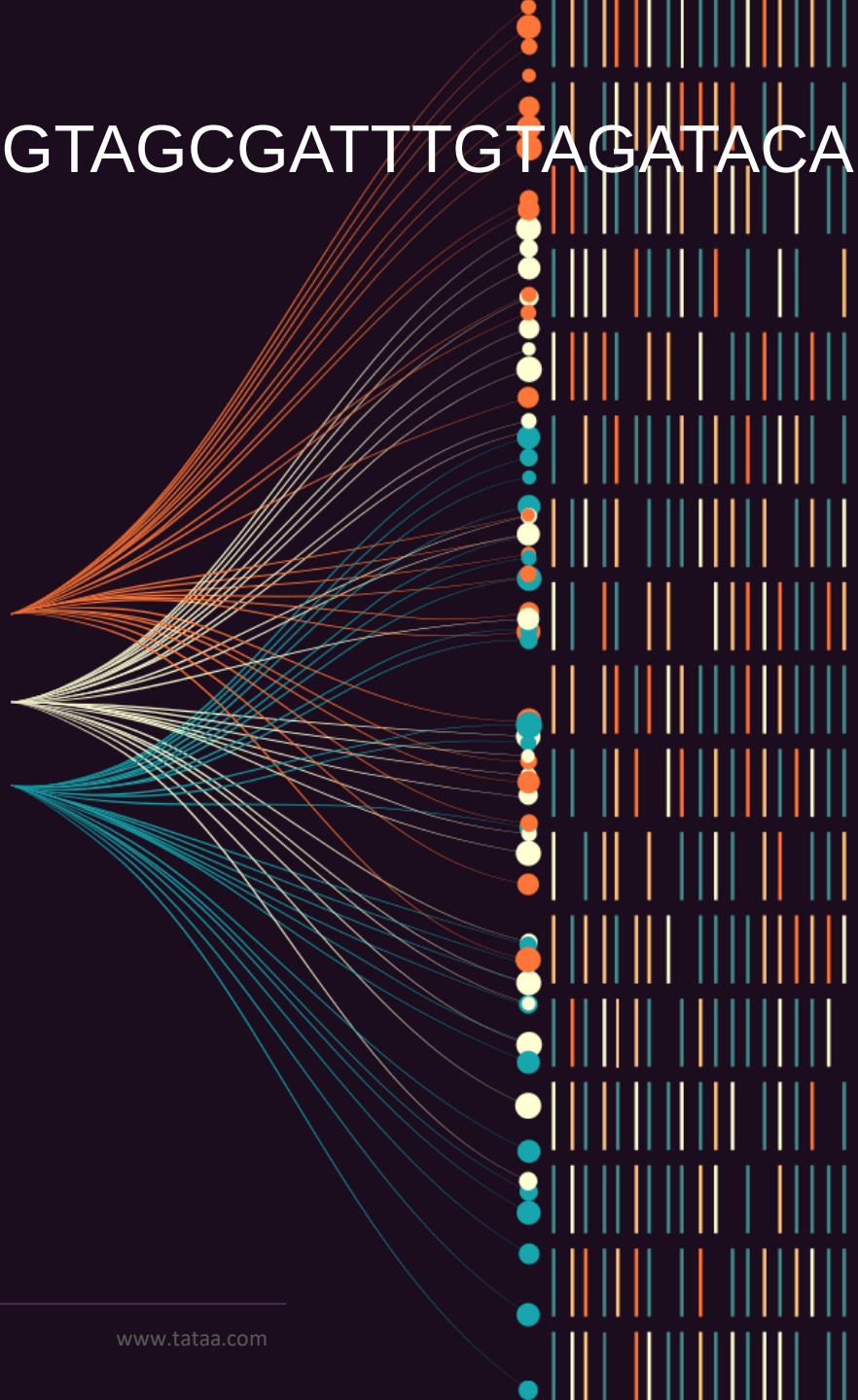
GCTTCACGTTATAAAGACGTGACGTAGCGATTTGTAGATACA



