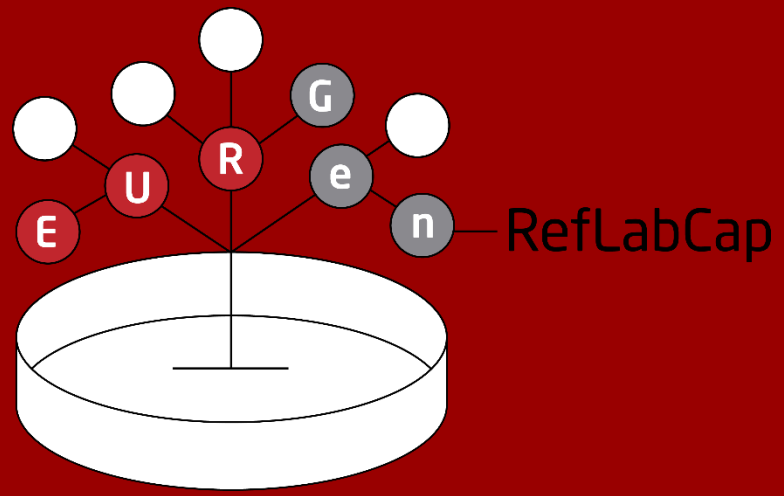
EURGen-RefLabCap webinar
19 January 2023
SC 2019 74 01



How to prepare an EQA for assessing AMR capability

Susanne Karlsmose Pedersen (suska@food.dtu.dk) DTU Food, Denmark

Aim of today's webinar

To support NRLs for capacity building in local and regional laboratories for detection and characterization of carbapenem and colistin resistant *Enterobacterales*, Carbapenem-resistant and/or colistin-resistant *Acinetobacter baumannii* complex and Carbapenem-resistant and/or colistin-resistant *Pseudomonas aeruginosa*

How to plan an External Quality Assessment (EQA)

- Give an overview of what is required when setting up an EQA, i.e.:
  - planning of activities,
  - launching activities, and
  - documenting that activities have been performed

Feel free to bring forward any input, questions, and suggestions – in the chat or orally

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO/IEC 17043

February 2010

ICS 03.120.20

English version

Conformity assessment - General requirements for proficiency testing (ISO/IEC 17043:2010)

Évaluation de la conformité - Exigences générales concernant les essais d'aptitude (ISO/IEC 17043:2010)

Konformitätsbewertung - Allgemeine Anforderungen an Eignungsprüfungen (ISO/IEC 17043:2010)

This European Standard was approved by CEN on 30 January 2010.

In short

An **Interlaboratory comparison** programme:

External quality assessment (EQA) programme or **proficiency testing (PT)** programme

i.e.:

