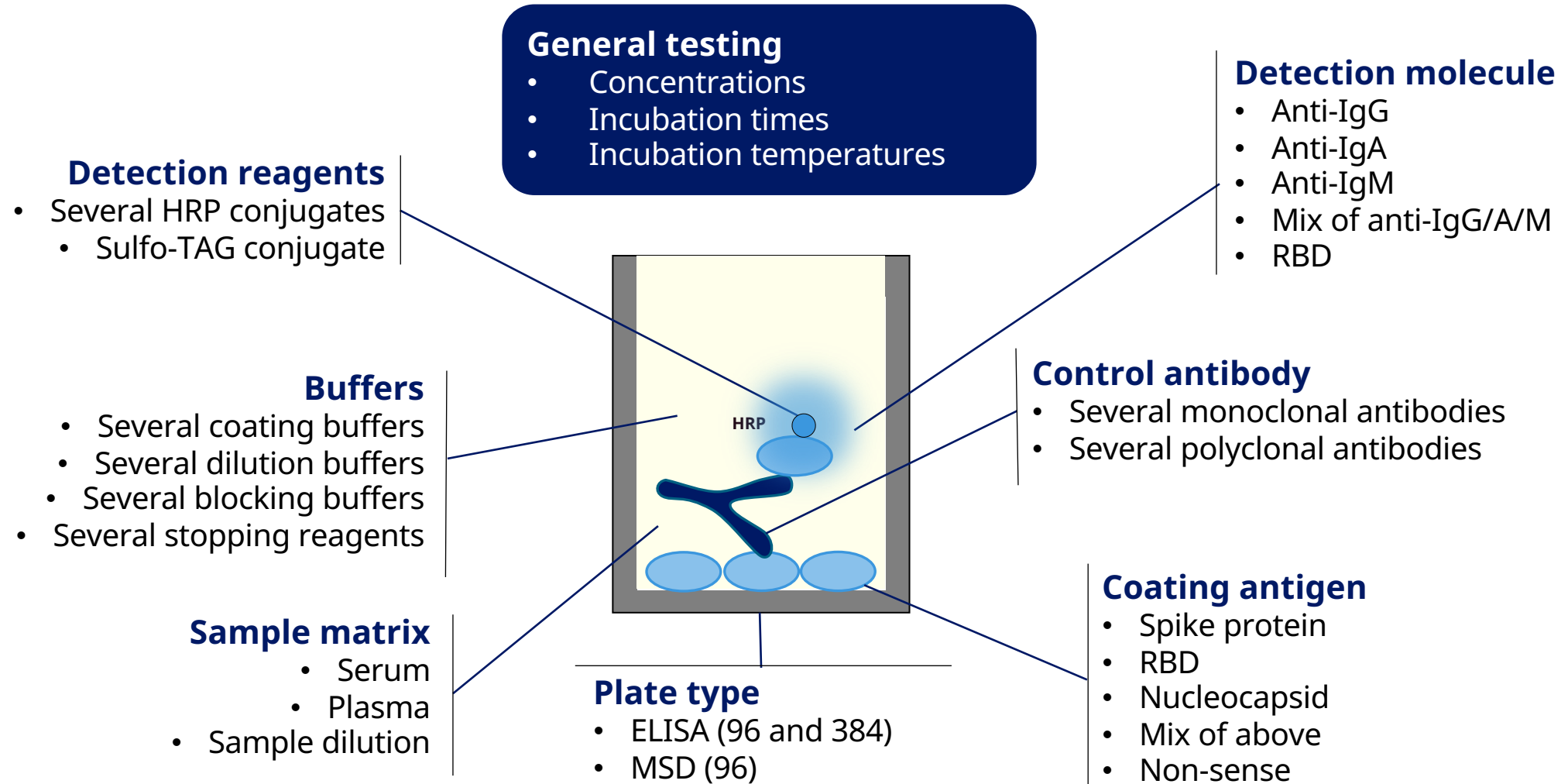


# Timelines for the antibody analysis

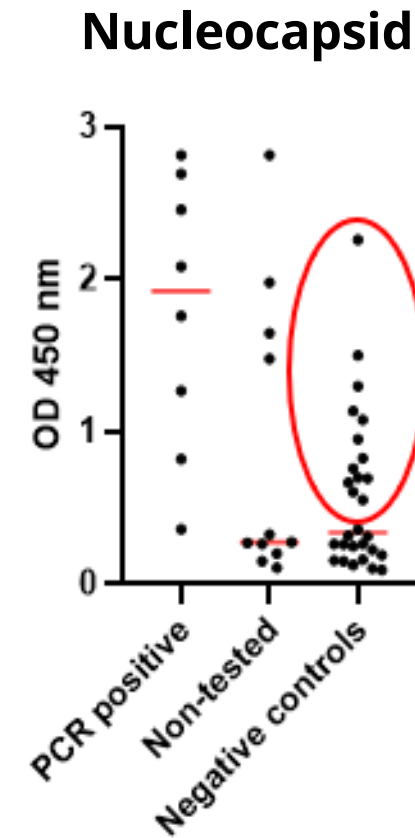
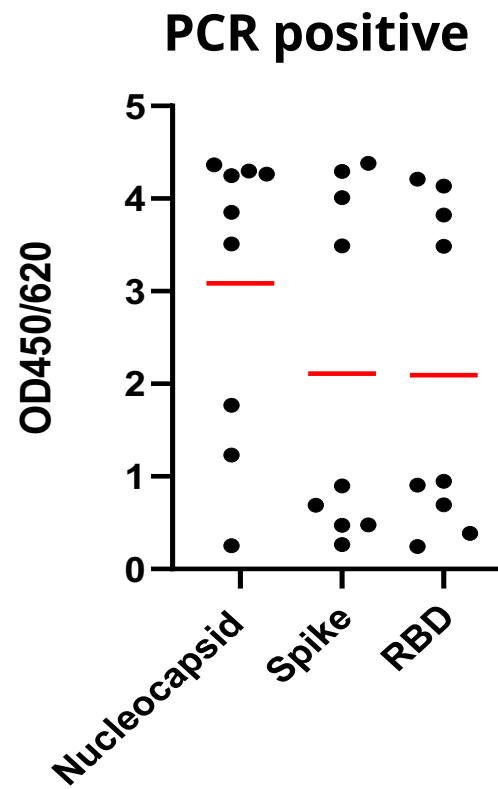
