Lower Saxony Federal State Office
for Consumer Protection and Food Safety
Food Laboratory Braunschweig

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27 April 2009

Quality assurance for GMO testing laboratories

- Why? The Phantom of Heilbronn
- Accreditation/Certification, -procedure
- Working areas, controls...

Location of Food Laboratory Braunschweig

Organisation of food surveillance in Lower Saxony

Lower Saxony Ministry for Nutrition, Agriculture, Consumer Protection and Rural Development

reports ↑ ↓ **supervision**

LAVES

results of analyses ↓ ↑ **samples** ↓ **advice coordination**

42 local authorities (e.g. veterinary offices)

measurements ↓ ↑ **samples** ↓ **inspection**

animal / food + feed / articles of daily use - enterprises

Control of genetically modified food, feed and seed in Lower Saxony

- development and establishment of GMO detection methods since **1993**
- first governmental gm food surveillance laboratory in the whole world at this time
- working out the first German Official Standard Detection methods, fixing the procedure which is meanwhile accepted by ISO and CEN
- molecular laboratory with GMO safety standard S1
- and of course is accredited according ISO/EN DIN 17025

Personal experiences

- since 1997 AKS assessor according ISO 17025
- DACH (Deutsche Akkreditierungsstelle Chemie GmbH) assessor
- chair of National German Working group for the development and standardisation of methods for the detection of genetically modified food (official collection of methods according § 64 German Food Act, formerly § 35)
- deputy chair person or member in different National and European Working groups working on establishment and standardisation of methods of molecular biology,
- workshops 2001 in China, 2002 Thailand, short time expert in Twinning projects (Lithuania, Estonia, Turkey, Poland), National expert in FVO missions

Why quality assurance ? (1)

Spiegel Online Thu, 26 Mar 2009

- A notorious German serial killer known as "**the Phantom of Heilbronn**" might not exist. Police believe DNA evidence which pointed to a 15-year trail of crimes across Germany was a case of contaminated cotton swabs.

Forensic magazine 10 April 2009

- Serial Killer was just DNA contamination

Why quality assurance ? (2)

- To guarantee the quality of test results
- To established a base for transparency, for tracing back
- To avoid unnecessary duplications of laboratory tests
- To gain mutual recognition of analytical results
- To avoid barriers to trade

Official food surveillance - Legally regulated area

- Directive 93/99/EEC of 29 October 1993, article 3 (1)
  Obligation for accreditation of official food laboratories
  until 1. November 1998
- 2 German accreditation bodies for official food laboratories
  - Staatliche **A**k**k**reditierungs**s**telle (AKS) Hannover
    (Accreditation Authority AKS Hanover of the Government Lower Saxony)
  - **S**taatliche **A**nerkennungsstelle der Lebensmittelüberwachung (SAL)
    (Hesse)

Legally regulated / non-regulated area

- Multilateral agreement (MLA, mutual recognition agreement) among accreditation bodies for mutual recognition of accreditations in the voluntary, i. e. legally non-regulated area.

Regulation (EC) No 882/2004 of 29 April 2004

- Article 12, Official laboratories,
  (2) ...only designate laboratories that operate and are assessed and accredited in accordance with the following European Standards:
  - EN ISO/IEC 17025 on “General requirements for the competence of testing and calibration laboratories“,....

Accreditation scope

- Regulation 882/2004, Article 12,
  (3) The accreditation and assessment of testing laboratories ... may relate to individual tests or groups of tests.
- The accreditation scope of a lab can be a mixture of
  - specific methods and
  - Methodology.

Accreditation *versus* Certification ?

- **ISO 17025**
  - Section 4: Management Systems requirements
  - Section 5: Requirements for the technical competence

Accreditation *versus* Certification ?

A laboratory´s fulfilment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both

- the technical competence requirements and the
- management system requirements

that are necessary for it to consistently deliver technically valid test results.

Base for transparency, tracing back

- *When* did *?*
- *Who ?*

Not documented means **not done!**

- *Which* equipment *?*
- *Which* methods and *why ?*

Accreditation procedure

Application for confirmation of the technical competence

pre check

check of application documents

on-site visit of the laboratory and planning of audit

Audit
check of technical competence by
• quality management documents (manual, test procedures, test reports, validation documents,...)
• on-site checks

Accreditation certificate

registered published/transparent in the internet

Some accreditation criteria (from the checklist)

Organisation

.....impartiality,.....responsibilities fixed?, ...job descriptions

Personnel

professional competence, education, training, experience, dated authorization and confirmation of competence

Document control

authorized editions, periodically reviewed, updated, unique and completely identified, master list

Management review

Considering **all** aspects according ISO 17025, 4.15.1

Access to the laboratory

Why ongoing story?