A system for objectively checking the laboratory's performance using an external agency or facility

EQA programmes:

Typically designed to cover the full workflow of the laboratory.
The testing and reporting of test result may be extended with interpretation of results.
Aims to provide education to participants and promote quality improvement

See also 'Johnson and Cabuang; Proficiency testing and ring trials': *Rev. Sci. Tech. Off. Int. Epiz.*, 2021, **40** (1), 189-203

Why EQAs?

The laboratory may apply a number of tools to ensure that the produced results are valid and reliable, among others:

- Method controls
- Functional checks of equipment
- Replicate testing
- …
- Participation in proficiency testing

Also, EQA's:

- Provides early warning for systemic problems
- Provides objective evidence of testing quality
- May identify areas that need improvement
- May identify training needs
- Is a tool for the accreditation body (ISO 15189 / ISO 17025)
- Provides knowledge for laboratories and organizer

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EQA provider

- Define EQA
- Register participants
- Select test material
- Determine assigned values
- Arrange shipment
- Define how to receive submitted results
- Analyse results
- Provide evaluation

Participant

DTU

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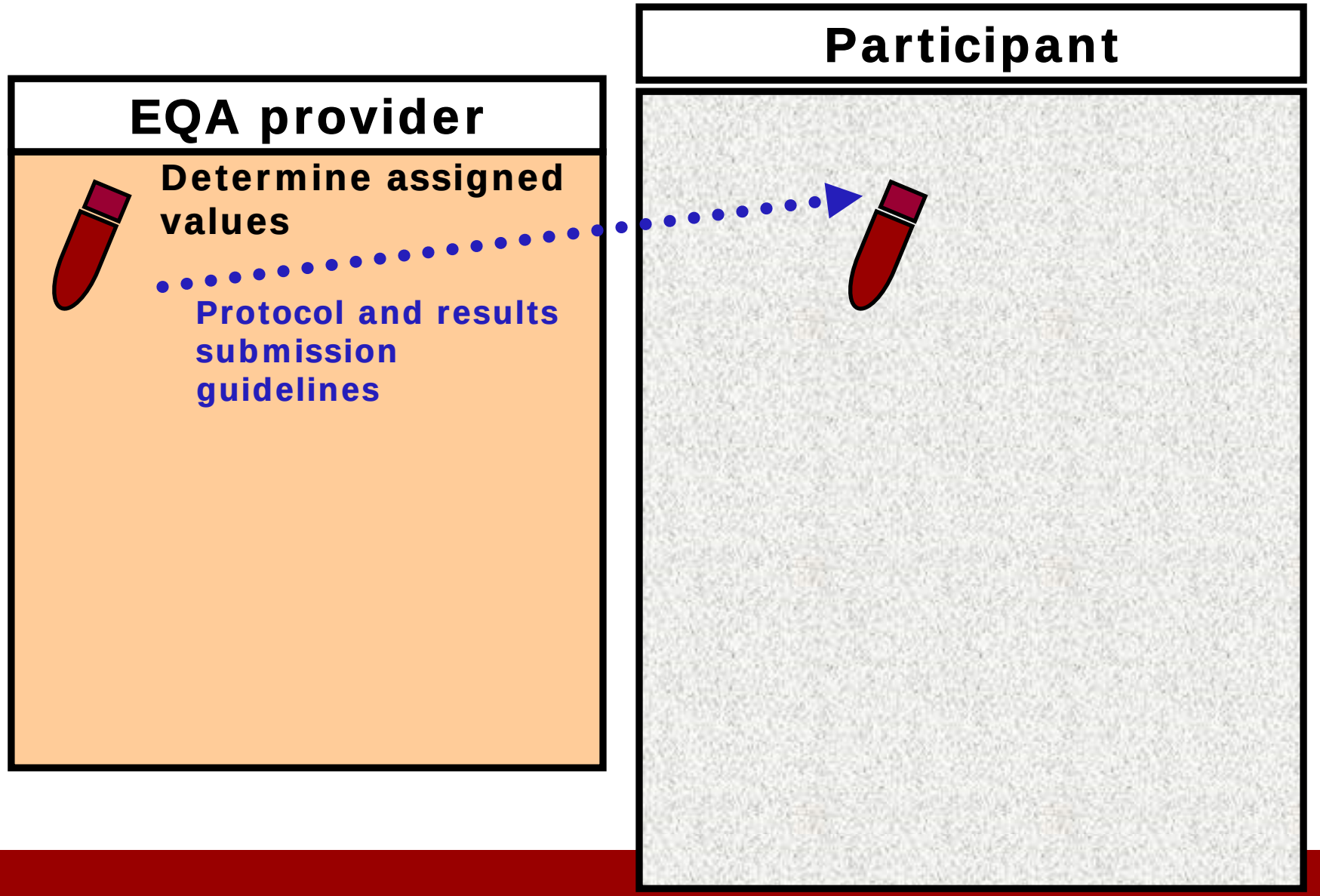
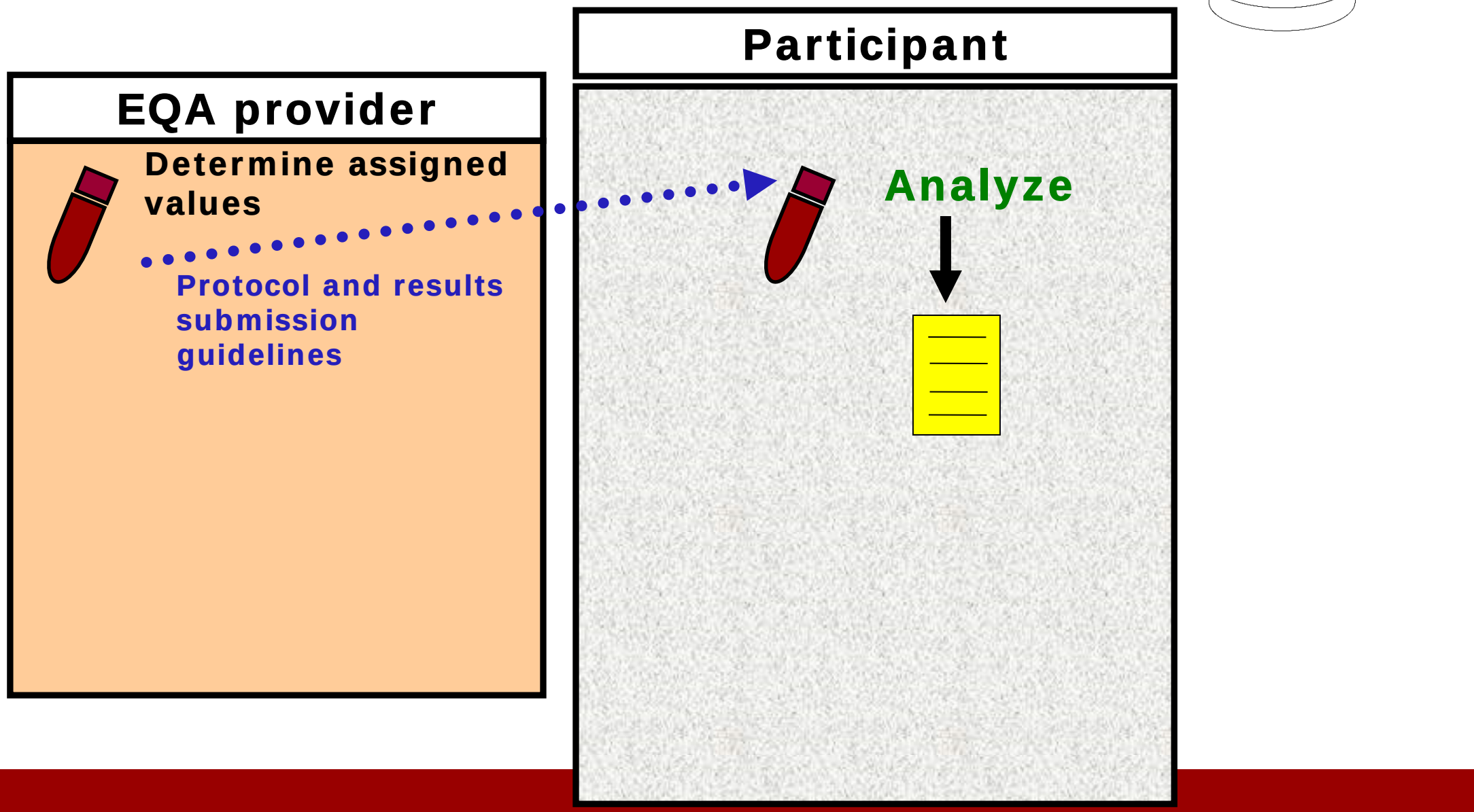
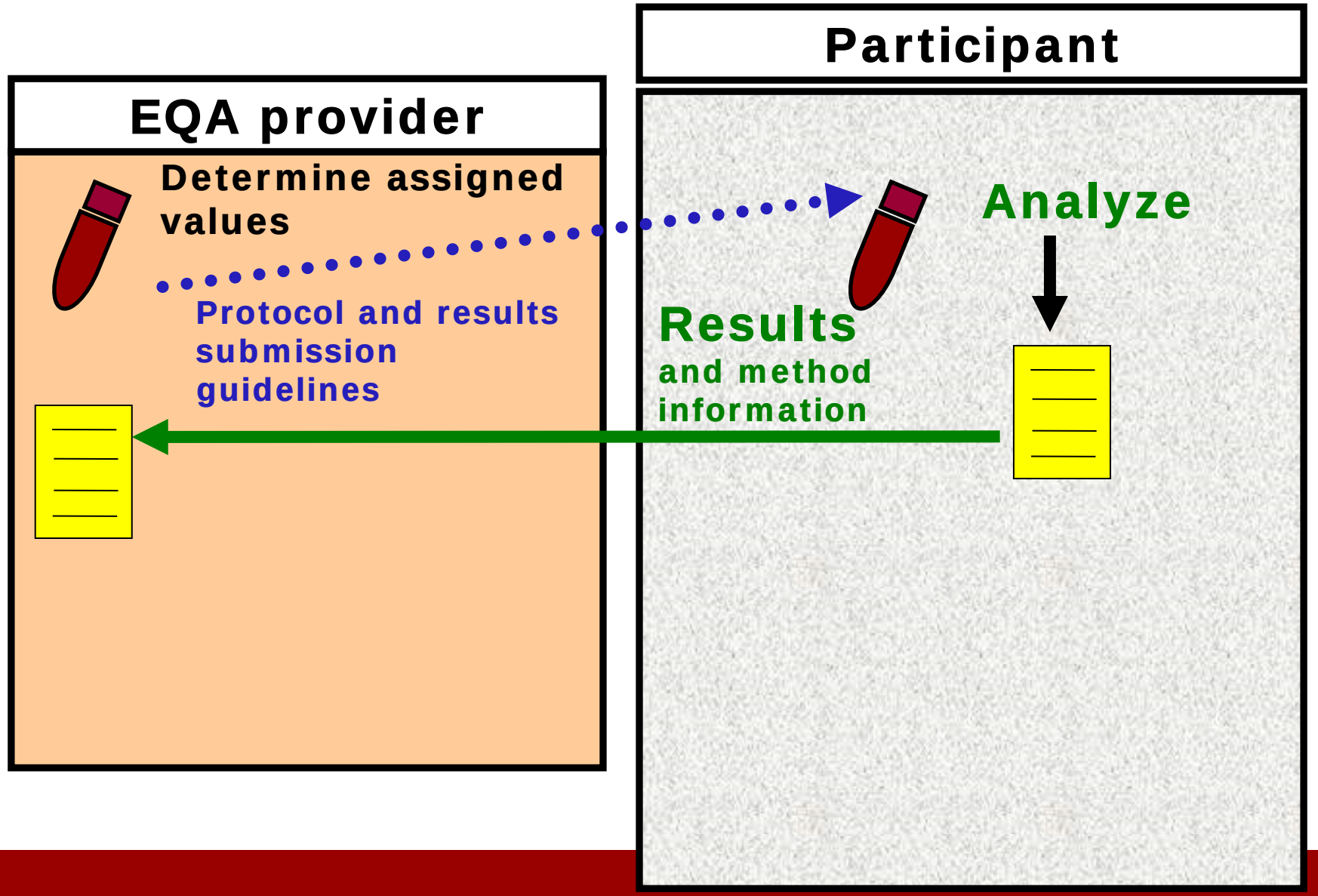
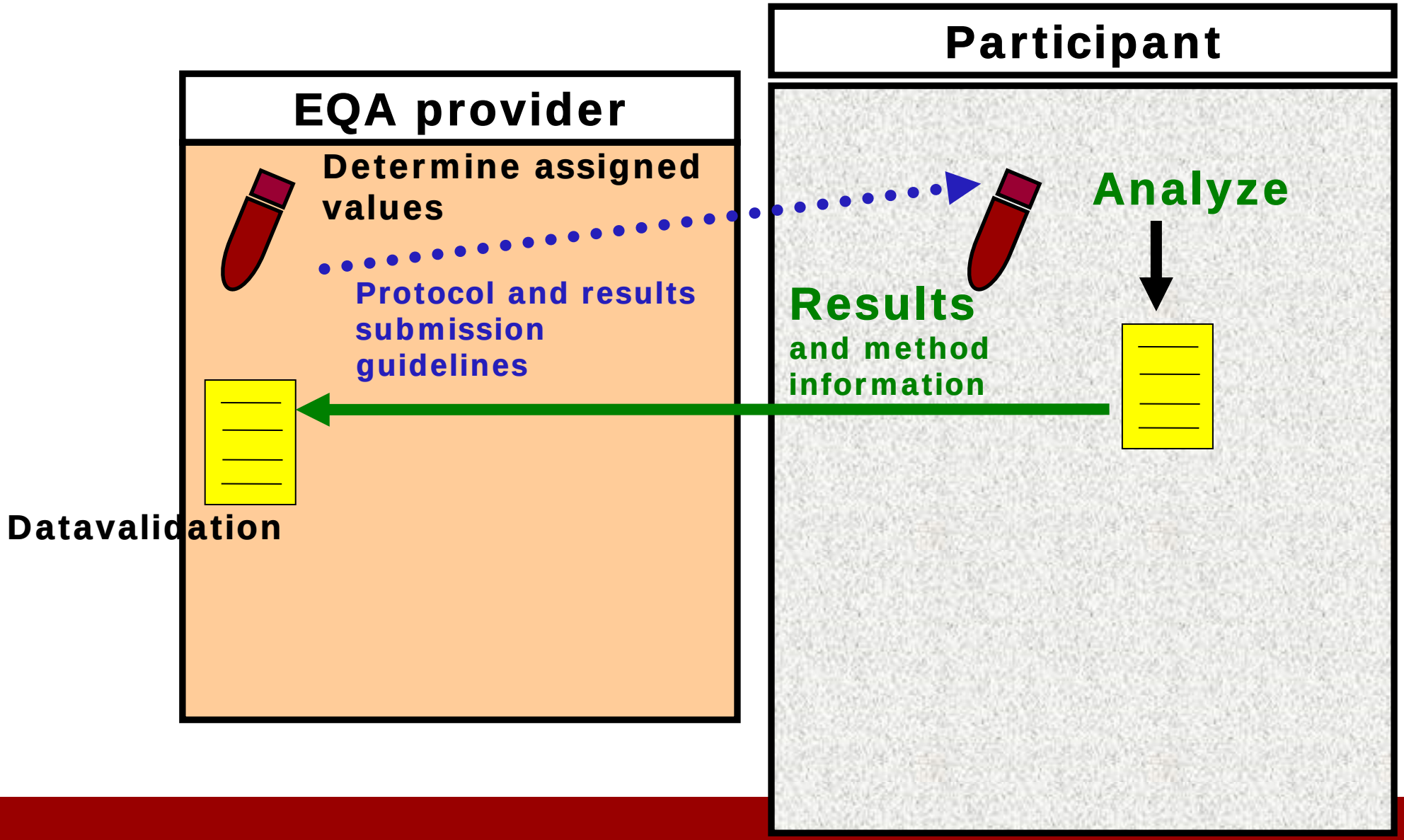
EQA provider

