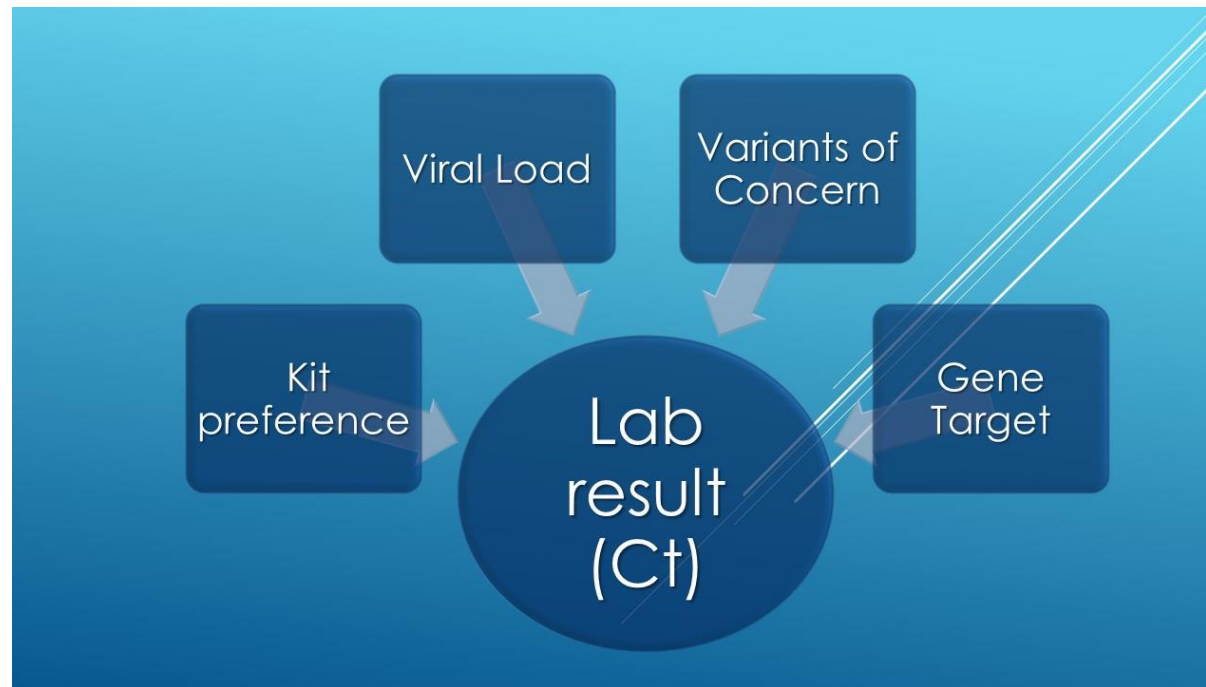


Endorsement of high quality standards for the molecular detection of Sars Cov-2 RNA in a Reference Laboratory in Athens, Greece

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The key role of External Quality Assurance (EQA) *what a clinician has to think*



Study the **efficiency of your method** in laboratory against a peer target (how close am I to a target?)



Laboratory performance –
study your self



Study the **efficiency of other methods** against the same target (which method has the highest popularity and efficiency?)



Illustration of current laboratory practices, in terms of **most commonly used kit manufacturer** and **genes targets** – **study others**

Two well-known External Quality Assurance Schemes, our laboratory -IN VITRO LABS- participates in

United Kingdom National External Quality Assessment Schemes

- UK NEQAS for Molecular detection of SARS-CoV-2

UK NEQAS
Microbiology



German – INSTAND

- Virus GENOME Detection -Coronaviruses



INSTAND

Opportunity for the analysis of almost all circulating variants in the lab – comparative results

Objective of the study

Efficiency

- ✓ **efficiency** of combined use of commercial **RT-PCR**

Interferences

- ✓ Factors may dynamically **interfere** with an analytical RealTime **PCR result** (Ct), are there any possible interactions?