TATAA

BIOCENTER

YOUR TRUSTED PARTNER
FOR DRUG DEVELOPMENT

TATAA at a glance

*2001

OUR TEAM

>60
employees

>50%
PhDs and Masters

~5
Quality control and QA

WHAT WE'VE DONE

>20
years of work

Multiple
supported drugs

Hundreds
publications

LOCATION

Göteborg, Sweden

New headquarter with expanded facilities in Gothenburg

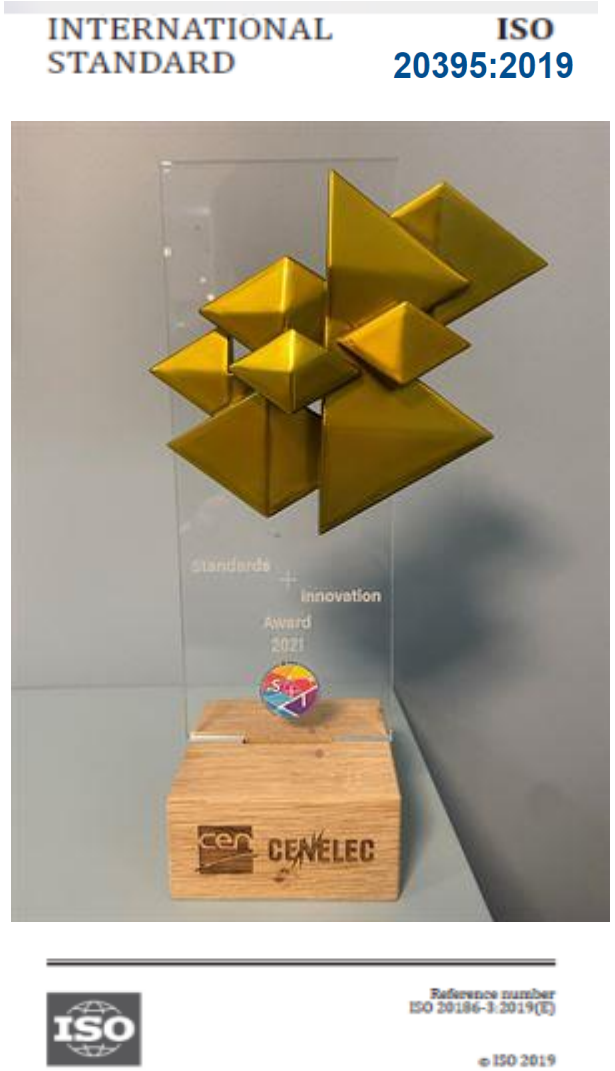
ISO17025:2018 accreditation

GLP/GCP compliance during 2023

US expansion planned

https://www.tataa.com/courses/upcoming-courses/

CEN & ISO Standard Documents and EQAs



- **Molecular in-vitro diagnostic examinations - Specifications for preexamination processes for**:
- Blood — Cellular RNA, gDNA, ccfDNA, ccfRNA
- Blood – Exosomes / Evs
- Blood Tumor Cells – DNA, RNA, staining
- Tissue (FFPE) — DNA, RNA, Protein
- Tissue (Frozen) – DNA, RNA, Proteins
- Tissue (FFPE) – in situ staining
- Fine Needle Aspirates – DNA, RNA, Proteins
- Saliva – DNA
- Urine & Body Fluids – cfDNA
- Metabolomics – Urine, Serum, Plasma
- Microbiome – Stool, Saliva etc.

Published CEN ⇒ progressing at ISO

Published ISO

Total:22

Clinical Chemistry 55:4
611–622 (2009)

Special Report

The MIQE Guidelines: *Minimum Information for Publication of Quantitative Real-Time PCR Experiments*

Stephen A. Bustin,[1*] Vladimir Benes,[2] Jeremy A. Garson,[3,4] Jan Hellemans,[5] Jim Huggett,[6] Mikael Kubista,[7,8] Reinhold Mueller,[9] Tania Nolan,[10] Michael W. Pfaffl,[11] Gregory L. Shipley,[12] Jo Vandesompele,[5] and Carl T. Wittwer[13,14]

