Cross-functional collaboration supporting developments in diagnostics

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Roche at a glance

127 years
founded in Basel in 1896

3 Nobel prizes and **44 Prix Galien,**
since 1974

CHF 58.7 billion*
in Roche Group sales in 2023

A leader in healthcare R&D
with CHF 13.2 billion invested in 2023

>22 million people treated with our medicines in 2023

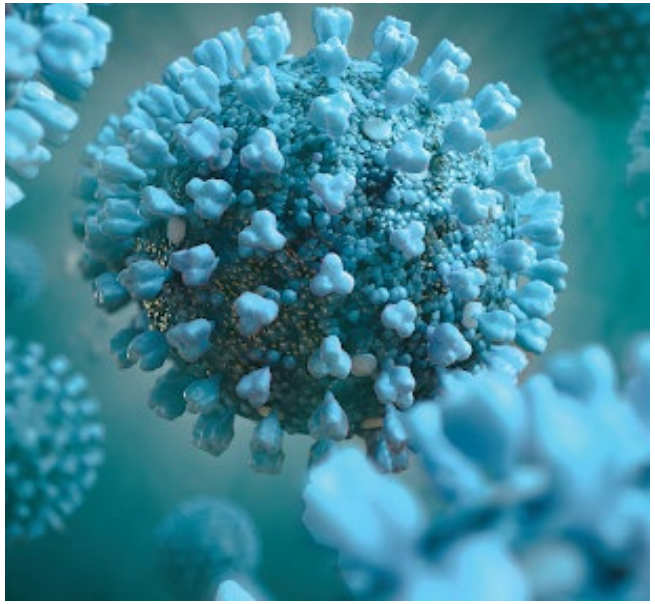
Multiple Roche medicines & diagnostics
on the WHO List of Essential Medicines & Tests

103,000+ dedicated employees worldwide

29 billion tests
conducted with our Diagnostics products in 2023

Study 1: SARS-CoV2 Duo assay and saliva as a sample

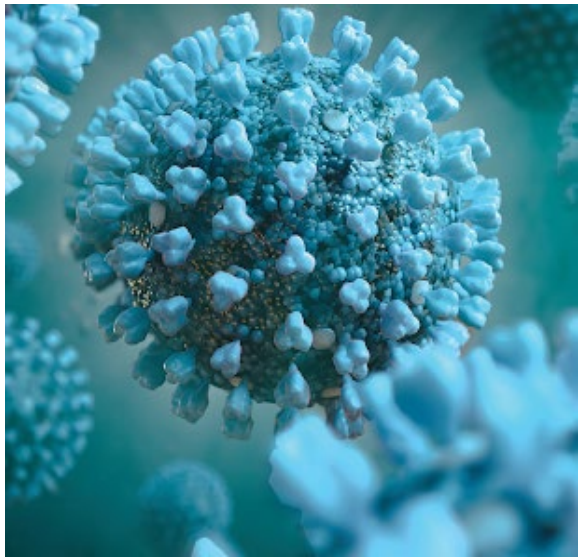
Aim of the study



Evaluate the performance of the cobas SARS-CoV-2 Duo assay for quantification of SARS-CoV-2 **in saliva**