Preferences

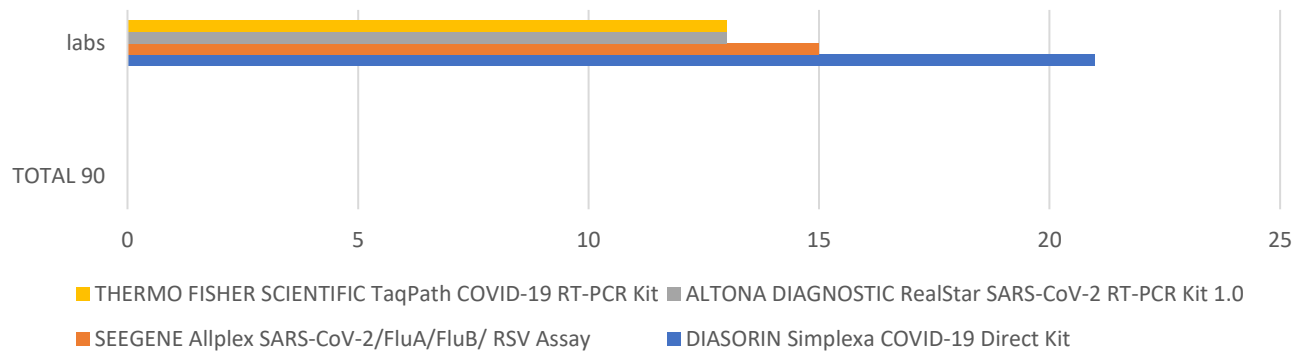
- ✓ **preference** of the laboratories, in terms of most commonly used *kit manufacturer* and *genes targets*

Efficiency

- There is evidence that some SARS Variants may present **S gene dropout**, leading to **false negative results** as regards the analysis of S gene, whereas certain PCR kit may be more susceptible to S gene dropout compared to others.
- In order to overcome this problem our laboratory uses combined analysis of S gene along with RdRp in the same fluorescent channel

The highest rate of S gene drop out (poor efficiency) was observed with Variant **Alfa B.1.1.7**

