

INSTAND

Promoting Quality in Medical Laboratories



Volume 3, July 2025

INSTAND NEWSLETTER

Dear Colleagues,

Welcome to the summer edition of the INSTAND newsletter with the following highlights:

- News about our EQA Schemes
 - EQA Scheme CAR-T Cells
 - RV-Online YouTube Videos
 - EQA Scheme Program 2026
- Contribution by INSTAND EQA Scheme Experts Prof. Gessner and Dr. Hiergeist: 'Microbiome proficiency tests and the future use of state-of-the-art fermenter technology'
- INSTAND Academie:
 - 470 - Cerebrospinal fluid cytodiagnosics training
 - New English-language seminar on biostatistics
- Future Events
- Introducing: our new member of staff in the logistics team
- INSTAND publications

Happy reading!

Kind regards,
Your INSTAND Team

Prof. Dr. med. Michael Spannagl
Prof. Dr. rer. nat. Ingo Schellenberg
Prof. Dr. med. Klaus-Peter Hunfeld

INSTAND EQA SCHEMES

EQA Scheme CAR-T Cells

A contribution by **Dr. Gerulf Hänel**
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CD19-directed CAR-T cell therapy is now standard in the treatment of aggressive and indolent lymphomas and relapsed BCP-ALL. CAR-T cell expansion after transfusion is associated with the occurrence of toxicities and therapy response and is therefore an important biomarker for therapy management in these patients.

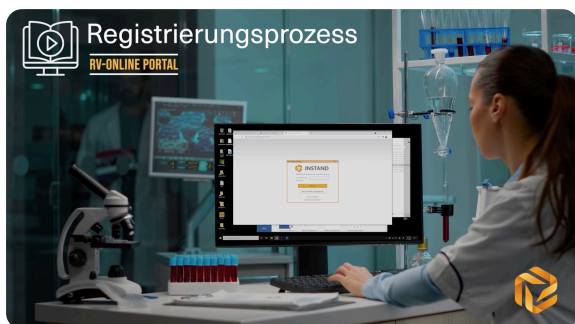
Following a pilot round robin test last winter, we were able to carry out the first regular round robin test in May with a total of 25 participating laboratories. This showed that the qualitative and, in particular, quantitative detection of CAR-T cells poses a number of challenges. On the one hand, the methodology used in the laboratories is heterogeneous. Although detection is based on flow cytometry in almost all laboratories, there are differences in the wet lab, for example, in the antibody panel and the detection reagent used for the CAR-T cells, as well as in the processing of the samples (e.g. lysis buffer for erythrocytes). Additionally, there are differences in the dry lab when analyzing the data e.g. in the gating of cell populations and calculation methods for quantitative detection. Another challenge is the above-average instability of CAR-T cells compared to normal leukocytes.

Overall, pioneering work is still being done here, although fortunately some laboratories have already harmonized their methods in advance, which has had a positive effect on the proficiency test results. We are therefore optimistic that we will see further major progress in the next round robin tests and plan to expand the number of round robin tests in the future to enable more laboratories to participate.

RV-Online Portal 'Support' Videos

On the INSTAND [YouTube Channel](#), you have access to videos that explain step-by-step how to register and enter values in the RV-Online portal. Click on the corresponding image to go directly to the video.

Registrationsprozess



Result Entry



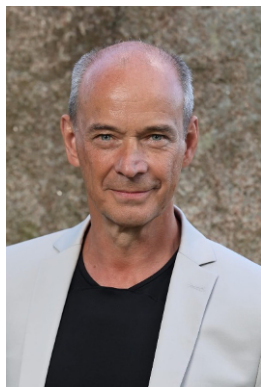
EQA Scheme Program 2026

Our new EQAS program and the catalog for 2026 will be published again this year at the end of August to give you timely insight into the current program.

You can view our current EQA scheme and the catalog [here](#) at any time.