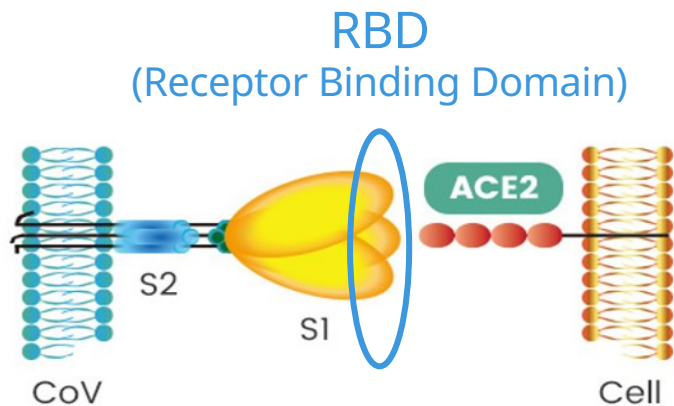
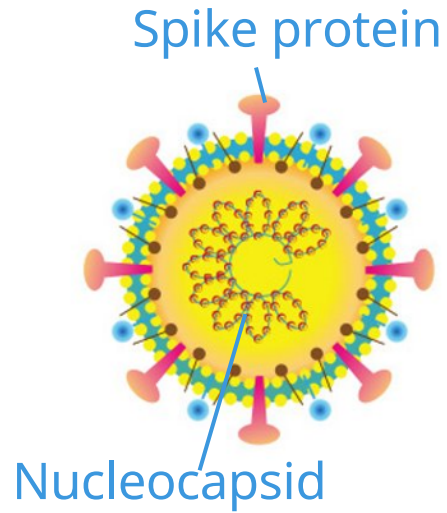


# Antibody assay development

(>16,000 samples)