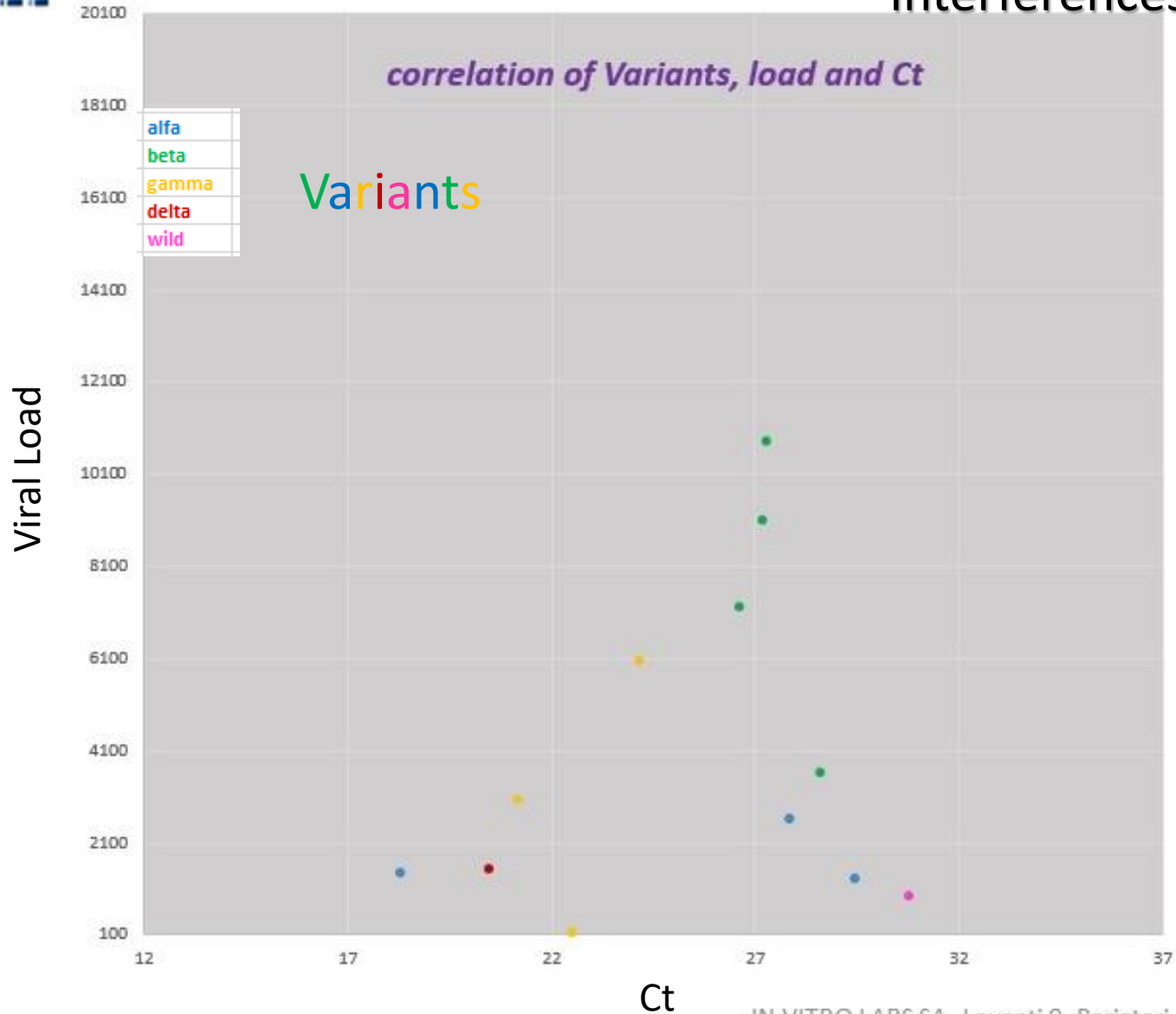
S gene



Kit preferences in terms of S gene analysis

S gene Drop out				
409006	POSITIVE	B.1.1.7 Alfa		
S gene	TOTAL 81		labs	success %
ALTONA DIAGNOSTIC RealStar SARS-CoV-2 RT-PCR Kit 1.0			18	
DIASORIN Simplexa COVID-19 Direct Kit			17	88.24%
THERMO FISHER SCIENTIFIC TaqPath COVID-19 RT-PCR Kit			14	0.00%
SEEGENE Allplex SARS-CoV-2/FluA/FluB/ RSV Assay			12	

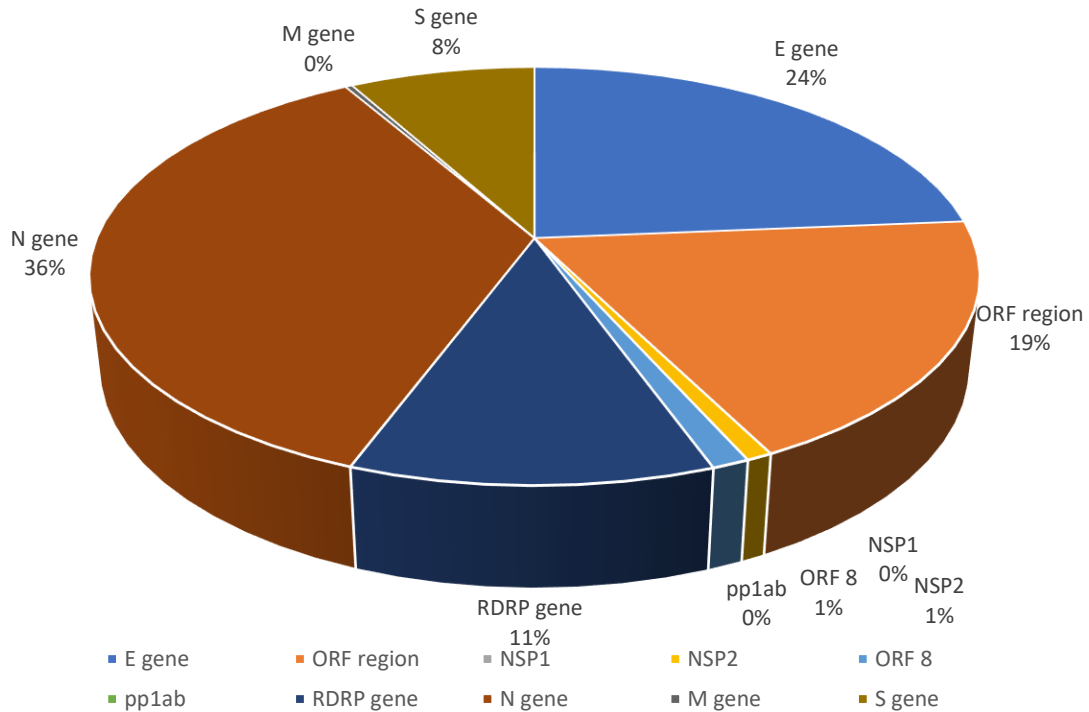
S gene Drop out				
409018	POSITIVE	B.1.1.7 Alfa		
S gene	TOTAL 90		labs	success %
DIASORIN Simplexa COVID-19 Direct Kit			21	95.40%
SEEGENE Allplex SARS-CoV-2/FluA/FluB/ RSV Assay			15	93.33%
ALTONA DIAGNOSTIC RealStar SARS-CoV-2 RT-PCR Kit 1.0			13	
THERMO FISHER SCIENTIFIC TaqPath COVID-19 RT-PCR Kit			13	15.38%



