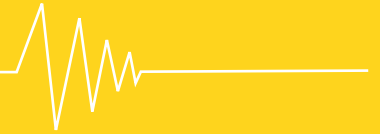


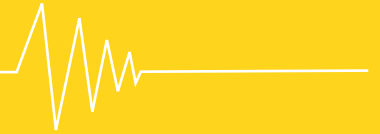
The alternative to supervision when providing urine samples:

RUMA-Marker-System



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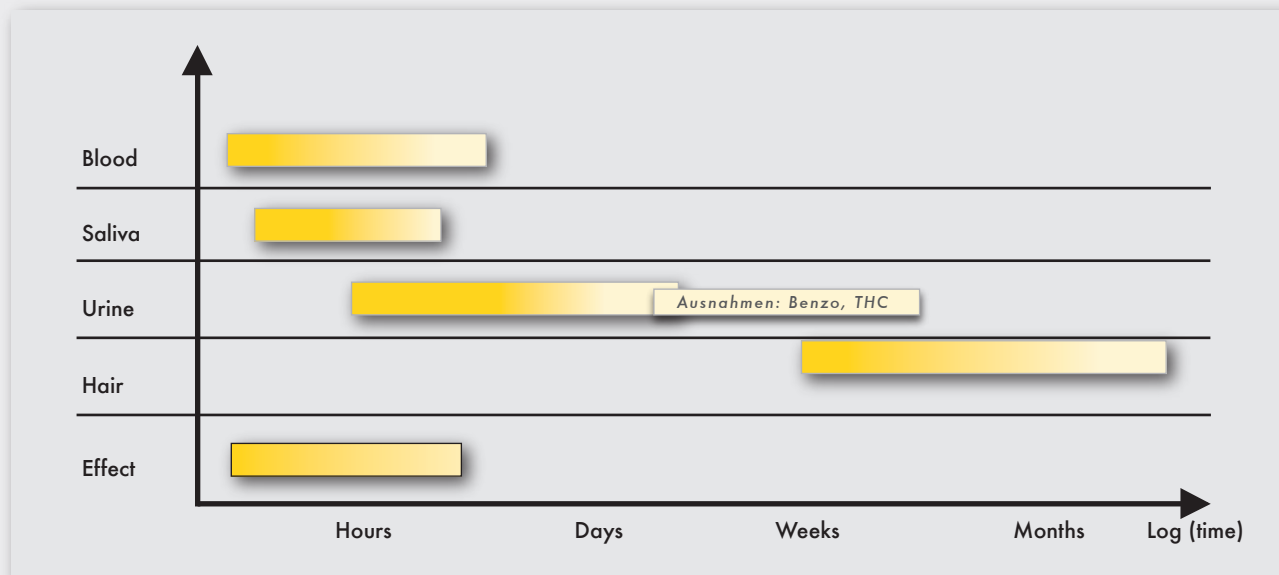
Why drug analysis?

- Regular supervisory checks are required for substitution drug patients.
- Checks must be made as to whether the patients are taking other drugs. This can endanger the success of methadone substitution.
- Use of other drugs may result in life-threatening conditions such as respiratory depression.

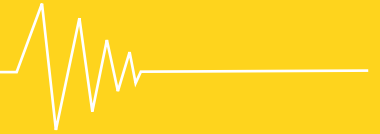


Why urine testing?

- Urine is easier to take than other body fluids, such as blood.
- Many medications and drugs as well as their metabolites reach higher concentrations in urine than in blood and can be detected for longer periods of time.



Detection periods

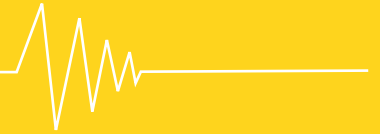


Falsifying samples

An unwanted positive result is manipulated so that a negative result is produced.

Reasons for manipulating samples

- The patient wants to receive benefits, e.g. "take home".
- The patient wants to hide a relapse.
- The patient fears adverse effects on the doctor-patient relationship if it is found she/he is taking other drugs.