Microbiome Proficiency Test and the future Use of State-of-the-Art Fermenter Technology

A Contribution by



Prof. Dr. med. nat. André Gessner

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Microbiome research has become a central pillar of modern medicine in recent years. Numerous studies have demonstrated the influence of microbial colonization on immune function, metabolism, therapy response, and disease progression - from chronic inflammatory diseases to cancer immunotherapy. At the same time, the translation of microbiome-related findings into clinical practice requires standardized, reproducible analytics that provide reliable data across all methods. Only through controlled sample collection, validated sequencing methods, standardized bioinformatic analysis workflows, and external quality controls (e.g., proficiency tests) can diagnostic and therapeutic applications be placed on a reliable foundation. This makes microbiome research not only scientifically relevant but also practically useful for precision medicine, risk stratification, and patient-specific therapy planning.

Quality Assurance and Therapeutic Application through Standardized Microbiota

The **Institute of Clinical Microbiology and Hygiene at the University Hospital Regensburg** has been one of the pioneers in the design and implementation of EQA programs for microbiome analysis since 2015. As an organizer and evaluation center, the Institute coordinates annual external quality control programs (EQA) supported by INSTAND e.V., in which participating laboratories analyze standardized stool samples with defined bacterial communities. These EQA programs test the entire microbiological analysis pipeline - from DNA extraction and amplification to bioinformatic evaluation - and allow a critical assessment of reproducibility and accuracy in microbiome diagnostics.

Standardized Reference Materials for Microbiome Diagnostics

Specially produced, precisely defined microbial communities (mock communities) and human stool samples, which have been mixed with several precisely quantified bacteria, are used in these interlaboratory tests. The materials are produced centrally, tested using quantitative PCR (qPCR), and analyzed by all participating laboratories using 16S rRNA or shotgun sequencing. The results regularly show significant variability between laboratories in the recovery and quantification of the added bacteria, which underlines the need for standardization of methods and materials.

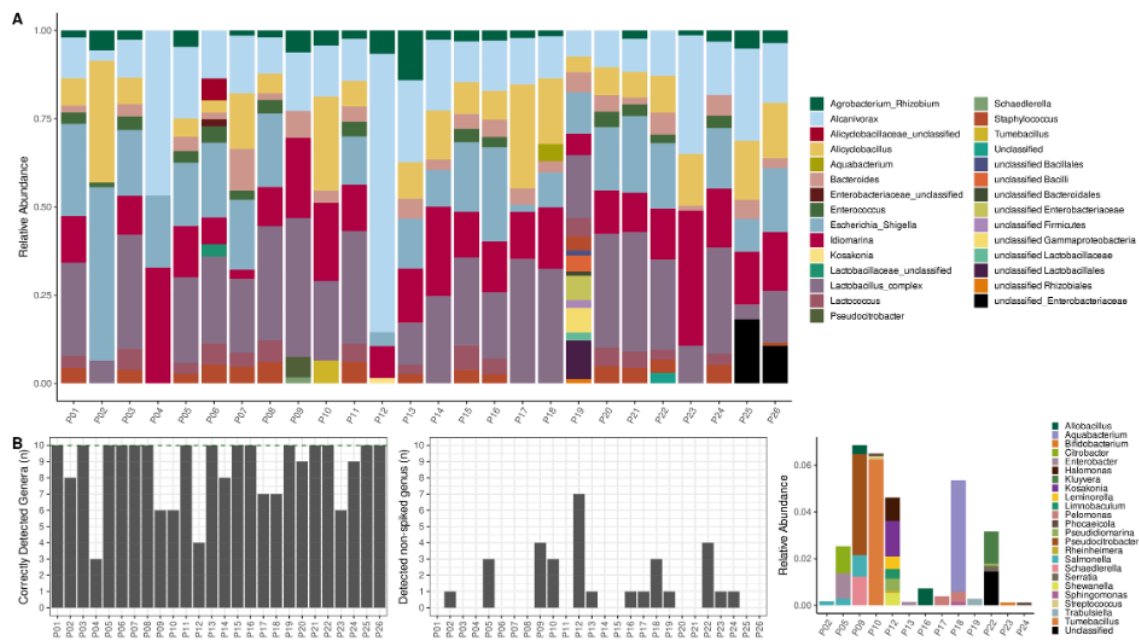


Figure 1: Recovery rates of the 14-species mock community (from 10 genera) in EQA scheme 580/2023 show high interlaboratory variability. A) Reported microbiome profiles of participants P01-P26. B) Recovery rates of the 10 target genera and false-positive detections.

