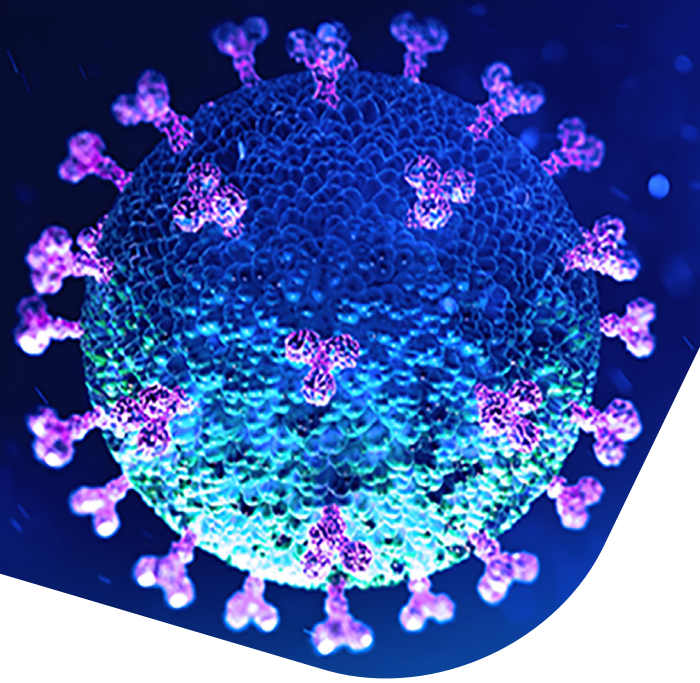
NEWS on diagnostics

2021 Special Edition

Proficiency Testing



COVID-19 has changed the world for everybody. Testing for SARS-CoV-2, and the associated validation of instrumentation or methods is key in fighting the pandemic. This special edition of News on Diagnostics covers proficiency testing as a way of demonstrating accuracy, precision, and most importantly, reliability of testing instrumentation results.

In this issue....

What is Proficiency Testing?

Proficiency Testing (PT) is the name used by the International Standards Organisation for a procedure also known as “inter-laboratory study” or “external quality assessment” or “ring test”. Proficiency testing, in simple terms, comprises a sample sent to a group of laboratories for measurement. The labs know what might be in the sample, but they don’t know exactly the composition or concentration. Their results are compared with the known or true value, and the lab is assigned a “Z” score to show how closely their result came to the target. We run proficiency testing as scheduled rounds or quick-turn/on-demand studies.

How PT Works:

Registration & Ordering 1
Upon ordering for the first time, the lab needs to register their account details through the online PT portal. Once the order is completed, registration will be approved and a lab code will be assigned.

Delivery 2
Blind samples are distributed accordingly. Each participant receives their samples.

Open Study 3
The study is open. Each lab analyzes the blind samples.

Reporting 4
Each lab reports their results through the PT portal before the study closes.

Data Processing 5
The data is processed and evaluated according to the z-score determination.

Evaluation Report 6
Reports are sent as PDFs via the PT Portal. If specified when entering the result, a copy will be sent to the lab's accreditation body.

Registering for a PT

Simple and quick registration via our portal, allows you to access your account, and report your PT results on our user-friendly system.

Learn more at **SigmaAldrich.com/pt**

Quick-Turn/On-Demand PT Studies

Quick-Turn PT rounds are available for the majority of our sample portfolio. Quick-Turns are provided at the same price as scheduled samples, where applicable.

In most cases, laboratories can usually use these samples for:

- Supporting new method validation
- As a tool for corrective action
- To demonstrate analytical competence
- To train new lab personnel

How Quick-Turn/On-Demand works:

- Find the samples you need and request them to be sent as a Quick-Turn. In this case, our SARS-CoV-2 Proficiency Testing Kit, PE5006-1KT.
- These samples will be dispatched as soon as possible.
- You have 45 days from time of shipment to complete the analysis.
- If you complete the analysis quicker than 45 days, submit your results to the PT reporting system. The day you submit your results, the study will close.
- Within 48 hours of data submission you will receive your evaluation report.

Sign up today for a quick-turn/on-demand study by visiting **SigmaAldrich.com/pt** or email

ptservice@merckgroup.com for more information on the study or samples.

NEW PT for SARS-CoV-2

To support your quality assurance efforts, we bring you our new SARS-CoV-2 proficiency testing kit and program for use with methods which detect the viral RNA by nucleic acid amplification.

Major features include:

- Qualitative & quantitative reporting assessment on Cq values and PCR efficiency
- Sample kits produced in accordance with ISO/IEC 17043 and ISO 13485
- Positive & negative controls across a wide copy number range
- Noninfectious, liquid specimen samples, targeting certain CDC and WHO consensus gene sequence regions such as RdRp, N (Nucleocapsid), E (Envelope), and/or S (Spike)
- Wide concentration range of samples, allowing for effective challenge of the instrument's sensitivity across its dynamic range
- Quick-turn or on-demand study options for optimal scheduling convenience.

Why proficiency testing for SARS-CoV-2 test methods?

In several countries, stakeholder groups are advocating for proficiency testing of COVID-19 clinical laboratory tests. In the US, for example, NILA (National Independent Laboratory Association) has declared proficiency testing essential to evaluate the accuracy and reliability of SARS-CoV-2 clinical laboratory tests by PCR.[1] Also, clinical evidence requirements for CE certification under the EU IVDR (In-Vitro Diagnostic Regulation) allow for use of proficiency testing data reports in demonstrating a device's clinical performance.[2]

SARS-CoV-2 Reference Material for Quality Control of PCR Test Methods

Issued by the Joint Research Centre (JRC), a Directorate-General of the European Commission, EURM-019 is intended for use as a positive quality control sample to verify correctness of the transcription and amplification steps for SARS-CoV-2 real-time RT-PCR assays. EURM-019, which we distribute, is a solution containing a stabilized *in vitro* transcripted (IVT) synthetic single stranded RNA (ssRNA) in buffer. It does not contain any viable virus.

This universal synthetic ssRNA of 880 nt contains the target regions which can be amplified by the following RT-PCR assays:

a. N1, N2 and N3 gene developed by the Centers for Disease Control and Prevention (USA)

b. E gene and the RdRP gene developed by the Charité (DE)

c. N gene developed by the Japanese National Institute of Infectious Diseases (JP)

d. N gene developed by the Ministry of Heath of Thailand (TH)

e. S gene developed by the Joint Research Centre of the European Commission (EU)

References

1. https://www.nila-usa.org/images/nila/2020/NILA%20PT%20Fact%20Sheet_FINAL.pdf
2. https://www.medtecheurope.org/wp-content/uploads/2020/05/MedTech-Europe-Clinical-Evidence-Requirements-for-CE-certification-eBook-2020.pdf

Meet our reference materials specialist team

We know in these difficult and challenging times we all have to work together to achieve a common goal.

Hence, why we want you to know that we are here for you. Our Reference Materials Specialist Team are here to support you and offer the best possible service.

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