Verification POC SARS-VoV-2 Rapid Antigen test RIVM - Erasmus MC - UMC Utrecht

Datum:	17 September 2020	
Aanwezig:	5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e	
Afwezig:	5.1.2e 5.1.2e	
Van:	5.1.2e	**Roche Diagnostics Nederland BV** **Product Manager POC SARS-CoV-2 rapid tests**
Verslag	Verification SARS-CoV-2 Rapid Antigen test.	

- Protocol appoach
  In total 1200 positive cases
  2400 negative cases
  For both providers of the tests. This means for Roche 2000 cases
  1000 low preference GGD
  1000 high preference GGD
  and 1500 lab evaluations in total 3600 test (144 packages of 25 tests)
  5.1.2e will share the protocol when it is final.
  The criteria that will be set for the SARS-CoV-2 Rapid antigen tests depend on the allocated results in the studies of the different suppliers and the used cases. Depending on the results of the different scenarios, the criteria will be set. The pursuit is >80% sensitivity.
  Planning is to start the study as soon as possible, completing is expected
  The aim is to complete the verification within 2-4 weeks.

- Precondition
  Before starting the following questions have to be answered: 1.What is the maximum time between the sample collection in the extraction buffer and putting the extracted sample into the device
  2. Data about the inactivation in the Buffer and or Device
  5.1.2e will come back to these questions ASAP.

- Detailed information
  The target of the SARS CCoV-2 antigen test is the Nucleocapsid antigen
  Detailed data of the test and the instruction for Use, will be shared by 5.1.2e ASAP
  Roche will contact the international organization for the detailed data on both studies in

India and Brazil.
-CT values viral load,
-Which PCR assay(s) and system(s) are used
-Days post symptoms
-Distinguish Sensitivity and Specificity in low and high prevalent areas

- Identification of the sample devices: 5.1.2e asks if the devices are provided with a (unique) identification.
  Roche will ask this question and come back to it ASAP.

- Data provided by other studies
  5.1.2e also works on a verification, this one is done with devices from other suppliers.
  The data produced by this study and the data from the RIVM will be offered combined to VWS.

- Reporting
  Idea is to produce a similar report as was produced for serology
  RIVM will collect and combine data and results from other labs, which do their own verification study
- Publication
  The RIVM will ask permission to for publication of the data.