New Perspectives through Fermenter Technology

Building on this experience, Instand e.V. supported the establishment of state-of-the-art fermenter systems for the controlled cultivation of complex microbiota under physiological conditions (e.g., anaerobic, pH-controlled, substrate-specific). The aim is to produce microbiological reference materials of the highest standardization, which can be used for proficiency testing as well as for preclinical and therapeutic applications.

Areas of application:

1. Externe Quality Assurance (EQAS)

- Production of resilient, long-term stable microbiota mixtures
- Dynamic model microbiota for sequencing, PCR and metabolomics ring experiments
- Expansion of existing proficiency testing programs to include functional microbiome characterization (e.g. resistome, metabolome)

2. Therapeutic Microbiomodulation

- *In vitro* modulation of individual microbiota (e.g. depletion of pathogenic species, targeted enrichment of health-promoting taxa)
- Production of personalized microbiome formulations, e.g. for use prior to autologous re-transplantation (FMT-optimized)
- Development of precise postbiotics or synbiotics based on fermented microbiota

The Institute of Clinical Microbiology and Hygiene in Regensburg, with its dual role as quality assurance and research facility, supports important developments that transform microbiome diagnostics from a purely academic discipline into a clinically validated, personalized instrument of precision medicine - with the highest standards of quality, standardization and therapeutic perspective.

INSTAND ACADEMY

470 - Cerebrospinal Fluid Cytodiagnostics Training

There are still places available for the 470 - CSF cytodiagnosics training course in Jena. **This course is in German only.**

Interested participants can still register **until 15.08.2025** using the following form. We look forward to your participation.

[Register now](#)

New English-Language Seminar Biostatistics

The INSTAND Academy is pleased to offer you a one-day training course in biostatistics **in English**.

In this one-day workshop, you will receive a clear introduction to the basic concepts of biostatistics - without using any software. Topics such as p-values, confidence intervals, regression coefficients, and statistical significance are explained step by step. The aim is to develop a solid mathematical understanding that will help you to apply statistical methods correctly - from the t-test to more complex models. The workshop is aimed at anyone who wants to understand statistics better, whether for laboratory analysis, quality control, or data interpretation.

Continuing education points will be applied for from the North Rhine State Medical Association and the DiW-MTA.

As the maximum number of participants is limited, we recommend that you quickly secure one of the coveted places [here](#).

You can find additional information [here](#).

[Registration Form](#)

FUTURE EVENTS

Events 2025

Euromedlab was a complete success in Brussels in May 2025. Our team on site was delighted with the lively interest. Come and connect with us at one of our future events this year.

We look forward to your visit.

[All Events](#)



Medlab Asia
July 16-18 2025
Kuala Lumpur, Malaysia

More Information [here](#).

ADLM
July 29-31, 2025
Chicago, USA

Further Details [here](#).

AAL
September 12-13, 2025
Leinfelden, Echterdingen,
Germany

Current information (in
Germany) can be found [here](#).



ESCV
September 17-20, 2025
Greece

Further Details [here](#).



EQALM
October 15-17, 2025
Leiden, Niederlande

Current information can be
found [here](#).



DKLM
October 23-24, 2025
Leipzig, Germany

More Information [hier](#).

WE INTRODUCE: NEW EMPLOYEES

Please join us in welcoming our new employee

Markus Weißkircher - Logistics/EQA Scheme shipping since July 1, 2025.

You can find the complete INSTAND team [here](#).

INSTAND PUBLICATIONS



ScienceDirect

**From crisis to routine - Standardization of
SARS-CoV-2 genome detection by enhanced
EQA schemes in a scientific pandemic network**

Martin Kammel, Hans-Peter Grunert, Anika Zimmermann, Annemarie Martin, Vanessa Lindig Samuel Samuleit, Ulf Dühring, Mechthild Adams-Bagusche, Dirk Sander, Hannah Zeichhardt, Christian Drost, Victor M. Corman, Sandra Ciesek, Holger F. Rabenau, Martin Obermeier, Robert Ehret, Rolf Kaiser, Jim Huggett, Denise O'Sullivan, Peter M. Vallone, Heinz Zeichhardt

Artikel



All INSTAND News

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