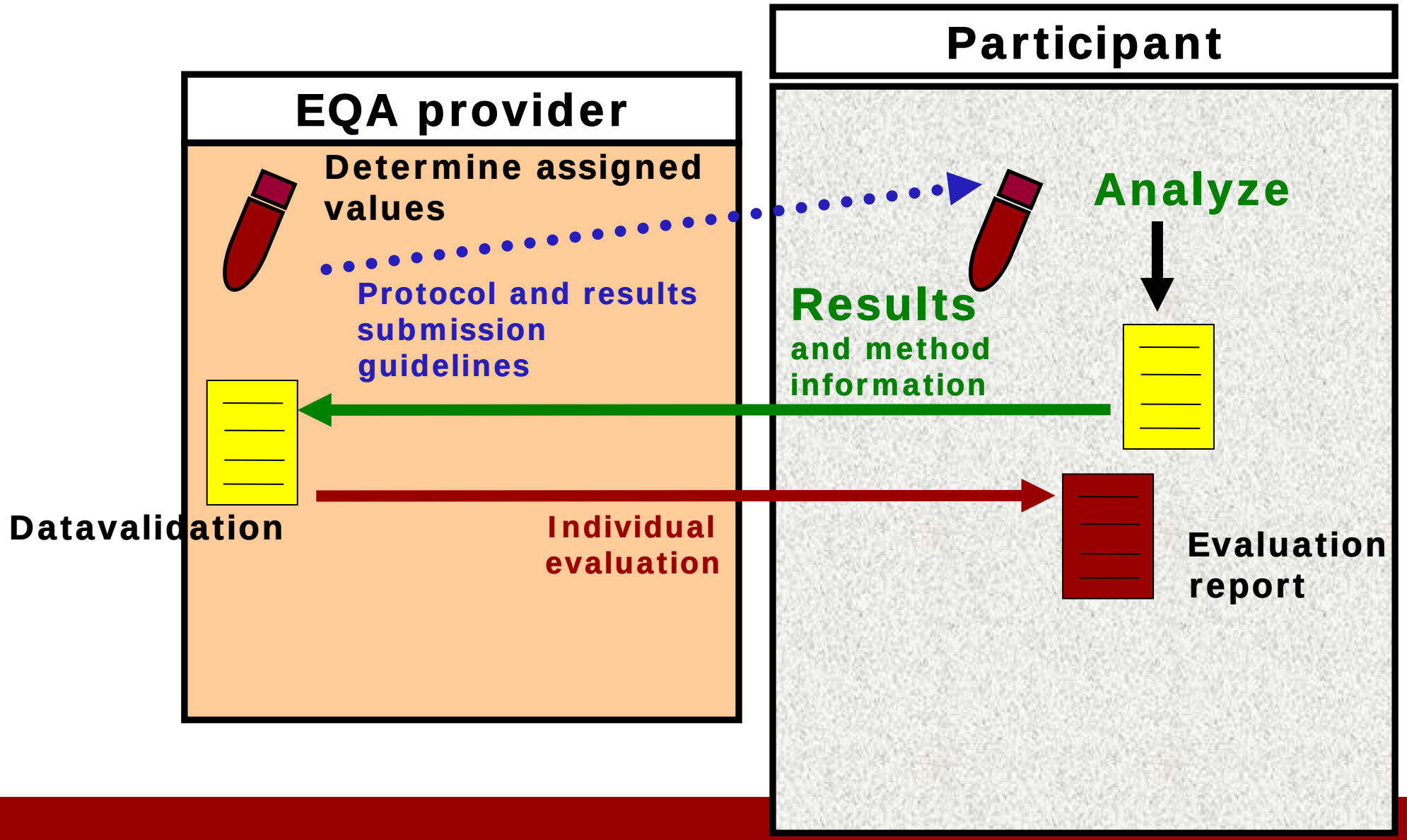
Participant

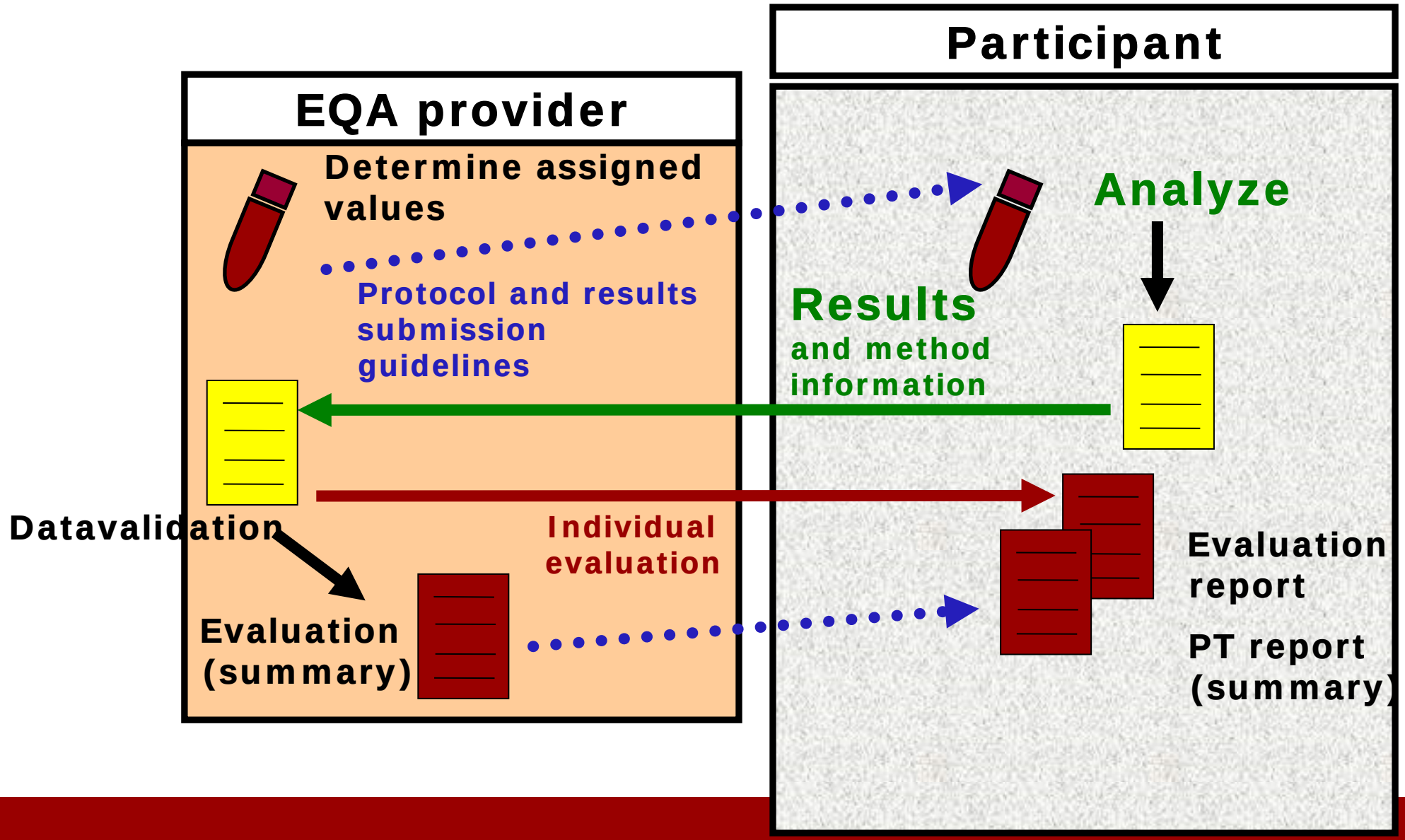

Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines

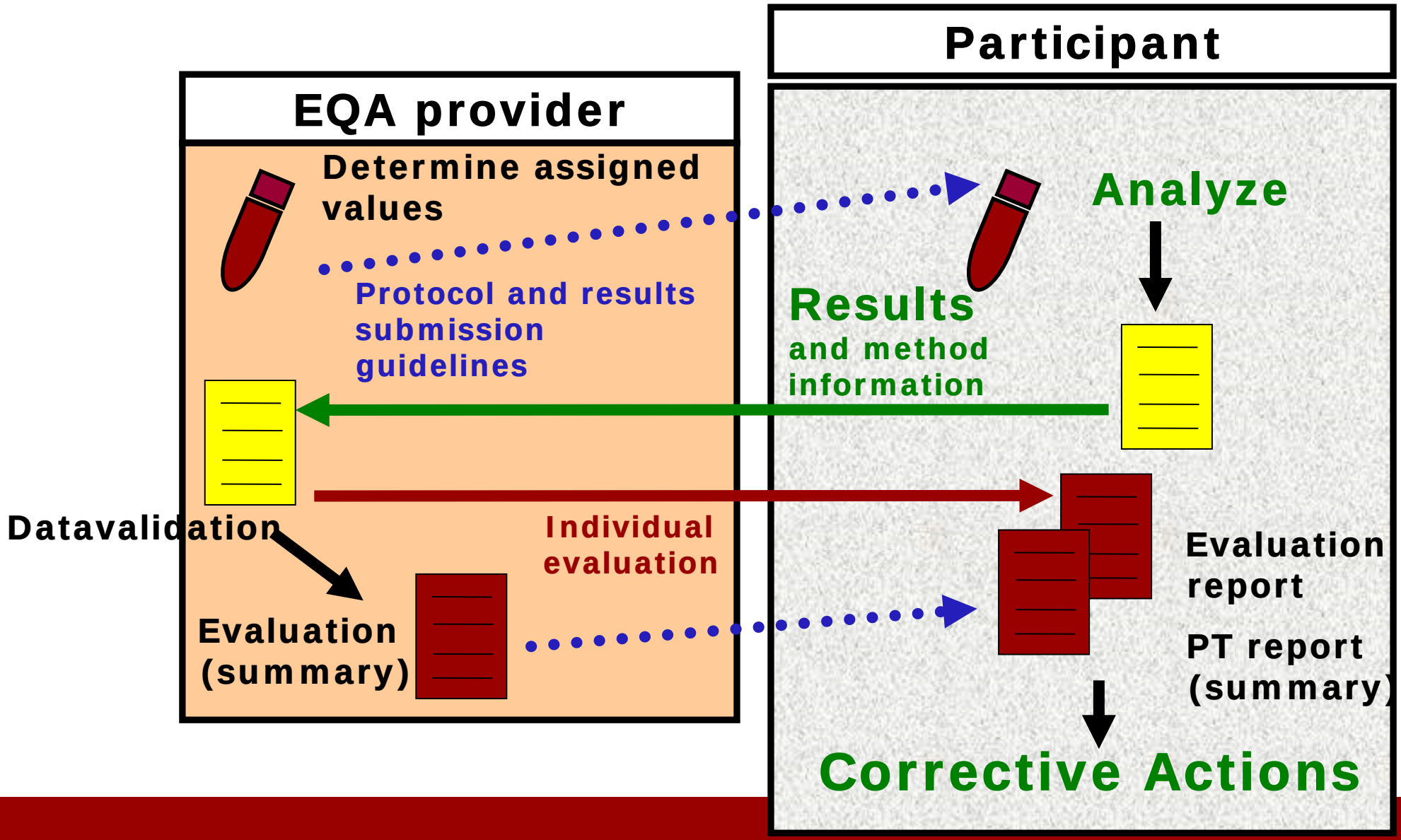

Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines
Analyze


Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines
Analyze
Results
and method information


Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines
Analyze
Results
and method information
Datavalidation


Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines
Analyze
Results
and method information
Datavalidation
Individual evaluation
Evaluation report


Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines
Analyze
Results
and method information
Datavalidation
Individual evaluation
Evaluation (summary)
Evaluation report
PT report (summary)


Participant
EQA provider
Determine assigned values
Protocol and results submission guidelines
Analyze
Results
and method information
Datavalidation
Individual evaluation
Evaluation report
PT report (summary)
Evaluation (summary)
Corrective Actions

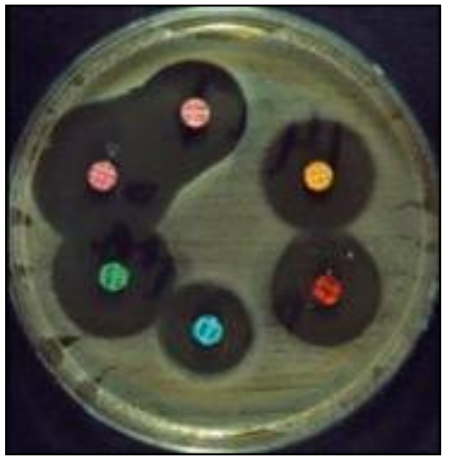
EQA test material

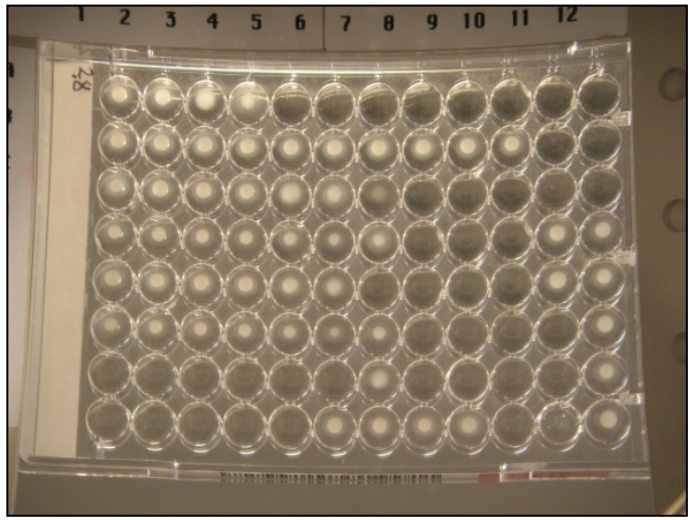
Pure cultures of microorganisms (DNA and/or sequences)

- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Acinetobacter baumannii*
- *Pseudomonas aeruginosa*

Methods for phenotypic antimicrobial susceptibility testing (AST)

- Broth microdilution
- Disk diffusion
- Whole genome sequencing





Technical requirements of the laboratory

EQA providers must

- Have **competence** to conduct interlaboratory comparisons (e.g. has ISO 15189 or ISO/IEC 17025 accreditation to demonstrate competence)
- Have (access to) **expertise** with the particular type of proficiency test items
  - Handling
  - Analysis (wet-lab)
  - Data analysis

Technical requirements of personnel

EQA providers' personnel must

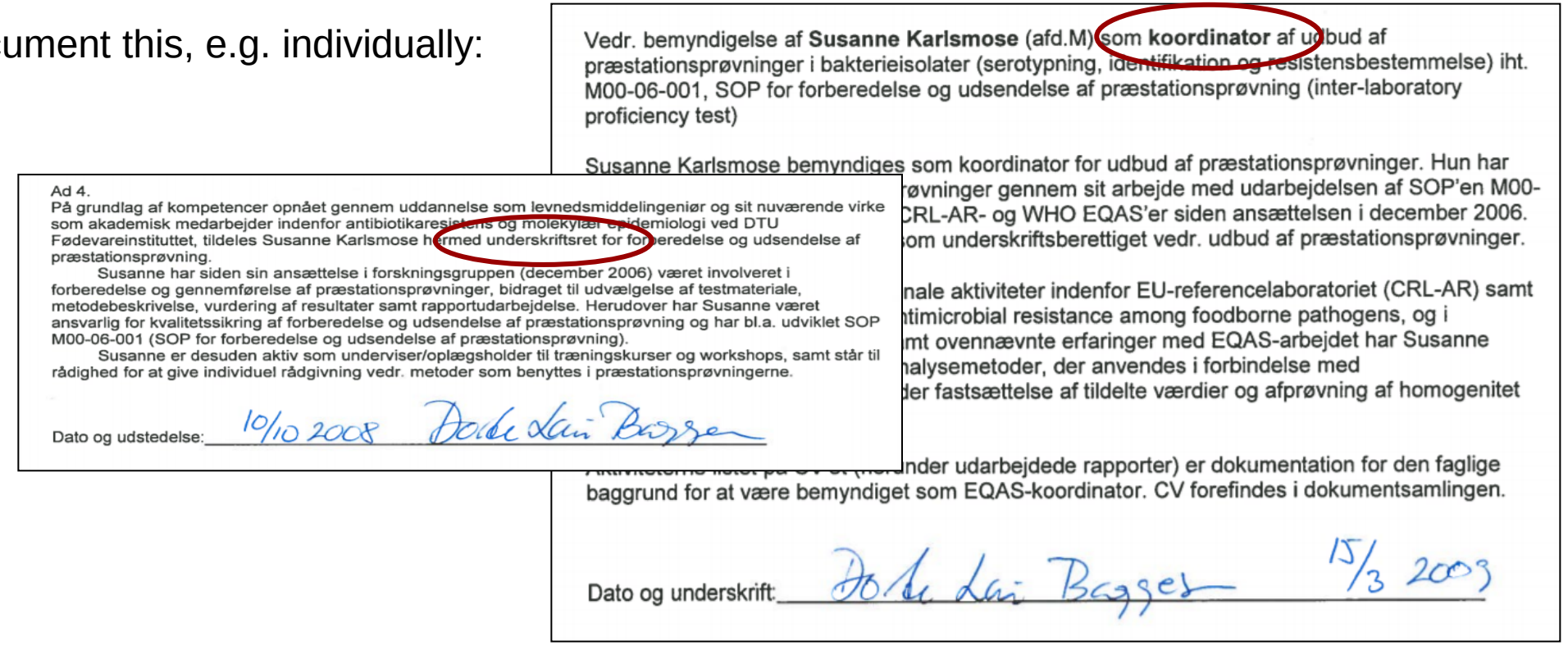
- Have necessary **authority, resources and technical competences** to perform their duties