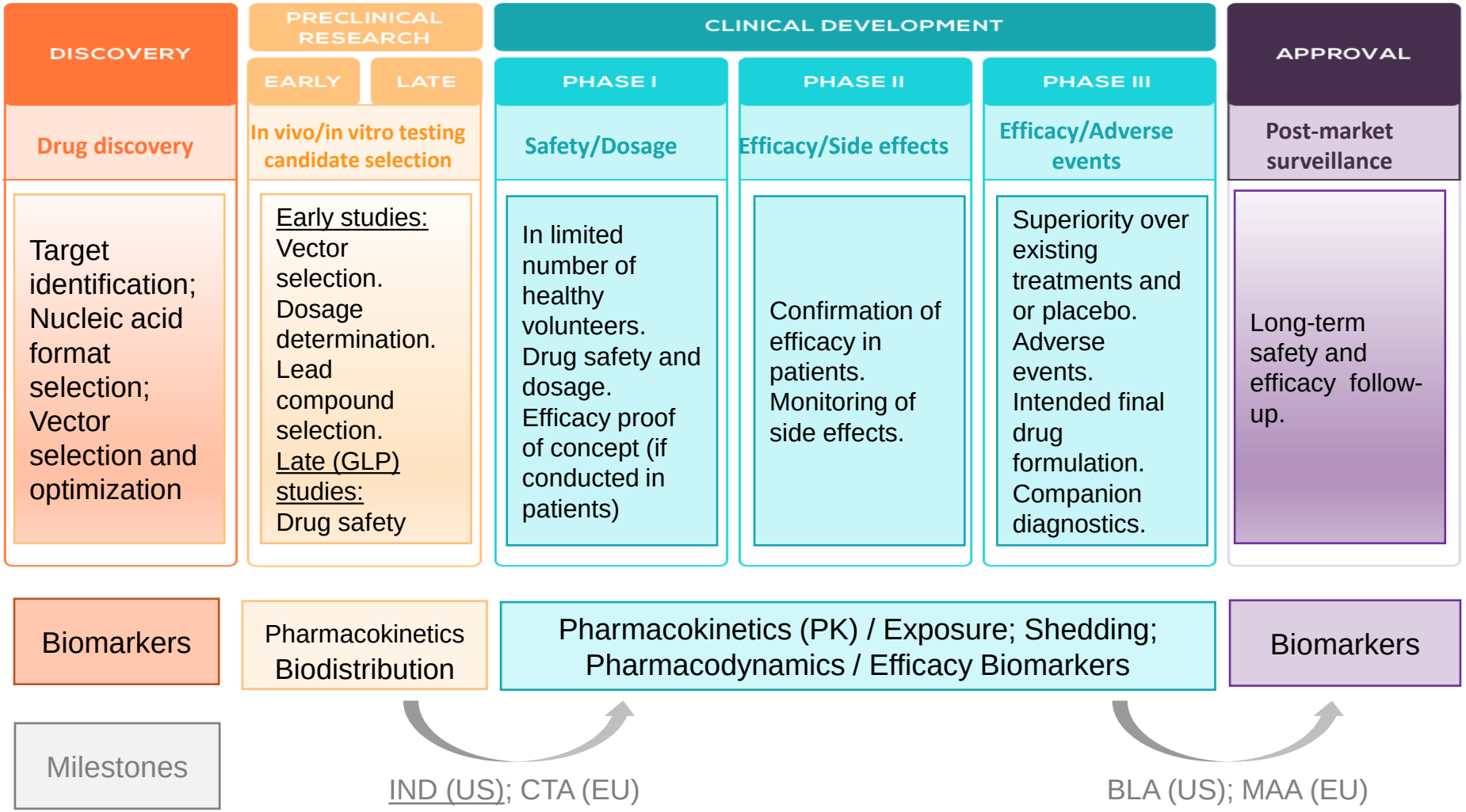
BACKGROUND: Currently, a lack of consensus exists on how best to perform and interpret quantitative real-time PCR (qPCR) experiments. The problem is exacerbated by a lack of sufficient experimental detail in many publications, which impedes a reader's ability to evaluate critically the quality of the results presented or to repeat the experiments.

