Correct handling of urine samples -

Facts, guidelines & best practice

Urine samples are one of the most commonly used diagnostic tools in healthcare. Yet up to half of these samples are discarded due to contamination (e.g. mixed flora), leading to delayed diagnosis, increased costs, and a burden for both patients and staff.

What is the extent and impact of mixed flora in urine samples?

- A primary care study showed that 54.9% of all urine samples were contaminated [Hansen, 2022].
- In specialised urology clinics, the prevalence of mixed flora was 46.2% [Whelan, 2022].
- Factors such as female sex, pregnancy, age and overweight increased the risk of contamination [Hansen, 2022].
- Contaminated samples often result in unnecessary antibiotic treatment and misdiagnosis - 22.9% of symptomatic patients with a contaminated sample received antibiotics [Hansen, 2022].

Average cost and burden of discarded samples and re-analysis

- Re-analysis of a single urine sample (incl. request, transport, new collection set, laboratory time and staff) is estimated to cost 300-500 DKK per sample (approx. 40-65 Euro). [Note: This is an estimate.]

Causes of contamination include

- Lack of or unclear instructions to the patient.
- Poor hygiene and insufficient cleansing of the genital area.
- Use of non-sterile urine collection sets and cups that are not CE-IVDR approved (for example coffee cups).
- Incorrect technique for collecting the midstream sample.

Evidence from seven clinical studies shows that cleansing as such does not necessarily reduce contamination rates significantly – but correct enforcement of the technique helps reduce mixed flora. [LaRocco, 2015]

Best practice for urine collection – step by step:

1. Wash hands thoroughly.
2. Cleanse the genital area with sterile wipes.
3. First allow the initial urine stream to go into the toilet.
4. Collect the midstream urine in a sterile, CE-IVDR-approved container.
5. Close immediately and deliver the sample as quickly as possible.

This procedure reduces mixed flora and contamination [Cumpanas, 2020].

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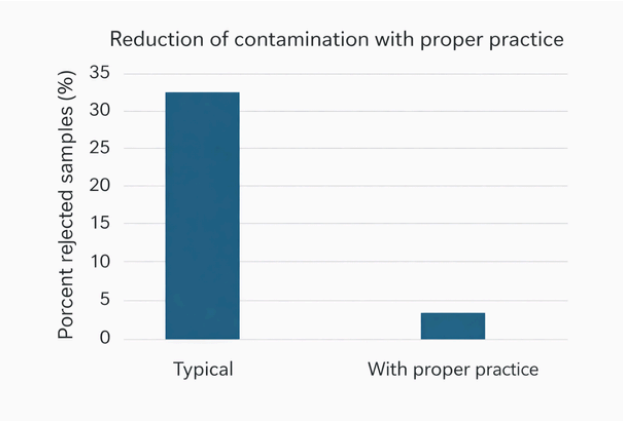
Benefits of correct practice

By combining the correct midstream procedure with sterile CE-IVDR-compliant products for collection, you achieve:

- Fewer than half of samples discarded (reduced from typically 33% to possibly 4-5%).
- Significant time savings and cost reductions.
- Improved patient safety and diagnostic quality.
- **Compliance with national and EU regulatory requirements (CE-IVDR, ISO standards).**



Why must urine collection sets be approved and certified?

- CE-IVDR approval ensures that the collection set complies with European legislation.
- Approval of the supplier/manufacturer via national medicines agencies ensures quality and traceability. In Denmark, the Danish Medicines Agency (Lægemiddelstyrelsen) approves suppliers and manufacturers. You can look up a manufacturer at the Danish Medicines Agency if you want to know whether they provide approved products: https://laegemiddelstyrelsen.dk/da/udstyr/registrering/liste-over-registrerede-virksomheder/
- ISO 13485 certification guarantees that the supplier operates under a quality management system targeted at medical devices.

Briefly about regulatory requirements and quality assurance

- CE-IVDR (the EU In Vitro Diagnostic Regulation 2017/746) has applied since 26 May 2022, with a phased transition depending on risk class (e.g. class D until May 2025). [Regulation (EU) 2017/746]
- IVDR sets requirements for risk classification, Notified Body involvement, Unique Device Identification (UDI), increased surveillance and EUDAMED registration. [CE marking Regulation (EU) 2017/746]

Choosing the correct and approved collection set is not just a matter of legislation - it is an investment in patient safety, diagnostic quality and optimal use of resources.

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