Technical requirements of personnel

EQA providers' personnel must

- Have necessary **authority, resources and technical competences** to perform their duties

And document this, e.g. individually:



Vedr. bemyndigelse af **Susanne Karlsmose** (afd.M) som **koordinator** af udbud af præstationsprøvninger i bakterieisolater (serotypning, identifikation og resistensbestemmelse) iht. M00-06-001, SOP for forberedelse og udsendelse af præstationsprøvning (inter-laboratory proficiency test)

Susanne Karlsmose bemyndiges som koordinator for udbud af præstationsprøvninger. Hun har
røvninger gennem sit arbejde med udarbejdelsen af SOP'en M00-
RL-AR- og WHO EQAS'er siden ansættelsen i december 2006.
om underskriftsberettiget vedr. udbud af præstationsprøvninger.

nale aktiviteter indenfor EU-referencelaboratoriet (CRL-AR) samt
timicrobial resistance among foodborne pathogens, og i
mt ovennævnte erfaringer med EQAS-arbejdet har Susanne
nalysemetoder, der anvendes i forbindelse med
der fastsættelse af tildelte værdier og afprøvning af homogenitet

nder udarbejdede rapporter) er dokumentation for den faglige baggrund for at være bemyndiget som EQAS-koordinator. CV forefindes i dokumentsamlingen.

Dato og underskrift: Dorte Lau Baggesen 15/3 2003

Ad 4.
På grundlag af kompetencer opnået gennem uddannelse som levnedsmiddelingeniør og sit nuværende virke som akademisk medarbejder indenfor antibiotikaresistens og molekylær epidemiologi ved DTU Fødevareinstituttet, tildeles Susanne Karlsmose hermed underskriftsret for forberedelse og udsendelse af præstationsprøvning.

Susanne har siden sin ansættelse i forskningsgruppen (december 2006) været involveret i forberedelse og gennemførelse af præstationsprøvninger, bidraget til udvælgelse af testmateriale, metodebeskrivelse, vurdering af resultater samt rapportudarbejdelse. Herudover har Susanne været ansvarlig for kvalitetssikring af forberedelse og udsendelse af præstationsprøvning og har bl.a. udviklet SOP M00-06-001 (SOP for forberedelse og udsendelse af præstationsprøvning).

Susanne er desuden aktiv som underviser/oplægsholder til træningskurser og workshops, samt står til rådighed for at give individuel rådgivning vedr. metoder som benyttes i præstationsprøvningerne.

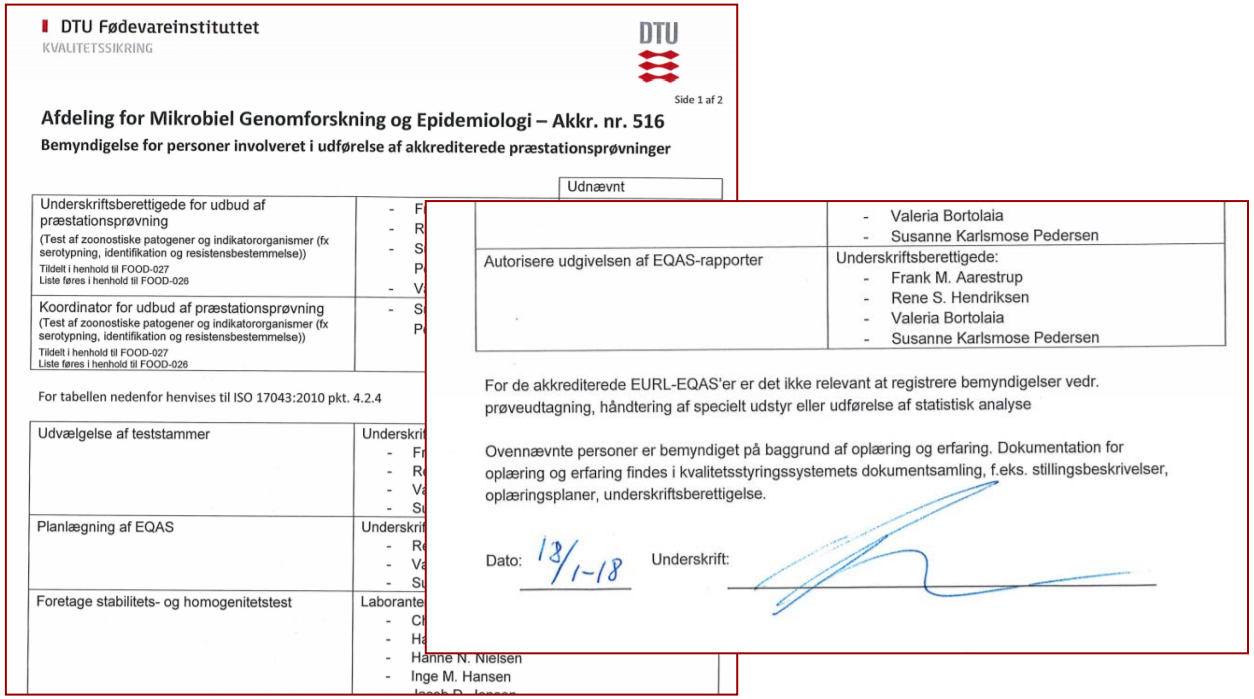
Dato og udstedelse: 10/10 2008 Dorte Lau Baggesen

Technical requirements of personnel

EQA providers' personnel must

- Have necessary **authority, resources and technical competences** to perform their duties

And document this, e.g. as a group:



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Side 1 af 2

Afdeling for Mikrobiel Genomforskning og Epidemiologi – Akkr. nr. 516

Bemyndigelse for personer involveret i udførelse af akkrediterede præstationsprøvninger

	Udnævnt
Underskriftsberettigede for udbud af præstationsprøvning (Test af zoonostiske patogener og indikatororganismer (fx serotypning, identifikation og resistensbestemmelse)) Tildelt i henhold til FOOD-027 Liste føres i henhold til FOOD-026	- F - R - S P - V
Koordinator for udbud af præstationsprøvning (Test af zoonostiske patogener og indikatororganismer (fx serotypning, identifikation og resistensbestemmelse)) Tildelt i henhold til FOOD-027 Liste føres i henhold til FOOD-026	- S P

For tabellen nedenfor henvises til ISO 17043:2010 pkt. 4.2.4

Udvælgelse af teststammer	Underskrif - Fr - R - Va - Su
Planlægning af EQAS	Underskrif - R - Va - Su
Foretage stabilitets- og homogenitetstest	Laborante - Ch - Ha - Hanne N. Nielsen - Inge M. Hansen

	- Valeria Bortolaia - Susanne Karlsmose Pedersen
Autorisere udgivelsen af EQAS-rapporter	Underskriftsberettigede: - Frank M. Aarestrup - Rene S. Hendriksen - Valeria Bortolaia - Susanne Karlsmose Pedersen

For de akkrediterede EURL-EQAS'er er det ikke relevant at registrere bemyndigelser vedr. prøveudtagning, håndtering af specielt udstyr eller udførelse af statistisk analyse

Ovennævnte personer er bemyndiget på baggrund af oplæring og erfaring. Dokumentation for oplæring og erfaring findes i kvalitetsstyringssystemets dokumentsamling, f.eks. stillingsbeskrivelser, oplæringsplaner, underskriftsberettigelse.

Dato: 13/1-18 Underskrift:

Technical requirements – facilities, equipment

Facilities and **equipment** must be in place for

- Handling EQA items
- **Producing EQA items**
- Testing
- **Storage**
- **Packing**
- **Despatch**
- Data processing
- Communications
- Retrieval of materials and records

- Document when necessary:

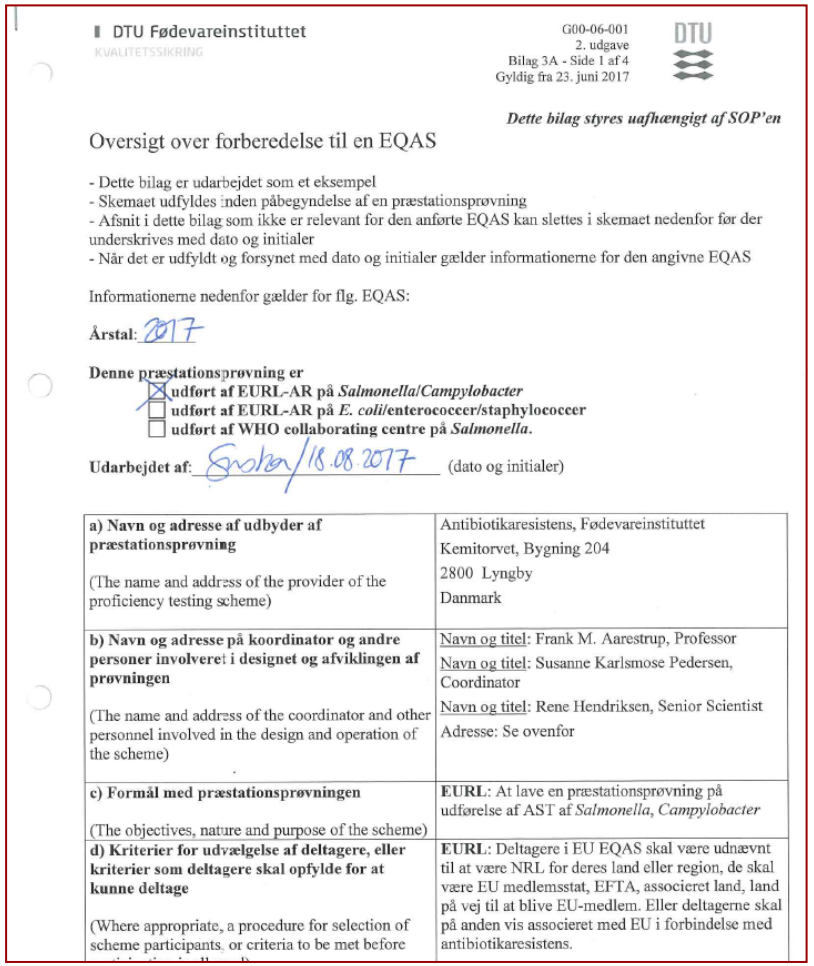
For equipment, consider the same principles as for ISO 15189 and ISO 17025