SUMMARY: Following these guidelines will encourage better experimental practice, allowing more reliable and unequivocal interpretation of qPCR results.

The fluorescence-based quantitative real-time PCR (qPCR)[15] *(1–3)*, with its capacity to detect and mea-

13643 (3 per day) citations

Bioanalysis during ATMP drug development process



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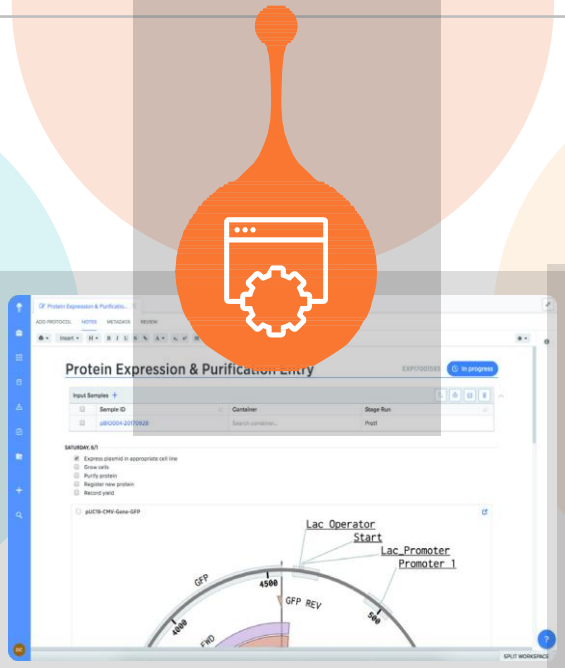
Questions answered by bioanalysis

• How much ATMP is in the body? • How long does it stay? • How does the concentration evolve with time?	**Pharmacokinetics (PK)**	**Measure drug**
• In which tissue(s) does the ATMP go? • How long does it remain?	**Biodistribution**	
• How is the ATMP eliminated into the environment through secretions?	**Shedding**	
• Is the drug active in the body? • Does it accomplish its intended action? • Is there a relationship between the drug dose and the concentration of its target?	**Pharmacodynamics (PD) and Biomarkers**	**Measure target (direct or not)**

TATAA's Operating Infrastructure

10 M€ invested 2021-2023

Robust infrastructure that can handle large and pivotal projects with precision and speed



Highest quality hardware

High-throughput NGS, latest digital and quantitative PCR, automated nucleic acid extraction and liquid handlers