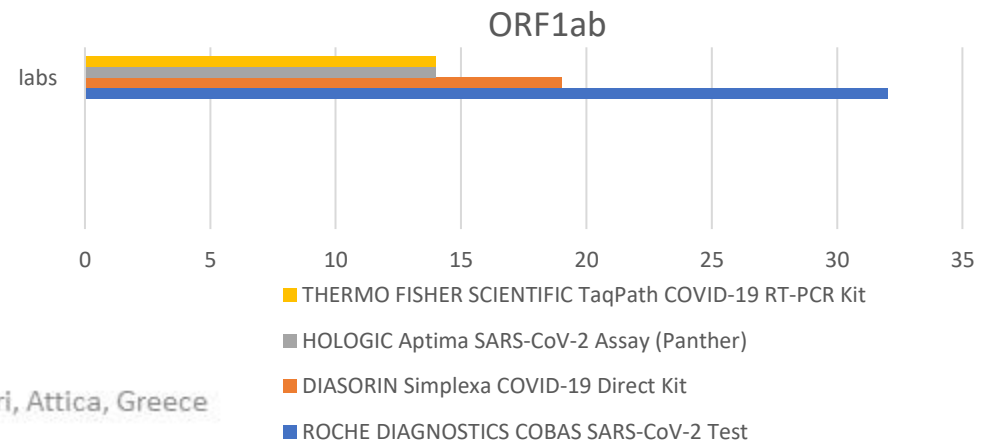
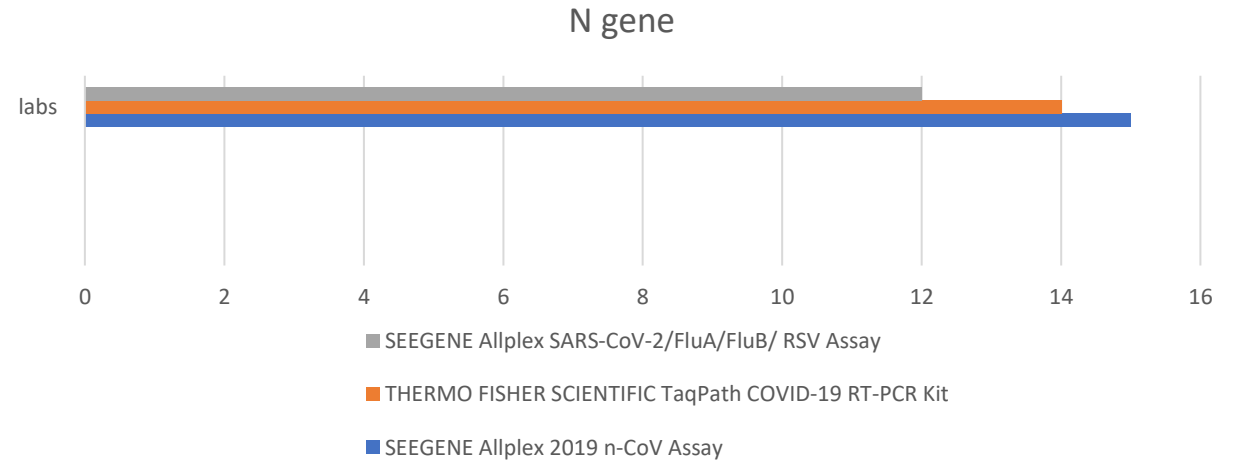
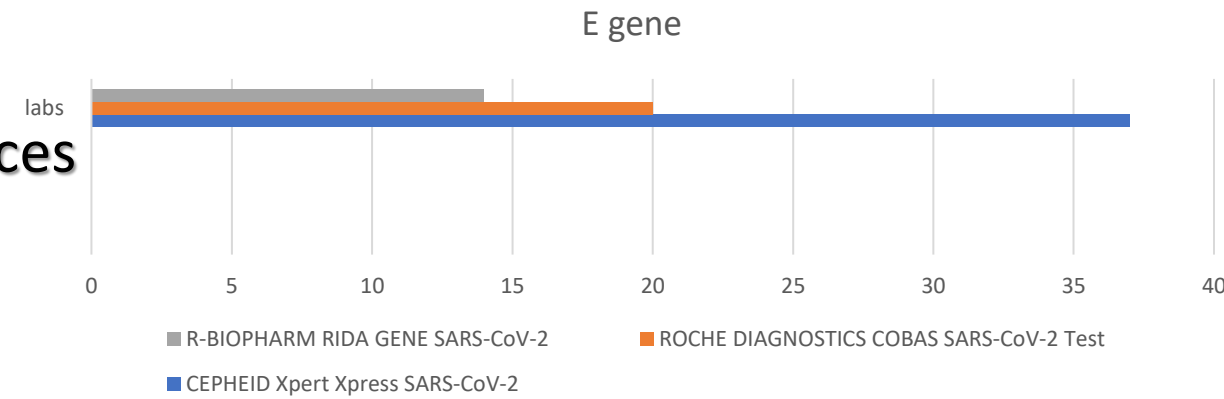
In the current analysis it appears that when different variants **with same level of viral load**, are analyzed for the same gene target, we might be leaded to different Ct values.