Design of an EQA scheme

- Plan
- Prepare EQA test items
- Perform homogeneity and stability tests
- Consider statistical design
- Determine assigned values

Design of an EQA scheme - plan

- **Plan**
- Prepare EQA test items
- Perform homogeneity and stability tests
- Consider statistical design
- Determine assigned values



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G00-06-001
2. udgave
Bilag 3A - Side 1 af 4
Gyldig fra 23. juni 2017

Dette bilag styres uafhængigt af SOP'en

Oversigt over forberedelse til en EQAS

- Dette bilag er udarbejdet som et eksempel
- Skemaet udfyldes inden påbegyndelse af en præstationsprøvning
- Afsnit i dette bilag som ikke er relevant for den anførte EQAS kan slettes i skemaet nedenfor før der underskrives med dato og initialer
- Når det er udfyldt og forsynet med dato og initialer gælder informationerne for den angivne EQAS

Informationerne nedenfor gælder for flg. EQAS:

Årstal: 2017

Denne præstationsprøvning er
- ☒ **udført af EURL-AR på *Salmonella/Campylobacter***
- ☐ **udført af EURL-AR på *E. coli*/enterococcer/staphylococcer**
- ☐ **udført af WHO collaborating centre på *Salmonella*.**

Udarbejdet af: Susan/18.08.2017 (dato og initialer)

a) Navn og adresse af udbyder af præstationsprøvning (The name and address of the provider of the proficiency testing scheme)	Antibiotikaresistens, Fødevareinstituttet Kemitorvet, Bygning 204 2800 Lyngby Danmark
b) Navn og adresse på koordinator og andre personer involveret i designet og afviklingen af prøvningen (The name and address of the coordinator and other personnel involved in the design and operation of the scheme)	Navn og titel: Frank M. Aarestrup, Professor Navn og titel: Susanne Karlsmose Pedersen, Coordinator Navn og titel: Rene Hendriksen, Senior Scientist Adresse: Se ovenfor
c) Formål med præstationsprøvningen (The objectives, nature and purpose of the scheme)	**EURL**: At lave en præstationsprøvning på udførelse af AST af *Salmonella*, *Campylobacter*
d) Kriterier for udvælgelse af deltagere, eller kriterier som deltagere skal opfylde for at kunne deltage (Where appropriate, a procedure for selection of scheme participants, or criteria to be met before	**EURL**: Deltagere i EU EQAS skal være udnævnt til at være NRL for deres land eller region, de skal være EU medlemsstat, EFTA, associeret land, land på vej til at blive EU-medlem. Eller deltagerne skal på anden vis associeret med EU i forbindelse med antibiotikaresistens.

Design of an EQA scheme - plan

- **Plan**
- Prepare EQA test items
- Perform homogeneity and stability tests
- Consider statistical design
- Determine assigned values

Example, checklist

For the relevant of the following tasks, the results are archived in the EQAS binder.

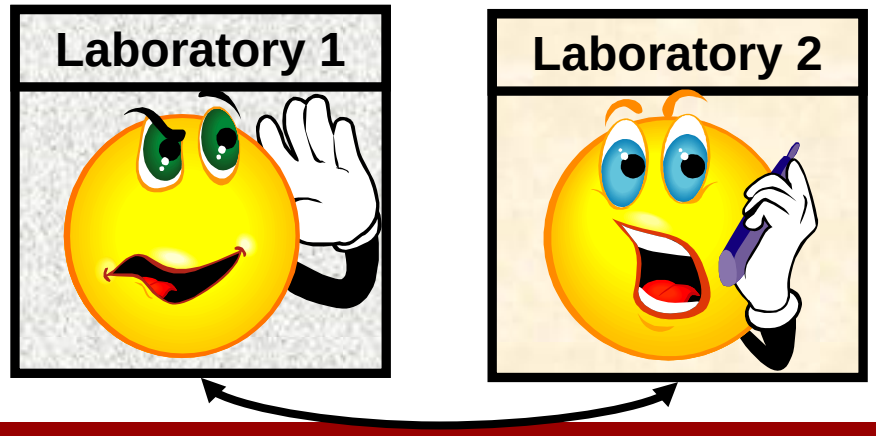
	Appendix (Bilag)	Date/initials
Project description made (for technician) (Projektbeskrivelse udarbejdet (til laboranten))		
Overview over preparation of EQAS filled in (Oversigt over forberedelse af en EQAS udfyldt)	3A	
Prenotification sent (Fremsendelse af prænotifikation)	4A	
Make sure we have the relevant ref-strains (ATCC), otherwise order new ones (Tjekke op på referencestammer, evt. bestille nye)	-	
Ask about import permits (Forespørge til eventuelle importtilladelser)	-	
Prepare test forms (Forberede testforms)	4D	
Prepare protocol (Forberede protokol)	4D	
Prepare 'Instructions for opening and reviving lyophilised cultures' (Forberede 'Instructions for opening and reviving	4E	

Design of an EQA scheme - plan

Planning includes having an overview (written/document, where relevant) of:

- Who is the provider (institution)
- Who is the coordinator (person)
- Activities subcontracted?
- Criteria to meet for participation
- Number and type of expected participants in the EQA
- Information on what the participants are to identify
- Reasonable precautions to prevent collusion/falsification of results

No discussion between labs!



Design of an EQA scheme - plan

Planning includes having an overview (written/document, where relevant) of:

- Who is the provider (institution)
- Who is the coordinator (person)
- Activities subcontracted?
- Criteria to meet for participation
- Number and type of expected participants in the EQA
- Information on what the participants are to identify
- Reasonable precautions to prevent collusion/falsification of results
- Origin of assigned values
- Criteria for the evaluation of the performance
- To which extent will the results and conclusions be made public?
- What will be done in case of lost of damaged EQA test items

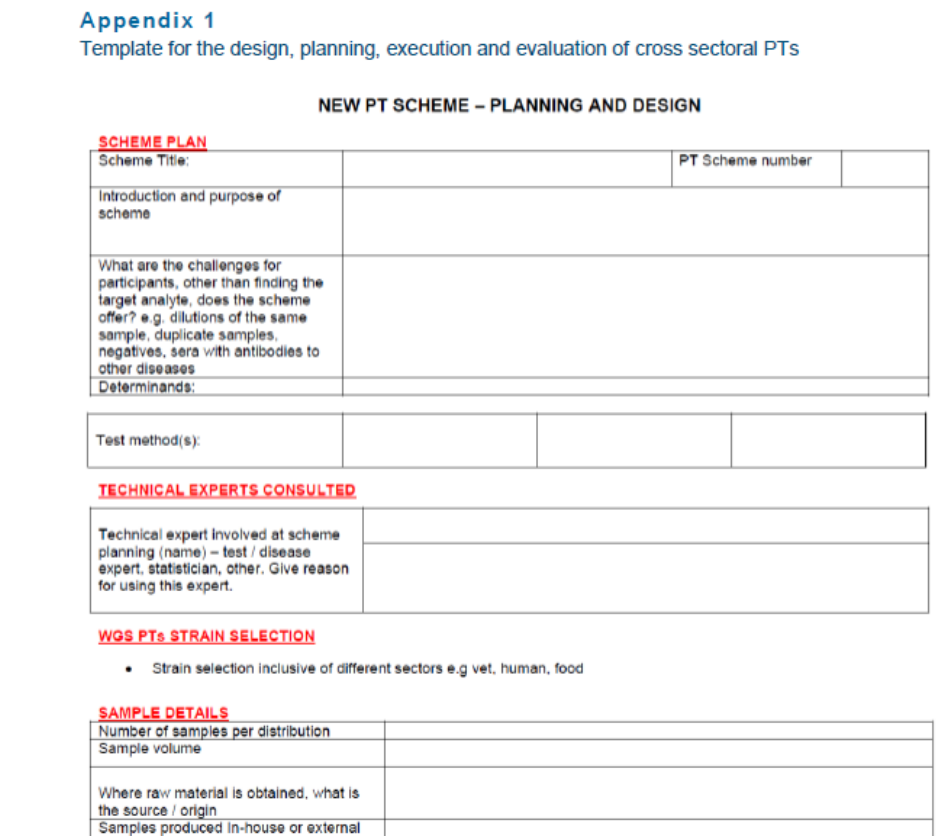
Design of an EQA scheme - plan

For a new EQA to be setup, consider **detailing** and **documenting** the plan

Suggestion for setup developed by the OHEJP CARE project:

‘D 1.3.2 SOPs for specific WGS proficiency testing distributions’

(available via: https://zenodo.org/record/7467902#.Y8F8Z3bMKUl)



Appendix 1

Template for the design, planning, execution and evaluation of cross sectoral PTs

NEW PT SCHEME – PLANNING AND DESIGN

SCHEME PLAN

Scheme Title:		PT Scheme number	
Introduction and purpose of scheme			
What are the challenges for participants, other than finding the target analyte, does the scheme offer? e.g. dilutions of the same sample, duplicate samples, negatives, sera with antibodies to other diseases			
Determinands:			
Test method(s):			

TECHNICAL EXPERTS CONSULTED

Technical expert involved at scheme planning (name) – test / disease expert, statistician, other. Give reason for using this expert.	

WGS PTs STRAIN SELECTION

- Strain selection inclusive of different sectors e.g vet, human, food

SAMPLE DETAILS

Number of samples per distribution	
Sample volume	
Where raw material is obtained, what is the source / origin	
Samples produced in-house or external	

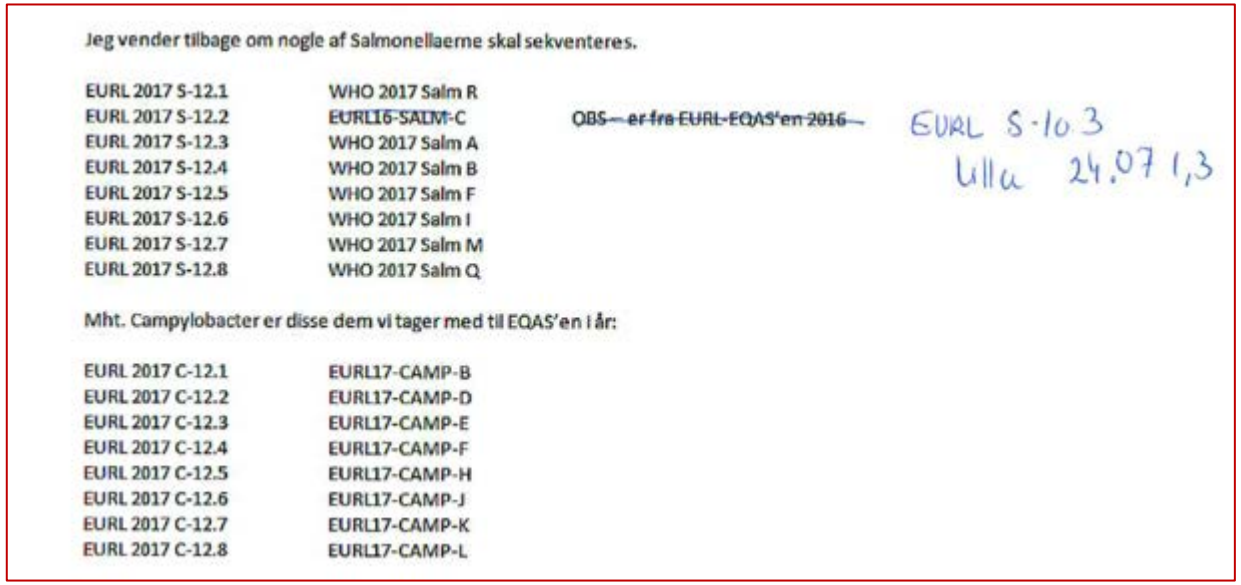
Design of an EQA scheme – EQA test items

- Plan
- **Prepare EQA test items**
- Perform homogeneity and stability tests
- Consider statistical design
- Determine assigned values

For the selected EQA test items:

Metadata for the archives

Material transfer agreements?