Compare qualitative results between nasopharyngeal and saliva samples

The use of saliva as a diagnostic sample

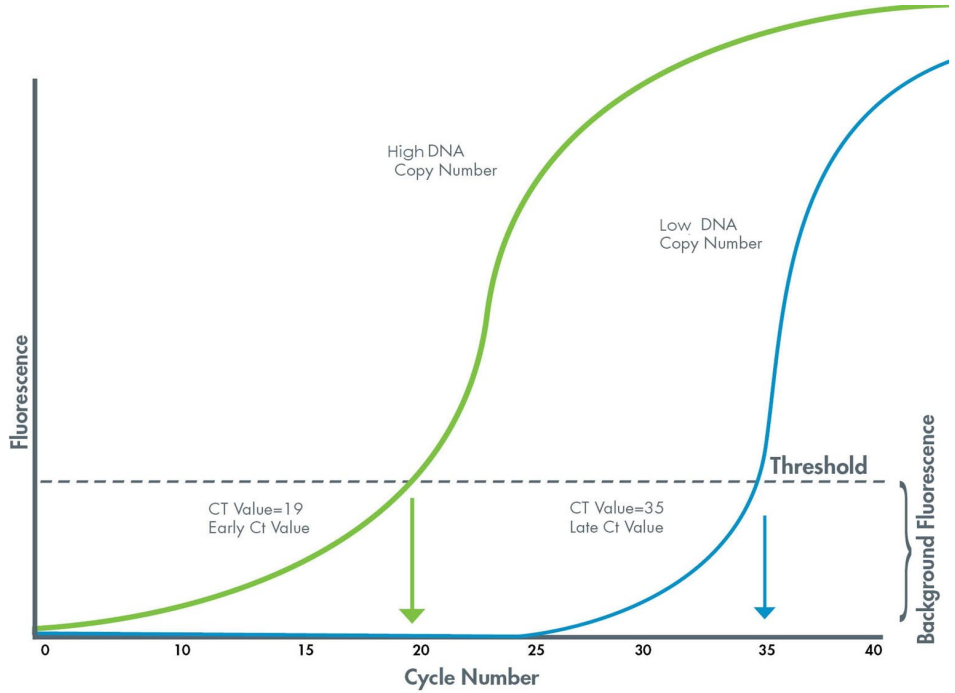


- The current **golden standard** in COVID-19 diagnostics is RT-PCR assay for detecting coronavirus 2 RNA in **nasopharyngeal swab** (NPS) samples

- Several studies have indicated a lower sensitivity of saliva compared with other respiratory samples in RT-PCR analysis

Reverse transcriptase Polymerase Chain Reaction(RT-PCR)

Detect extremely small amounts of pathogen RNA



- **Cycle threshold (Ct)** represents the number of amplification cycles needed for a fluorescence signal to surpass a set threshold, indicating the detection of the target nucleic acid.
- **Low Ct values** indicate high viral load
- **High Ct values** indicate low viral load

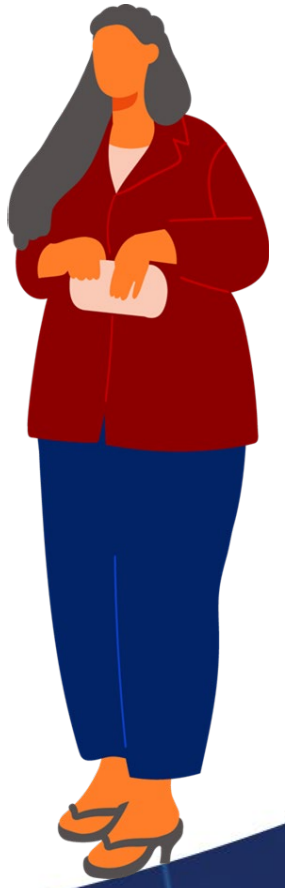
Cobas® SARS-CoV-2 assays

SARS-CoV2 assay		SARS-CoV2 Duo assay
Dual target, SARS-CoV-2 (Orf1a/b) and pan-Sarbeco (E gene). Mutation impacting SARS-CoV-2 target leads to 'presumptive positive' result.	**DESIGN** **Robust design specific for SARS-CoV-2**	**Dual target specific for SARS-CoV-2 (ORF 1a & ORF 1a/b non-structural regions)**. Mutation impacting SARS-CoV-2 target backed up with second target.
Qualitative result with **optional Ct value**	**RESULT** **Viral load result**	Quantitative result in **IU (WHO standard)**, Qualitative result with optional Ct value
Traceability to WHO standard, no correction for lot to lot variation in Ct value	**STANDARD** **Standardized result**	**Traceability to WHO standard, lot specific calibration**
Claim **limited to Qualitative** call	**CLAIM** **Dual claim for Quant/Qual call**	Claim **combines Quantitative (in IU) AND Qualitative call**

Qualitative result of COVID-19 samples meet the needs of clinical screening and diagnosis, while **quantitative result** provides more information to the research community.

Material

- 150 adults who have been referred to the HUSLAB Meilahti Corona Testing Point due to COVID-19 suspicion (Omaolo)
- Voluntary consent to biobank sampling
- Non-stimulated saliva sample
- Saliva samples were stored frozen



Results

This study supports the conclusion that saliva can be used as an alternative sample material for RT-PCR testing

Results will be published soon

The results will be utilized in the development of respiratory virus assays.

Study 2: Daycare study and cobas® Respiratory flex assay

Aim of the study

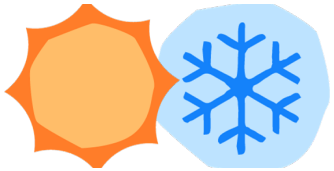
Which pathogens were circulating among the kids and their families (nasal swabs)?

Study whether pathogens in public spaces can be monitored using settle dust collection

Virus panel

15 common respiratory virus targets

Cobas Respiratory flex assay launched Oct 2024



Address seasonality

Nasal swabs will be tested for respiratory virus panel and results will be compared to the diary-data, absence data and data from dust samples.

Study is not ready yet!

Conclusions

- RWD
- Publications
- Collaborations

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