



COVID-19 diagnostics

State of the Art & New Developments

Anja Garritsen, CEO Innatoss Laboratories





"Catch it early"

Q fever (test development, vaccine development) Lyme Disease (test development, annual screening) COVID-19 (screening)





Start: Immune responses





Now: Comprehensive Diagnostics





Key aspects of COVID-19 tests

Biology

- Virus
 - RNA
 - Protein
- Host response
 - Choice of antigen
 - Antibody subtype
 - Kinetics

Technology

- Format
- Equipment
- Detection method
- Skills
- Safety
- Background





Fit-for-Purpose







Infected: RNA – the golden standard







Alternatives: LAMP (TNO)







Not easy







EasyCov – LAMP based

EasyCOV: Covid-19 salivary rapid and easy molecular test

Sensitivity: 88% – Specificity: 99% (validated by a clinical study)







Nobel prize-winning techology



Article Contents

Abstract

Author notes

Supplementary data

ACCEPTED MANUSCRIPT

Rapid, sensitive and specific SARS coronavirus-2 detection: a multi-center comparison between standard qRT-PCR and CRISPR based DETECTR @

Eelke Brandsma, Han J M P Verhagen, Thijs J W van de Laar, Eric C J Claas, Marion Cornelissen, Emile van den Akker ⊠ Author Notes

The Journal of Infectious Diseases, jiaa641, https://doi.org/10.1093/infdis/jiaa641 **Published:** 10 October 2020 Article history ▼





Infected vs infectious





The benefits of rapid ANTIGEN tests

- Faster isolation of infectious patients
- Return to normalcy once infectious period is over
- No or low cost equipment
- Easy to perform





Infectious





Semi-quantitative, traceable



Even Hugo de Jonge can do it



Training Gloves FFP2 masks Face shield Dedicated facilities





The good news: it works

SD Biosensor F-LINE





What's next







Immune response: antibodies

- Nucleocapsid protein
 - Many diagnostic tests
- S1-Spike protein
 - Correlation with Virus Neutralization
- Receptor-binding domain of spike protein
 - BIOSYNEX LFA test
 - Binding to ACE2 → cPass[™]







Key aspects of COVID-19 tests

Biology

- Virus
 - RNA
 - Protein (which protein?)
- Host response
 - Choice of antigen
 - Antibody subtype
 - Kinetics

Technology

- Format
- Equipment
- Detection method
- Skills
- Safety
- Background





Rapid ANTIBODY tests

- Easy to perform
- No blood collection needed
- No extensive lab skills required
- No or low cost equipment
- Performed on location

Antibodies -> Protection?







Do antibodies last?



- Kessel (Peel en Maas, Limburg)
- ~ 100 clients
 - Positive in rapid test (April May 2020)
 - Positive in NCP / S1 ELISA (May 2020)
- 1st Follow-up in July 2020
- 2nd Follow-up in Oct/Nov 2020

NCP – S1 - cPass





Kinetics of antibody responses





Garritsen et al., medRxiv



cPass[™] - DUKE-NUS

- sVNT
- Species independent
- CE/IVD marked
- FDA EUA
- Scalable







Neutralizing Antibodies



- Induced by the natural immune response
- Aim of vaccines
- Key to protection against a new infection
- cPass[™]: easy & accessible

24



Take home messages

- Diagnostics should be Fit-for-Purpose
- High-tech is not necessarily better than low-tech
- Identifying **infectious** people should have highest priority
- Natural infections provide protection but not for all and not for ever. Neither will vaccines. Monitoring will be required.
- To control corona we need to monitor virus and host

"Alleen samen...."







Stay strong, stay healthy