Jeg vender tilbage om nogle af Salmonellaerne skal sekventeres.

EURL 2017 S-12.1	WHO 2017 Salm R	
EURL 2017 S-12.2	~~EURL16-SALM-C~~	~~OBS – er fra EURL-EQAS'en 2016~~
EURL 2017 S-12.3	WHO 2017 Salm A	
EURL 2017 S-12.4	WHO 2017 Salm B	
EURL 2017 S-12.5	WHO 2017 Salm F	
EURL 2017 S-12.6	WHO 2017 Salm I	
EURL 2017 S-12.7	WHO 2017 Salm M	
EURL 2017 S-12.8	WHO 2017 Salm Q	

EURL S-10.3
Lilla 24.07 1,3

Mht. Campylobacter er disse dem vi tager med til EQAS'en i år:

EURL 2017 C-12.1	EURL17-CAMP-B
EURL 2017 C-12.2	EURL17-CAMP-D
EURL 2017 C-12.3	EURL17-CAMP-E
EURL 2017 C-12.4	EURL17-CAMP-F
EURL 2017 C-12.5	EURL17-CAMP-H
EURL 2017 C-12.6	EURL17-CAMP-J
EURL 2017 C-12.7	EURL17-CAMP-K
EURL 2017 C-12.8	EURL17-CAMP-L

Design of an EQA scheme – EQA test items

- Plan
- **Prepare EQA test items** → Batch control of media
- Perform homogeneity and stability tests
- Consider statistical design
- Determine assigned values

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G06-00-006
1. udgave
Bilag 1 - Side 1 af 1

Bilag 1: Oversigt over udsæd, inkubation og aflæsning af substrater i forbindelse med performancekontrol

Organisme/test	Udsæd og inkubation	Aflæsning	Udsæd (dato/init.)	Aflæsning (dato/init.)	OK (ja/nej)	Evt. kommentar
Nutrient agar stik (1 rør) **TSA-plader med blod** (2 plader)		Batch nr./holdbarhed: 2017 - 11-19 Batch nr./holdbarhed: 2017 / 06 / 27				
Intern referencestamme (*S.* Enteritidis 9874091-5 eller *Salmonella* spp. 7522438)	Stik: Tilsåning og inkubation ved 37°C i 16-24 timer.	Synlig vækst i stik ✓	30/5-17 Imhq	1/6-17 Imhq		
	Blodplade: Udsæd på TSA med blod og inkubation ved 37°C i 16-24 timer.	Vækst: god og ukontamineret ✓	29-5-17 IMHA	30-5-17 IMHA	✓	
Sterilkontrol (TSA)	Utilsået plade inkuberes ved 37°C i 16-24 timer	Sterilkontrol: Ingen kolonier efter 16-24 timer ✓			✓	
Luria Bertani bouillon med 15% glycerol (2 rør)		Batch nr./holdbarhed:				
Steril kontrol	Fra de utilsåede rør udtages 100 µl medium der plades ud på en blodplade. Inkubation ved 37°C i 48 timer.	Sterilkontrol: Ingen vækst, aflæses efter 24 og 48 timer				
Intern referencestamme (*S.* Enteritidis 9874091-5 eller *Salmonella* spp. 7522438)	Rendyrket *Salmonella*-stamme overføres ved hjælp af øjepodenål til røret, der placeres ved -80°C i 16-24 timer. Udsæd på TSA med blod og inkubation ved 37°C i 16-24 timer.	Vækst: god og ukontamineret				

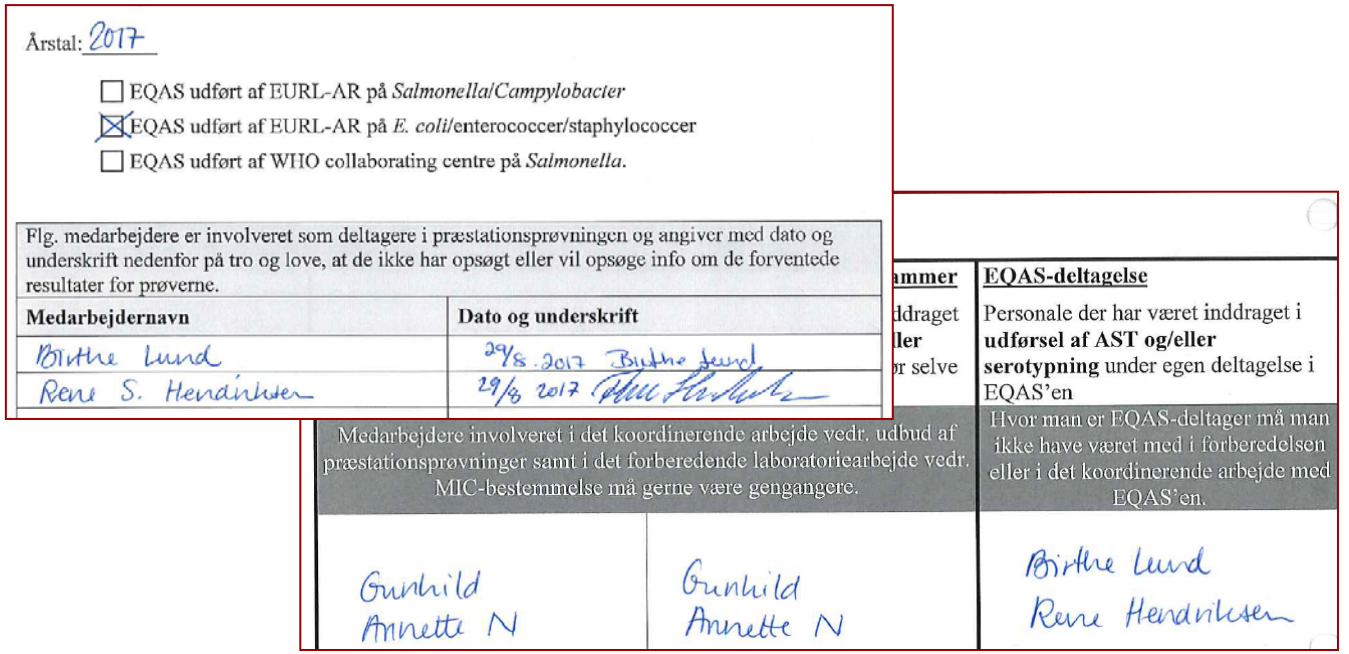
Udskrevet d.: 18-05-2015

Design of an EQA scheme – EQA test items

- Plan
- **Prepare EQA test items**
- Perform homogeneity and stability tests
- Consider statistical design
- Determine assigned values

Consider – should provider's own personnel participate in the EQA?

If so, consider making colleagues participating sign that they 'solemnly declare' they will not look for data/info from the preparatory work



Årstal: 2017

☐ EQAS udført af EURL-AR på *Salmonella/Campylobacter*

☒ EQAS udført af EURL-AR på *E. coli*/enterococcer/staphylococcer

☐ EQAS udført af WHO collaborating centre på *Salmonella*.

Flg. medarbejdere er involveret som deltagere i præstationsprøvningen og angiver med dato og underskrift nedenfor på tro og love, at de ikke har opsøgt eller vil opsøge info om de forventede resultater for prøverne.

Medarbejdernavn	Dato og underskrift
Birthe Lund	29/8.2017 Birthe Lund
Rene S. Hendriksen	29/8 2017

ammer	EQAS-deltagelse
ddraget ller r selve	Personale der har været inddraget i **udførsel af AST og/eller serotypning** under egen deltagelse i EQAS'en

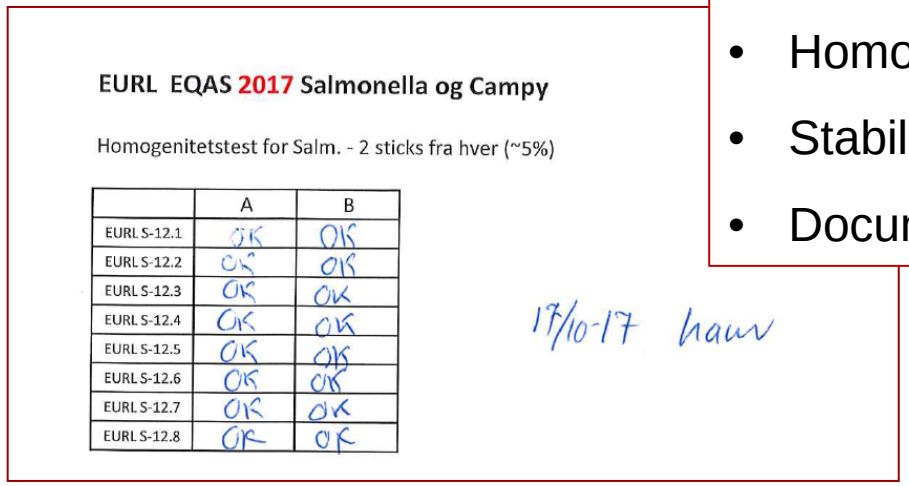
Medarbejdere involveret i det koordinerende arbejde vedr. udbud af præstationsprøvninger samt i det forberedende laboratoriearbejde vedr. MIC-bestemmelse må gerne være gengangere.		Hvor man er EQAS-deltager må man ikke have været med i forberedelsen eller i det koordinerende arbejde med EQAS'en.
Gunhild Annette N	Gunhild Annette N	Birthe Lund Rene Hendriksen

Design of an EQA scheme – homogeneity and stability

- Plan
- Prepare EQA test items
- **Perform homogeneity and stability tests**
- Consider statistical design
- Determine assigned values

Participants must receive comparable EQA test items, i.e.:

- Establish criteria for suitable homogeneity and stability tests - which extent is required?
- Homogeniety tests (viability/purity)
- Stability tests
- Document!



EURL EQAS 2017 Salmonella og Campy

Homogenitetstest for Salm. - 2 sticks fra hver (~5%)

	A	B
EURL S-12.1	OK	OK
EURL S-12.2	OK	OK
EURL S-12.3	OK	OK
EURL S-12.4	OK	OK
EURL S-12.5	OK	OK
EURL S-12.6	OK	OK
EURL S-12.7	OK	OK
EURL S-12.8	OK	OK

17/10-17 hauv

Design of an EQA scheme – statistical design

- Plan
- Prepare EQA test items
- Perform homogeneity and stability tests
- **Consider statistical design**
- Determine assigned values

Design of an EQA scheme – assigned values

- Plan
- Prepare EQA test items
- Perform homogeneity and stability tests
- Consider statistical design
- **Determine assigned values**

Example:

- Select candidate bacterial isolates
- For these:
  - Previous test results?
  - In-house test
  - In-house re-testing
  - Verification of results at external laboratory
  - Select test isolates
  - Prepare test isolates for shipping
  - After production of the test strains, confirm results (and perform homogeneity test)

  => document!

Design of an EQA scheme – assigned values

- Plan
- Prepare EQA test items
- Perform homogeneity and stability tests
- Consider statistical design
- **Determine assigned values**

Or:

- Consensus value as the assigned value
  => document!

Operation of an EQA scheme

- Instructions for participants
- EQA test items handling and storage
- Packaging, labelling and distribution of EQA test items

Operation of an EQA scheme

Give detailed documented instructions to all participants, including

- Conditions of storage of EQA test items
- Methods to apply for the testing
- Timing of the testing
- Any appropriate instructions on handling the EQA test items (e.g. biosafety issues)
- Specific and detailed instructions on how to record and report test results
- Deadline for submitting results
- Contact details for the EQA provider

Operation of an EQA scheme

Give detailed documented instructions to all participants, including

- Conditions of storage of EQA test items
- Methods to apply for the testing
- Timing of the testing
- Any appropriate instructions on handling the EQA test items (e.g. biosafety issues)
- Specific and detailed instructions on how to record and report test results
- Deadline for submitting results
- Contact details for the EQA provider

Normally test method of the participants' choice, which should be consistent with their routine procedure – if so, take steps to assess participants' results based on the relevant methods.