Most advanced software

Fully integrated Benchling LIMS and ELN solution

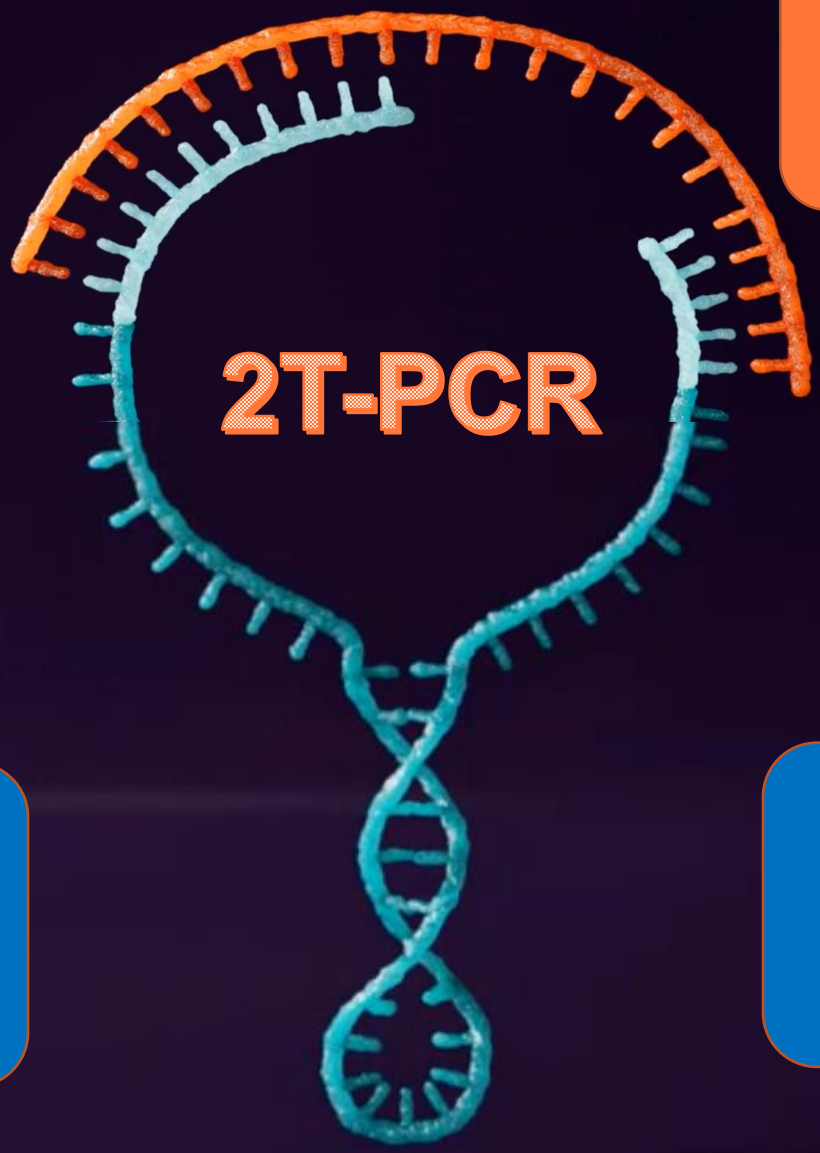
Enterprise-grade automation

Automated liquid handlers standardizing and propelling every workflow we support for clients

TATAA's Operating Infrastructure

Nucleic acids as short as some 15 bases can be analyzed

Up to 1000 times more sensitive to detect sequence variations



5′

Hemiprobe

3′

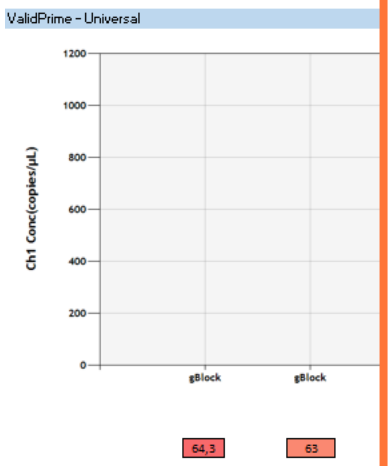
Hemiprobe

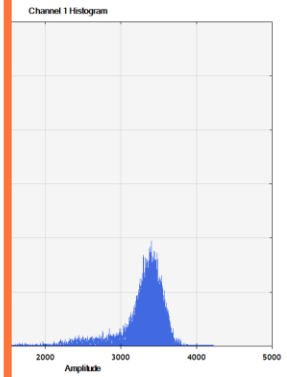
microRNAs
siRNA
ASO
FFPE material
Ancient samples