How samples are falsified

Manipulating the sample material

External (in vitro):

Vinegar, soap, acid, bleach, nitrite, glutaraldehyde, chromate

Internal (in vivo):

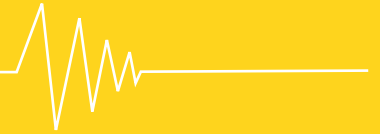
Teas, powders, herbal capsules, diuretics, vitamin B complex, creatine

Dilution:

Drinking water

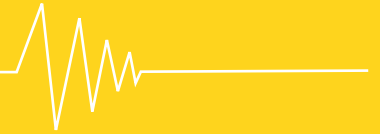
Exchanging the samples:

Providing “clean” urine, adding third-party urine to the bladder, preservatives, falsification kit

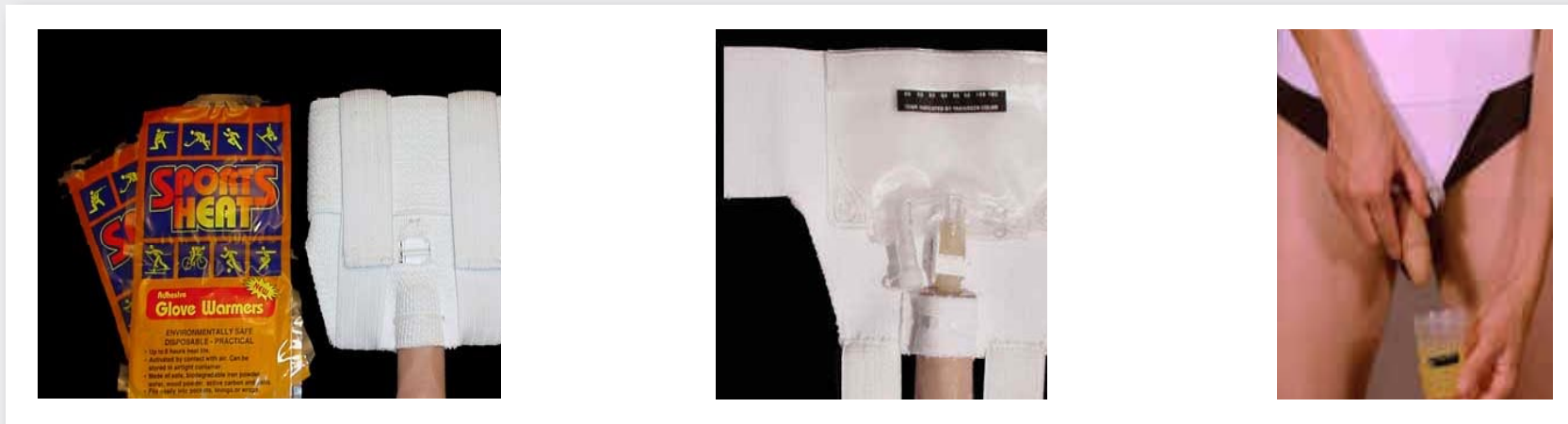


Detecting sample falsification

Dilution by adding water, excessive drinking etc.	Measuring urine creatine
External manipulation by adding acid etc.	Measuring the pH value, sample checks and other measurements in suspicious cases
Exchanging samples	Providing the urine sample under supervision

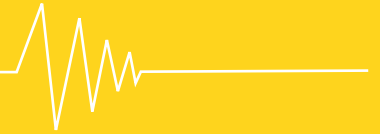


The “Whizzinator”: a commercial kit for falsifying samples



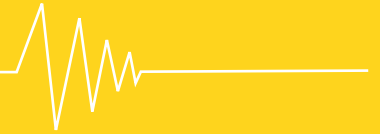
Contains:

- Tempering bag
- 1 sample of “clean” urine
- Drug test strip
- Needle for filling
- Artificial penis (various versions)
- Belt shaped like underwear with body warmed urine bag
- Discrete packaging and shipping
- Manual

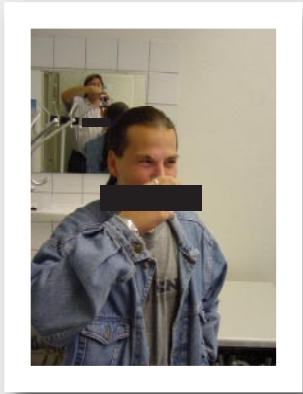


Practical problems when samples are provided under supervision

- Daily endless discussions affect the mutual position of trust (“I can’t go now”, “can’t I do it tomorrow?”, “I have other appointments”).
- Patients wait in the practice until they can urinate.
- A person of the same sex must be available for supervising the sample.
- Some patients have problems urinating whilst being watched.
>> Organisational delays/additional work, no planning security



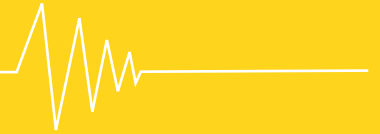
Identifying samples by administering marker substances orally



Principles

Marker substances were selected as per the following criteria:

- Not harmful to patient
- Easily detected in body liquids
- Easily absorbed from the contents of the intestine
- Quickly eliminated via the kidneys



Previous experience with attempts at falsification

1.) The predecessor's urine is taken from the toilet.