Though, instructions may be given to use a specified method.

Data analysis and evaluation

Consider how to receive results

Consider which data processing equipment and software to use

Ensure that computer system maintenance includes a back-up process and system recovery plan

Record and analyse results received from participants by appropriate methods

- Procedures to check
  - The validity of data entry
  - Data transfer
  - Reporting
- Consider how to identify and handle potential outliers
  - Robust statistical method?!

Data analysis and evaluation

Everything does not always go according to plan…

EQA providers need to be able to identify and manage EQA items that have been distributed and are subsequently found to be **unsuitable for performance evaluation**, e.g. because of inhomogeneity, instability, damage or contamination

⇒ Experience with time
⇒ Case by case approach typically necessary

Data analysis and evaluation

Use valid methods for evaluation

- Describe the basis of the evaluation

- Where appropriate for the purpose of the EQA, provide expert comments on the participants' performance with regard to e.g.:
  - Overall performance
  - Variation within and between participants
  - Variation between methods
  - Possible sources of errors
  - Suggestions for improving performance
  - Advice and educational feedback
  - Conclusion

EQA report

Let an EQA report be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants

Let the report include

- Procedures used to establish assigned values
- Comments on participants performance by EQA provider (and technical advisors, if any)
- Comments or recommendations based on the outcomes of the EQA round

E.g.: Report in review with technical advisors before finally publishing the report

Communication with participants

Detailed information must be available about the EQA, i.e. on:

- the scope
- fees
- eligibility criteria for participation
- confidentiality arrangements
- how to apply/register

‘Black-on-white’ is preferred, i.e.:

Email, website, hard copy letters, submission database

Less recommendable, maybe: ftp-folder, phone

Communication with participants – prenotification

Example:

EURGen-RefLab
(EQA) 2022

Prenotification

The EURGen-RefLabCap Extern
contract with the European He
Directorate-General for Health
European Centre for Disease P
the provision of EU networking
antimicrobial resistance in prio
jointly by the lead of the contr
and the co-contractor National
Statens Serum Institut (SSI).

1 WHY PARTICIPATE IN THE

The External Quality Assessme
production of reliable and accu
of whole genome sequencing
strengths and weaknesses in t
actions for improvement of th
of high-risk clones of the patho

2 WHAT IS THE EURGEN-RE

In the EURGen-RefLabCap EQA
FASTA files are sequences of t
read sequencing (Illumina tech
The results requested from the

(MLST), plasmid replicon types
antimicrobial resistance and in

Note that the analysis related
between a bioinformatician an
resistance.

The EQA organizers encourage
the laboratory's standard proc
to use FASTA files as input, the
corresponding to the test mate

3 WHO CAN PARTICIPATE?

Laboratories from the EURGen

4 COSTS FOR PARTICIPATIO

There is no participation fee fo
are, however, expected to cov
files in relation to their particip

5 HOW TO REGISTER FOR P

Sign-up for the EURGen-RefLab
09-2022

The provided test material (FA
technology (short reads) or on
registration form allows for sig
technologies.

6 PROTOCOL AND FURTHER INFORMATION

The protocol including appendices will be made available for download via this website:
https://www.eurgen-reflabcap.eu/resources/eqa

Each participating laboratory will receive an individual summary with an evaluation of the obtained results. Moreover, an overall report summarizing the results in an anonymized form will be published after written consultation with the participants. The report will be shared with the EC, the ECDC and will be publicly available on the EURGen-RefLabCap website.

Authors and co-authors of the publications will be those who have contributed to the preparation and execution of the EQA. Due to the anonymity of performance results, the individual participating coordinators and colleagues in the laboratories will not be acknowledged in the publications. Instead the participating laboratories will be asked if they would like to be acknowledged in the publications, and by which specific laboratory name, place and organization as indicated via the sign-up form.

7 TIMELINE

Registration to participate in the EURGen-RefLabCap EQA 2022 by **16 September 2022.**

Test material (FASTA files) and protocol are made available on **30 September 2022.**

Results must be submitted electronically **no later than 31 October 2022.**

Individual feedback reports made available to all participants **in December 2022.**

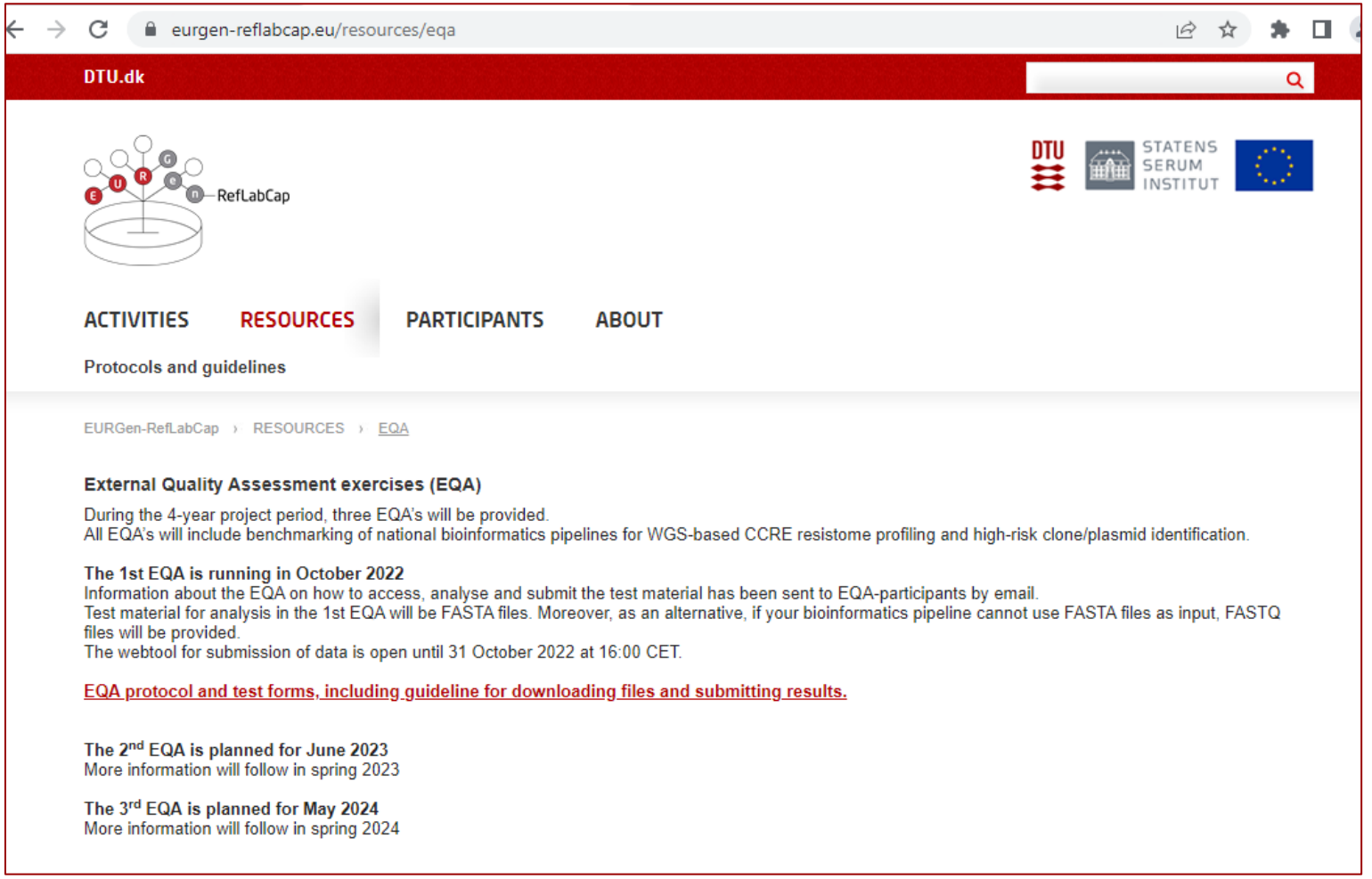
The overall report will be distributed by email to all participants for consultation in **February 2023.**

8 CONTACT

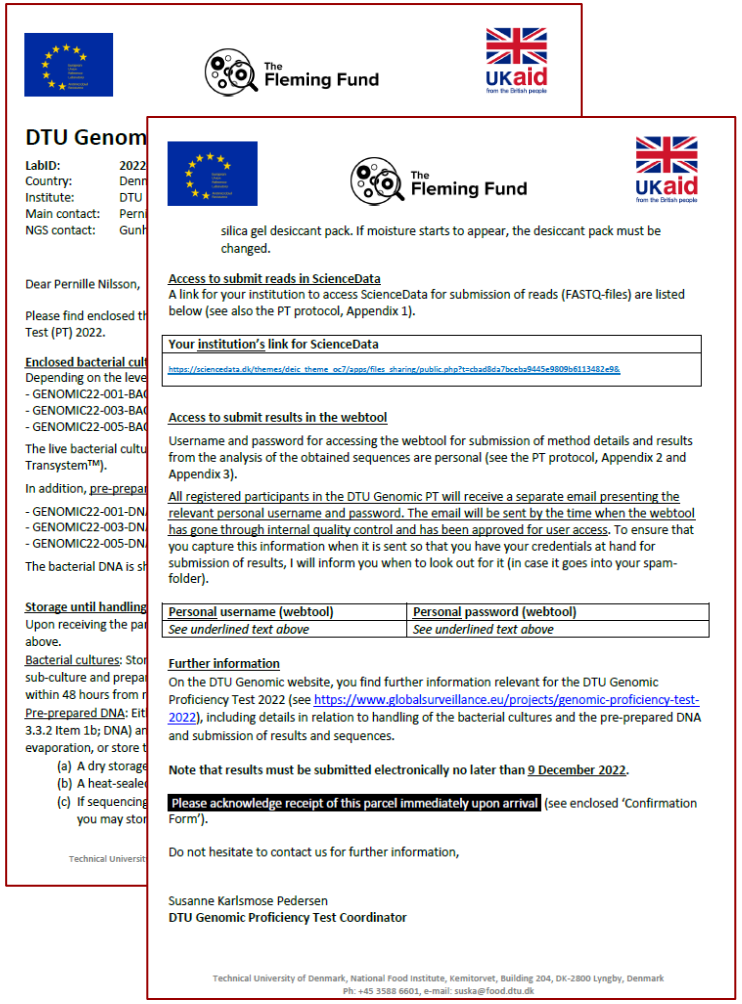
If you have questions for the EURGen-RefLabCap EQA 2022, please contact the EURGen-RefLabCap EQA 2022 Coordinator, Susanne Karlsmose Pedersen (suska@food.dtu.dk)

EURGen-RefLabCap EQA 2022 PROTOCOL - Page 3 of 3

Communication with participants – website



Communication with participants – hard copy letters



DTU Genom

LabID: 2022
Country: Denm
Institute: DTU
Main contact: Pern
NGS contact: Gunh

Dear Pernille Nilsson,

Please find enclosed th
Test (PT) 2022.

Enclosed bacterial cult
Depending on the leve
- GENOMIC22-001-BA
- GENOMIC22-003-BA
- GENOMIC22-005-BA

The live bacterial cultu
Transystem™).