ctDNA (cancer)
NIPT
Graft rejection
Forensic samples
Microbiology

Design and validation of an assay

dPCR Calibration of gBl





ELSEVIER

Biomolecular Detection and Quantification

Volume 12, June 2017, Pages 1-6

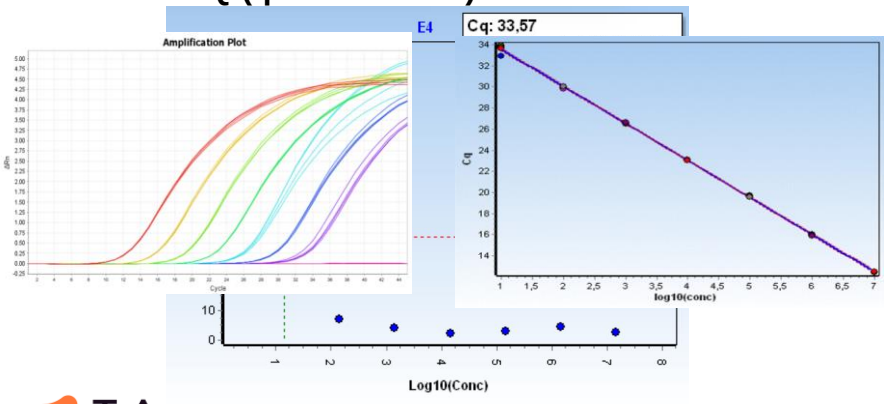
Research paper

Methods to determine limit of detection and limit of quantification in quantitative real-time PCR (qPCR)

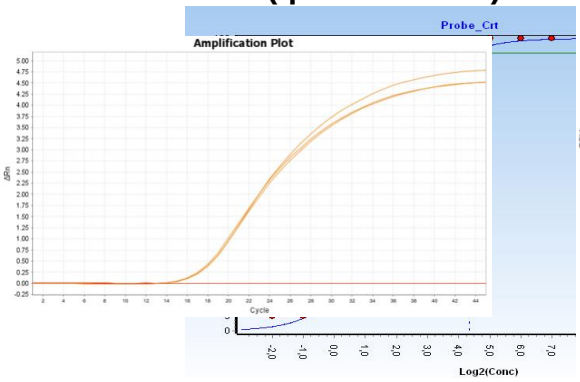
Amin Forootan [a, b], Robert Sjöback [c], Jens Björkman [c], Björn Sjögreen [b], Lucas Linz [d], Mikael Kubista [c, e]

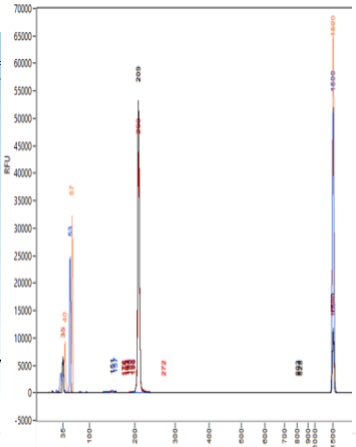
Concentration determined with ValidPrime

LOQ (qPCR – Probe)



LOD (qPCR – Probe)