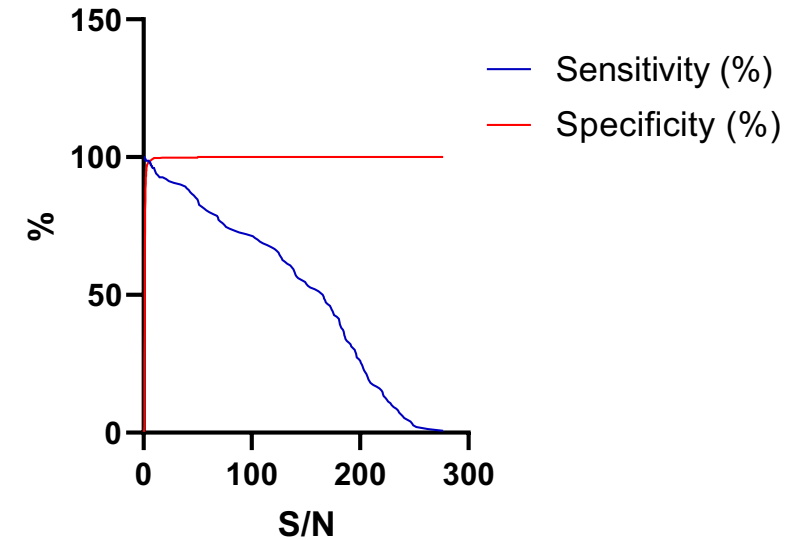
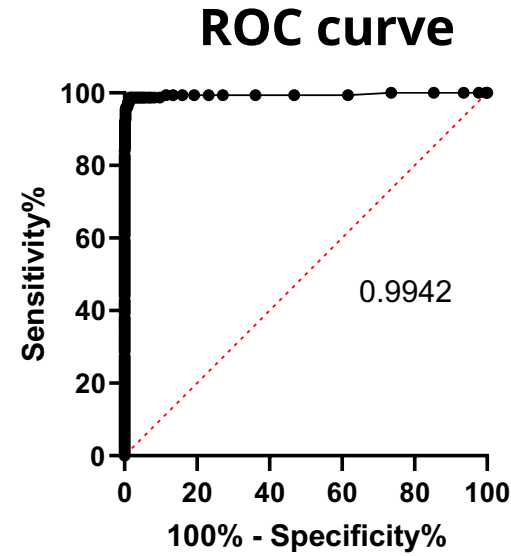
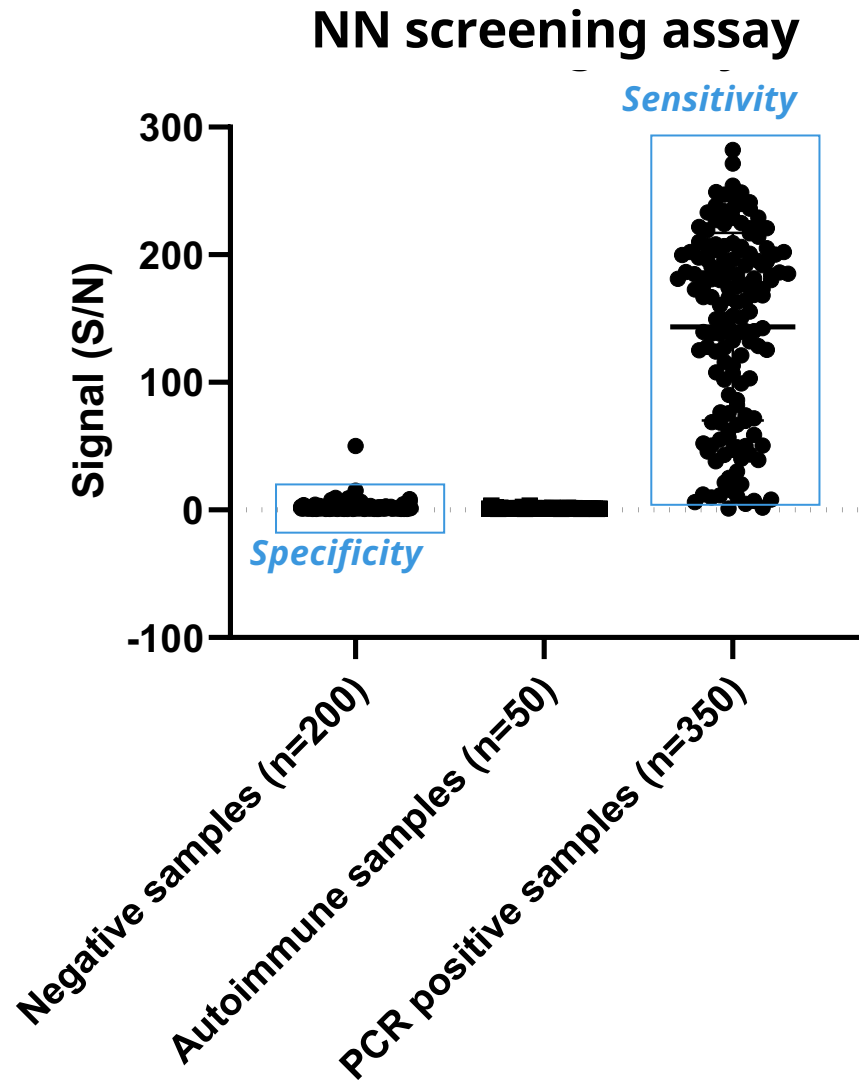