In addition, pre-prepar
- GENOMIC22-001-DN
- GENOMIC22-003-DN
- GENOMIC22-005-DN

The bacterial DNA is sh

Storage until handling
Upon receiving the par
above.
Bacterial cultures: Stor
sub-culture and prepar
within 48 hours from r
Pre-prepared DNA: Eit
3.3.2 Item 1b; DNA) ar
evaporation, or store t
(a) A dry storage
(b) A heat-seale
(c) If sequencing
you may stor

Technical Universit

The Fleming Fund

UKaid from the British people

silica gel desiccant pack. If moisture starts to appear, the desiccant pack must be changed.

Access to submit reads in ScienceData
A link for your institution to access ScienceData for submission of reads (FASTQ-files) are listed below (see also the PT protocol, Appendix 1).

Your institution's link for ScienceData
https://sciencedata.dk/themes/deic_theme_oc7/apps/files_sharing/public.php?t=cbad8da7bceba9445e9809b6113482e98

Access to submit results in the webtool

Username and password for accessing the webtool for submission of method details and results from the analysis of the obtained sequences are personal (see the PT protocol, Appendix 2 and Appendix 3).

All registered participants in the DTU Genomic PT will receive a separate email presenting the relevant personal username and password. The email will be sent by the time when the webtool has gone through internal quality control and has been approved for user access. To ensure that you capture this information when it is sent so that you have your credentials at hand for submission of results, I will inform you when to look out for it (in case it goes into your spam-folder).

Personal username (webtool)	Personal password (webtool)
See underlined text above	*See underlined text above*

Further information
On the DTU Genomic website, you find further information relevant for the DTU Genomic Proficiency Test 2022 (see https://www.globalsurveillance.eu/projects/genomic-proficiency-test-2022), including details in relation to handling of the bacterial cultures and the pre-prepared DNA and submission of results and sequences.

Note that results must be submitted electronically no later than 9 December 2022.

Please acknowledge receipt of this parcel immediately upon arrival (see enclosed 'Confirmation Form').

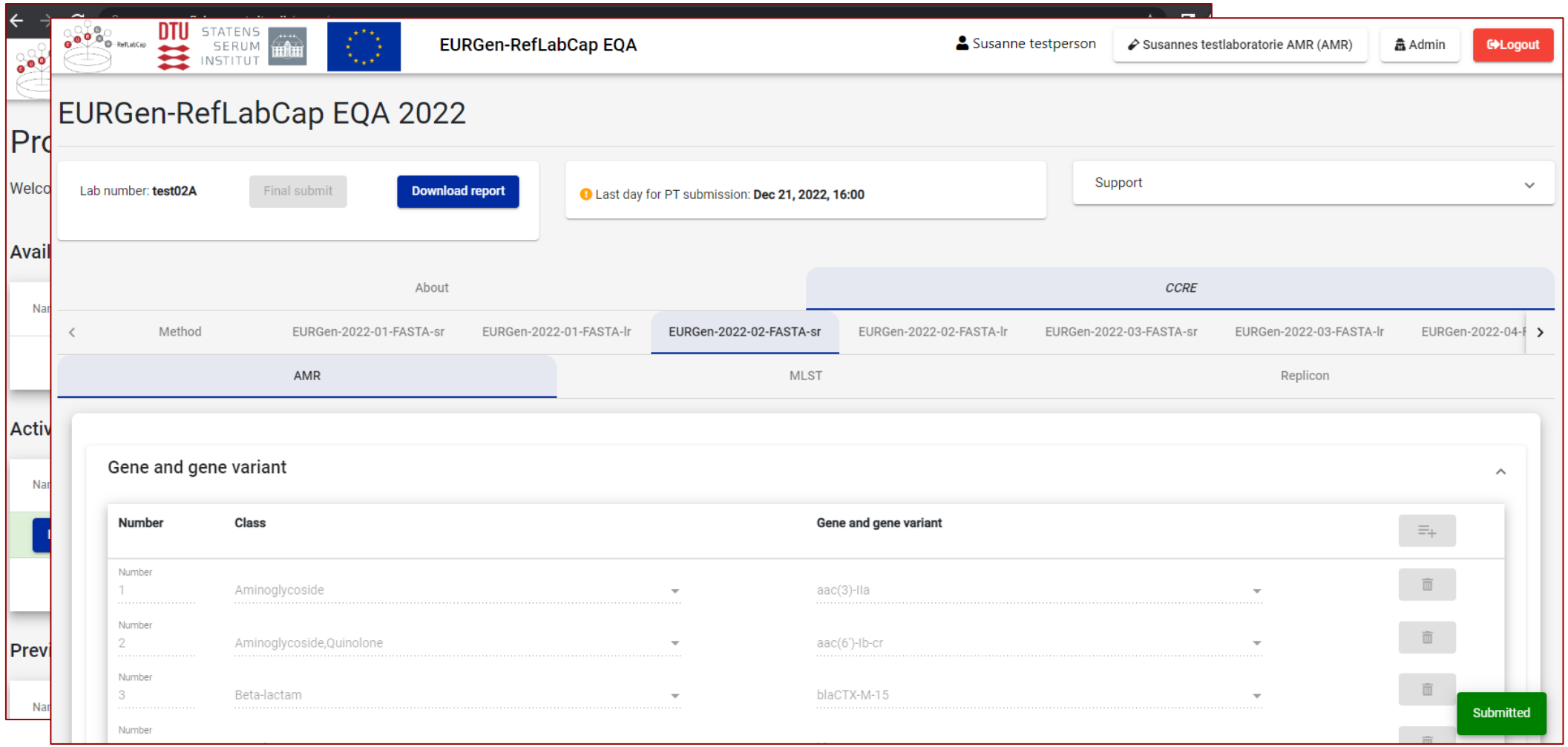
Do not hesitate to contact us for further information,

Susanne Karlsmose Pedersen
DTU Genomic Proficiency Test Coordinator

Technical University of Denmark, National Food Institute, Kemitorvet, Building 204, DK-2800 Lyngby, Denmark
Ph: +45 3588 6601, e-mail: suska@food.dtu.dk

Good idea to also follow up confirm this information by email!

Communication with participants – webtool



Communication with participants – appeal

Communicate to participants that they may appeal against the evaluation of their performance in a EQA scheme.

Example:

EURGen-RefLabCap-EQA-2022-GuideForSelf-evaluation_20.12.2022.pdf
786 KB

Dear participant in the EURGen-RefLabCap EQA 2022,

We are happy to inform you that the evaluation reports on the submitted results from the EURGen-RefLabCap EQA 2022 are now available.
I therefore invite you to login once again to the webtool to retrieve your evaluation reports.
Upon login, click on 'Download report', and you will see the overview of obtained and expected results (for the report to open, please ensure that pop-up-windows are allowed).

In addition, please see the attached 'Guide for score interpretation and self-evaluation', which presents background information regarding the scores assigned by the webtool, ho the expected results were generated as well as overviews of the submitted data on: a) multi locus sequence typing, b) detection of plasmid replicons, c) detection of genes and chromosomal mutations mediating antimicrobial resistance (AMR) and prediction of AMR phenotypes. This document is intended to assist you when performing your self-evaluation; however, please contact the EQA organisers in case you need extra support when performing the self-evaluation.

Login to the webtool
This URL takes you to the webtool: https://eurgen-reflabcap-pt.dtu.dk (remember to open the link in an 'incognito window')

Participant feedback (anonymous)
We should like to hear your feedback in relation to this EQA and we welcome any comments you might have for the EURGen-RefLabCap EQA providers.
Via this link, please find four questions which will take 5-7 minutes to respond to.
We ask that you submit your feedback via this survey no later than 31 January 2023.

Should any of the above lead to questions or comments, or should you wish to appeal against the obtained evaluation, please do not hesitate to contact me.

In January, I and the rest of the EURGen-RefLabCap EQA 2022 team will be back in office and will be available for responding to any questions you may have in this regard.

On behalf of the EURGen-RefLabCap team,
Best wishes for the holiday season,

Susanne K. Pedersen
EURGen-RefLabCap EQA 2022 coordinator

Communication with participants – certificate

If issuing a ‘statement of participation or performance’, make these contain sufficient information to not be misleading

Example:

Certificate of participation

This is to certify that

[Institute name], [Country]

Institute and country

participated in the EURGen-RefLabCap EQA 2022

assessing

technical and analytical skills for WGS-based carbapenem-resistant Enterobacterales (CRE) and colistin-resistant CRE (CCRE) resistome profiling and high-risk clone/plasmid identification

Prof. René S. Hendriksen
National Food Institute
Technical University of Denmark

The EQA is an activity in the EURGen-RefLabCap project funded by the European Union (SC20197401)

Confidentiality

The identity of participants in a EQA scheme shall be confidential and known only to persons involved in the operation of the EQA scheme, unless the participant waives confidentiality.

All information supplied by a participant to the EQA provider shall be treated as confidential.

NOTE: Participants may choose to waive confidentiality with in the EQA scheme for the purpose of discussion and mutual assistance, e.g. to improve performance.

If an interested party requires the EQA results to be directly provided by the EQA provider, the participants must be told in advance of participation.

Complaints and appeals

Have a procedure for the resolution of complaints and appeals received from participants. Maintain records for all complaints, appeals, investigations and corrective actions taken by the EQA provider.

Control of nonconforming work

Follow a system to handle non-conforming work e.g. related to:

- participant complaints
- internal or external audits
- QC
- preparation of EQA test material items
- homogeneity and stability tests
- data analysis
- instructions to participants
- materials handling
- storage

Improvement of the EQA

Aim to continually improve the EQA’s, e.g. based on audit results, analysis of data, corrective and preventive actions and management review.

Or based on reports and comments from the participants.

Consider official participant feedback.

Follow-up on an EQA

Depending on the setup of the provided EQA, potentially:

- Participating laboratories are responsible for self evaluation, i.e. for follow-up on any deviating results
- Follow-up samples may be requested
- Participants may contact the organizer for discussions

Limitations with an EQA

EQA’s will not detect all problems in the laboratory!

Problems with the pre- and post examination procedures may not be detected!

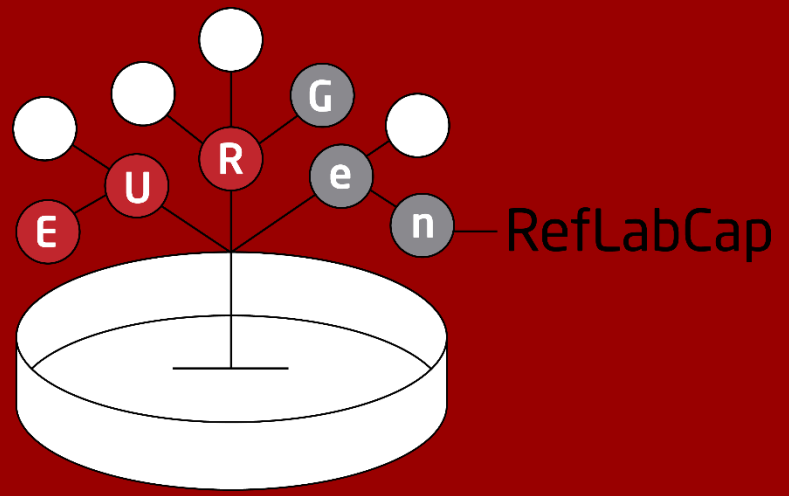
DTU STATENS SERUM INSTITUT

RefLabCap

Why EQA's?

- Provides external evaluation of laboratories
  - Analytical competence, usage of methods, documentation
  - Comparison among different test sites
- Provides early warning for systemic problems
- Provides objective evidence of testing quality
- May identify areas that need improvement
- May identify training needs
- Is a tool for the accreditation body (ISO 15189 / ISO 17025)
- Provides knowledge for laboratories and organizer

Thanks for your attention!



Questions? Comments?

Ref.: – and further information, see: www.who.int/ihr/training/laboratory_quality/en/