



Breakout session: Impact of pre-analytical treatment of samples on the analytical quality provisions

**14 July 2020
14:30-15:30**

1



Impact of pre-analytical treatment of samples on the analytical quality provisions

- What does *pre-analytical sample treatment* mean?
- Do you currently teach/provide training in pre-analytical treatment?
- How do you avoid alteration of sample composition?
- Have there been any significant changes in regulatory/accreditation requirements in relation to pre-analytical treatment of samples?
- What are the challenges?
- Which are the pre-analytical quality indicators? / Is further guidance needed?
- Can *pre-analytical treatment of samples* compromise analysis quality?

2



Impact of pre-analytical treatment of samples on the analytical quality provisions

Do you currently teach/provide training in pre-analytical treatment?

- 14 participants in the session (9 different countries)
- 3 PhD students in their second or final year
- 7 teaching on either part-time or full-time basis
- 4 R&D staff
- Not much focus on the pre-analytical stage during the undergraduate training
- Post-graduate training addresses briefly the subject, but most programmes lack sufficient practical training

3



Impact of pre-analytical treatment of samples on the analytical quality provisions

What does *pre-analytical sample treatment* mean?

- Sampling, sample preservation, storage and handling before any representative specimen is collected and given the specific identification code are all part of the *pre-analytical sample treatment*
- It needs more attention as it holds for 85 % of the reported errors

4



Impact of pre-analytical treatment of samples on the analytical quality provisions

How do you avoid alteration of sample composition?

- Following the recommended sampling procedure, if any
- Making use of literature information and personal experience
- Running repeated sample collection

July 2020

5

5



Impact of pre-analytical treatment of samples on the analytical quality provisions

Have there been any significant changes in regulatory/accreditation requirements in relation to pre-analytical treatment of samples?

- EN ISO 17025 is the main regulatory document in use (7.3 chapter in particular and all general and specific requirements for reporting in section 7.8.3)
- EN ISO 17189 and EN ISO 15190 address the preanalytical and post-analytical stage in the medical laboratories
- Some laboratories are accredited for the analytical part of the measurement
- Some laboratories are accredited for the sampling process

July 2020

6

6



Impact of pre-analytical treatment of samples on the analytical quality provisions

What are the challenges?

- Not compromising the sample quality
- Incomplete documentation when the client carries on the sampling and sample preservation stage
- Ensuring reliable documentation on the stages before the sample is injected in the measuring system
- Suitable training focus, especially for master students

July 2020

7

7



Impact of pre-analytical treatment of samples on the analytical quality provisions

Which are the pre-analytical quality indicators? / Is further guidance needed?

- Uncertainty is the key quality indicator
- Proper evaluation of uncertainty sources is time consuming and tedious
- There are software packages to assist analysts in the realistic evaluation of uncertainty in the pre-analytical stages

July 2020

8

8



Impact of pre-analytical treatment of samples on the analytical quality provisions

Can *pre-analytical treatment of samples* compromise analysis quality?

- Yes, 80 % of out of range variability in intermediate precision comes from sampling, preservation and storage
- In case of abnormal results of an analysis, the laboratory should take the subject with the client and ask for complete documentation on the sample history
- Pre-analytical stage may compromise the entire measuring process
- Proper personell training should be set to cover the pre- and post-analytical stages of a measurement for all type of laboratories, conformity checking organizations included

Eurachem presentation February 2014

9