# Generation of assay reagents





# Analysis of national validation cohort

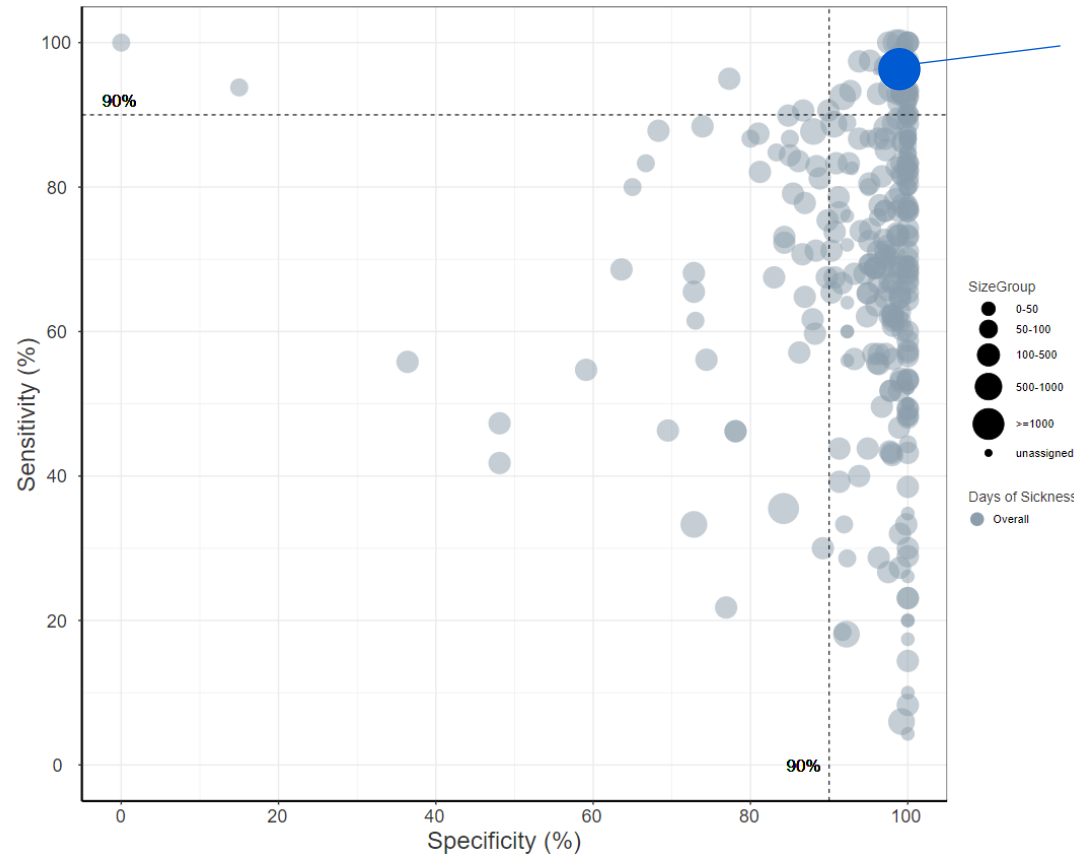


**Cut point 6.95:**  
Sensitivity = 97.3%  
Specificity = 99.0%

# How good is the assay?

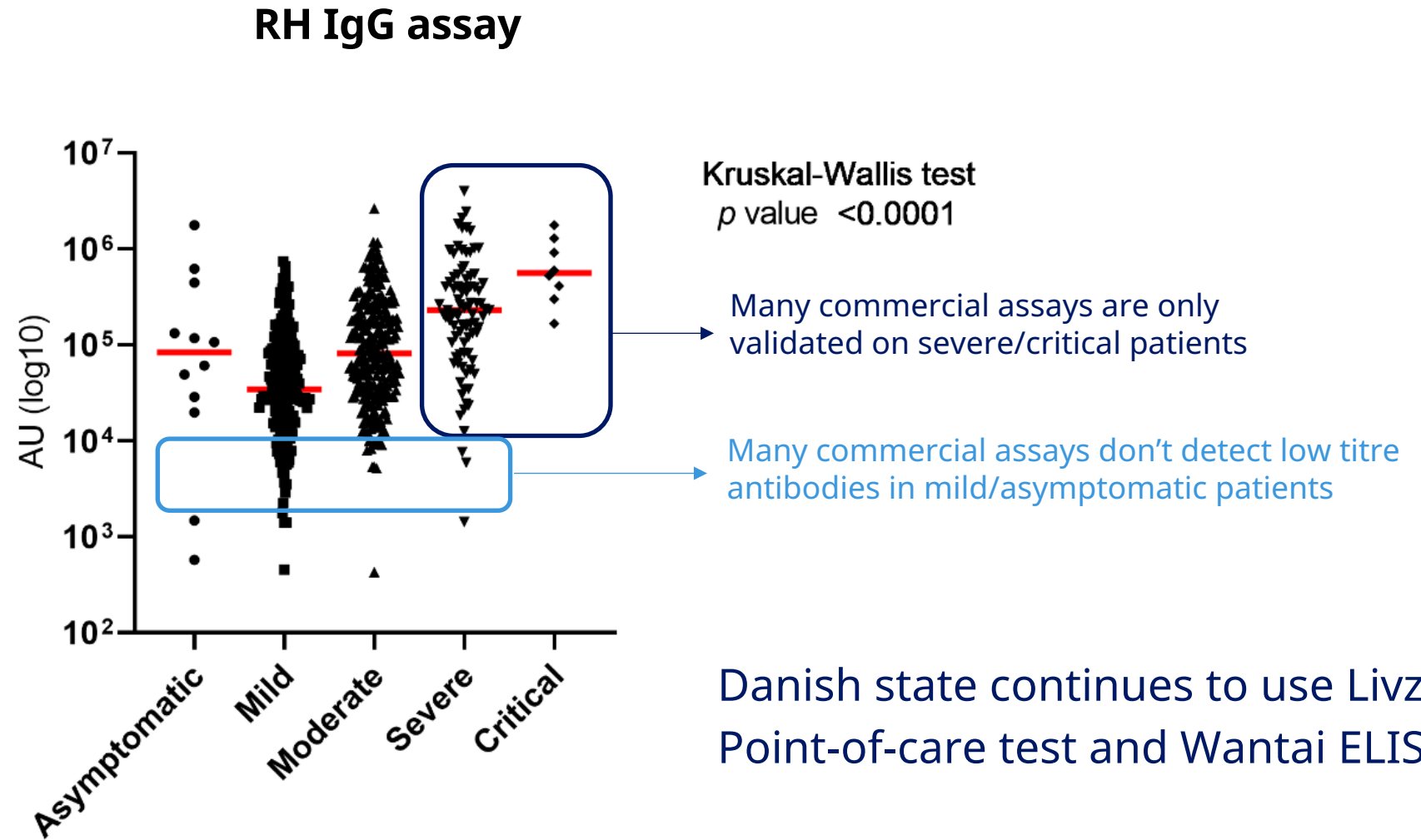


## SARS-COV-2 DIAGNOSTIC PERFORMANCE DATA



RBD antibody assay

# Correlation of symptoms to antibody titre



# Research project

## “Dynamic characteristics of the antibody response towards SARS-CoV-2 in a company-based population”

- **Aim:** To investigate the antibody incidence and dynamic development towards SARS-CoV-2 in a large population-based cohort and in their adult household members.
- **Study population:** Employees located in Denmark of Novo Nordisk A/S, Novozymes A/S, Novo Holdings A/S and the Novo Nordisk Foundation and their adult household members.
  - No fee is paid for participation in the project
  - Expected number of participants: approx. 16,000
  - **Funded by Novo Nordisk Foundation by special grant**

# Some learnings

- High quality antibody tests can detect individuals without symptoms or with mild symptoms
- "Dark numbers" on no. of infected where not that high
- Measurement of antibodies less informative wrt. long-term immunogenicity
- Antibody analysis is valuable for epidemiological surveillance
  
- Public-private-partnerships can work very efficiently
- Agile is not only a way-of-working for it projects
- Corona can also generate fun & joy

# Acknowledgements



- Lone Hummelshøj
- Mette Loftager
- Theresa Back-Thomsen
- Anne-Charlotte Helgstrand
- Juliano Olsen
- Mette Schmidt
- James Love and applied automation

## Rigshospitalet:

- Peter Garred
- Mikkel-Ole Skjødt
- Cecilie Bo Hansen

## Statens Serum Institut:

- Charlotte Sværke Jørgensen

And many others.....

*Thank you for your attention*