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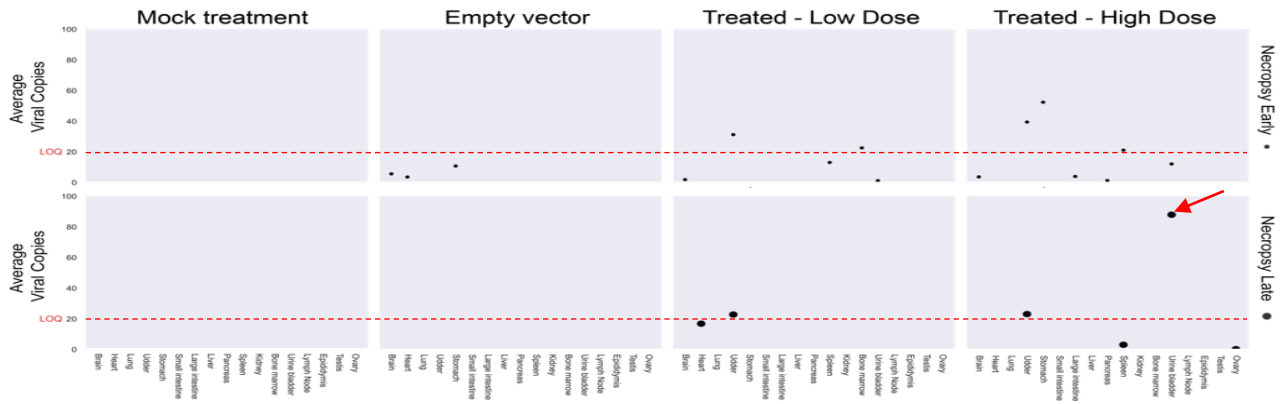
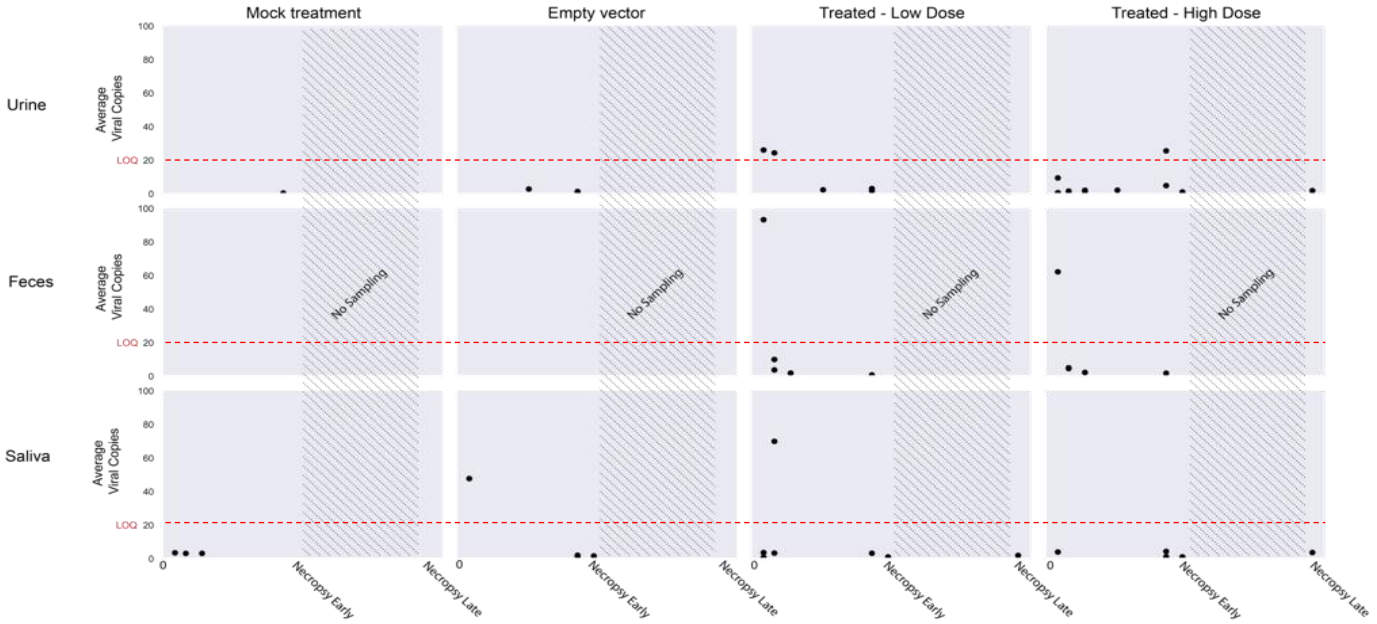
Example: Adenovirus + vector

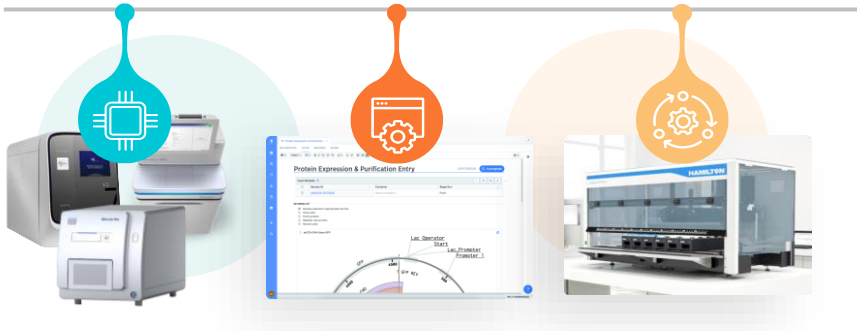
Biodistribution
17 tissues
2 time points



Shedding
3 specimens
6 time points



TATAA Biocenter shall be the preferred provider of regulated molecular analysis services to the Pharmaceutical industry



Highest quality hardware

Most advanced software

Enterprise-grade automation

Genomics – Transcriptomics – Proteomics