There are some thoughts that circulating variants might present different behavior in a given analytical procedure while this assumption remains under investigation.

Gene target analysis percentage according to laboratory participants



Preferences



Conclusions and thoughts

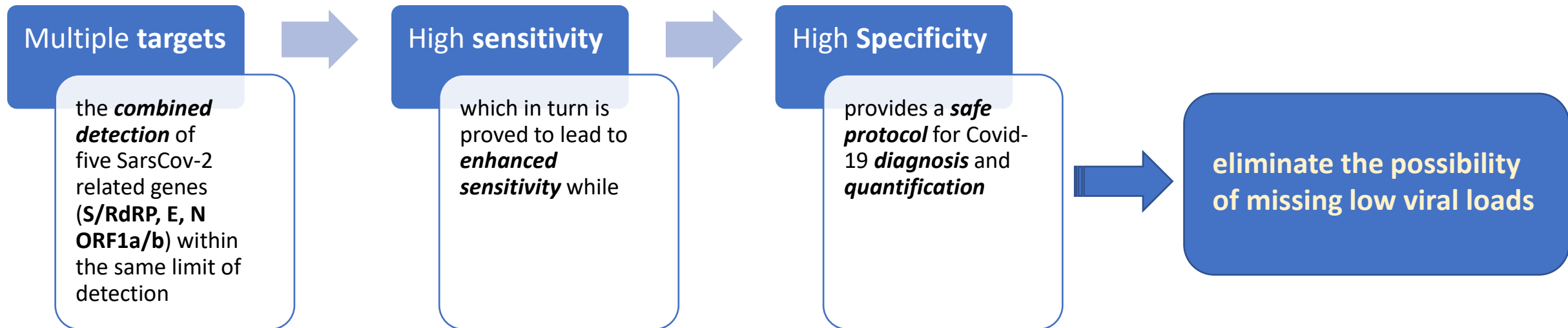
The main result was that a given **cycle cutoff (Ct)** should be **interpreted with care**

and in tandem with the **current stage of the pandemic**

as it **may not always** be directly connected with the **viral load**

Quality standards for the molecular detection of Sars Cov-2 RNA in our Laboratory

With a strong commitment to Quality, our laboratory's current Quality Assurance Practice follows:



Safe Diagnosis

IN VITRO LABS



Thank you for your attention