The number of different marker combinations was increased.

2.) The marker substances were spit into the sample containing "clean" urine.

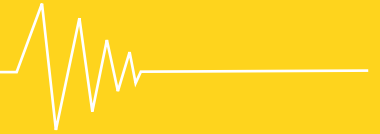
The marker substances are given with materials that are not secreted via the urine. >> sugar

3.) The urine sample was contaminated by chemicals.

Sample falsification is detected by control measurements.

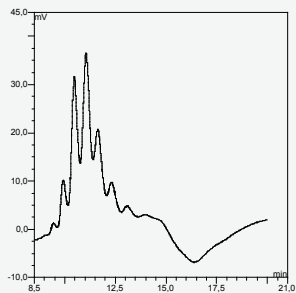
4.) Urine is diluted or mixed with third-party urine containing methadone.

Creatine determination: For dilution the marker concentration almost always falls below the cut-off before the drug test is negative.

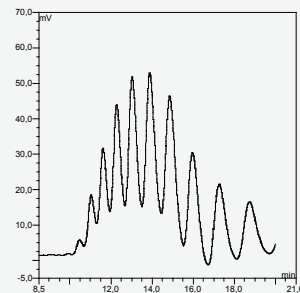


Three marker combinations: polyethylene glycol, chromatographic evidence via HPLC

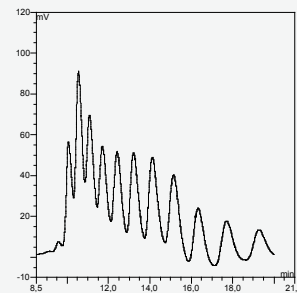
Marker A



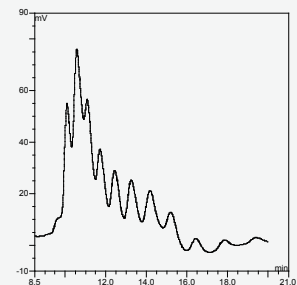
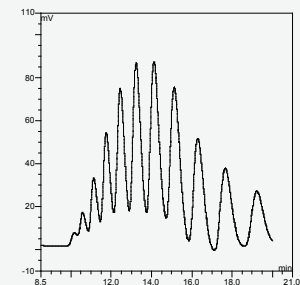
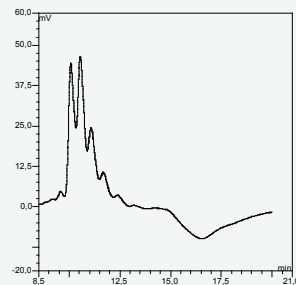
Marker B



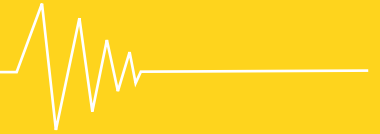
Marker C



Pure substance

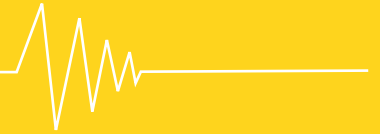


From Urine



Protocol for using marker substances

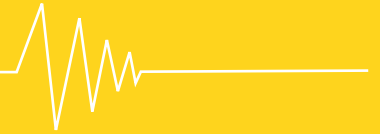
1. The markers are dissolved in Coca Cola, sugared tea or coffee and administered at least 30 minutes before the first urine sample.
2. Creatine, sugar, sample check, addictive drugs and marker substances are detected.
3. The data is communicated in the same way as other analysis results.



Marker results to date

As of 01.05.06

- Approx. 60,000 samples from a total of around 2000 patients were checked.
- Delayed samples occurred in less than 0.5% of patients. They have to wait 45 minutes before providing a sample.
- For all other patients a 30 minute waiting time is adequate.
- Markers have been used to date in methadone walk-in centres, prisons, medical practices, psychiatric practices.

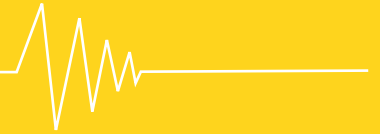


Experiences with marker analysis

- Markers are tolerated and even welcomed by the majority of patients.
- The waiting time (at least 30 mins) is often seen as a break, and frequently used for discussions.
- No side effects were reported.
- No discussions before providing a supervised sample.
- Patients do not need to wait in the practice until they can urinate.
- Manpower intensive supervision is no longer required.
- The samples can be assigned securely.
- Other advantages of marker analysis include:
invoicing via exemption number, no strain on the budget, not covered by Medical Product or Food Laws.

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