The accreditation is „valid for“ 5 years.

- Relevant changes have to be reported directly.
- Each year the laboratory has to send an up-date verification.
- Between the main on site audits observation audits are performed.

„After accreditation“ is

„before re-accreditation“.

Access to the laboratory

sample handling
sample registration, sample identification

„One way!!!“

corn sample

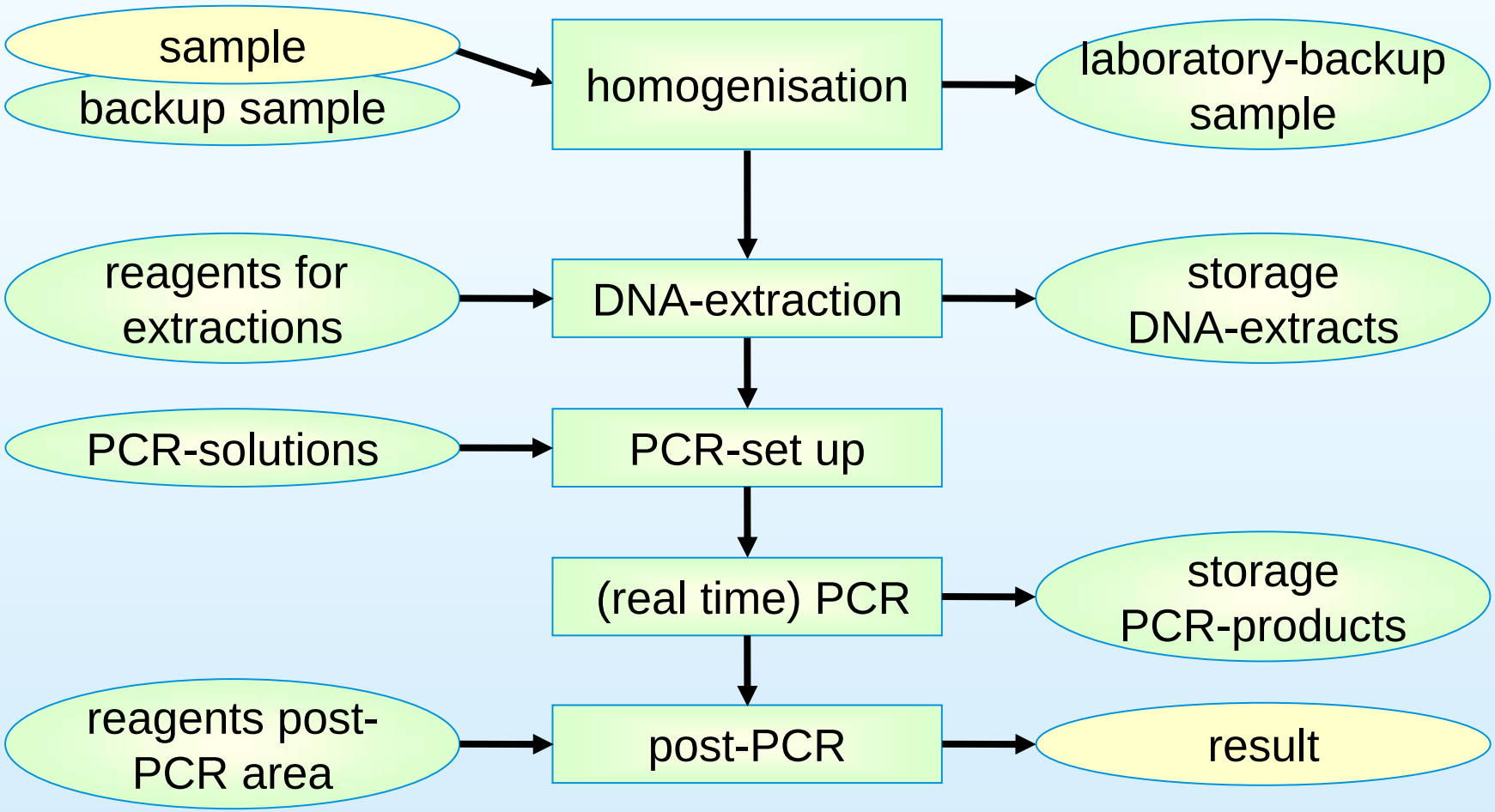
adequate equipment, e.g. seed counting

Determination of 1000 corn weight, documentation of subsamples

Grinding (homogenisation)

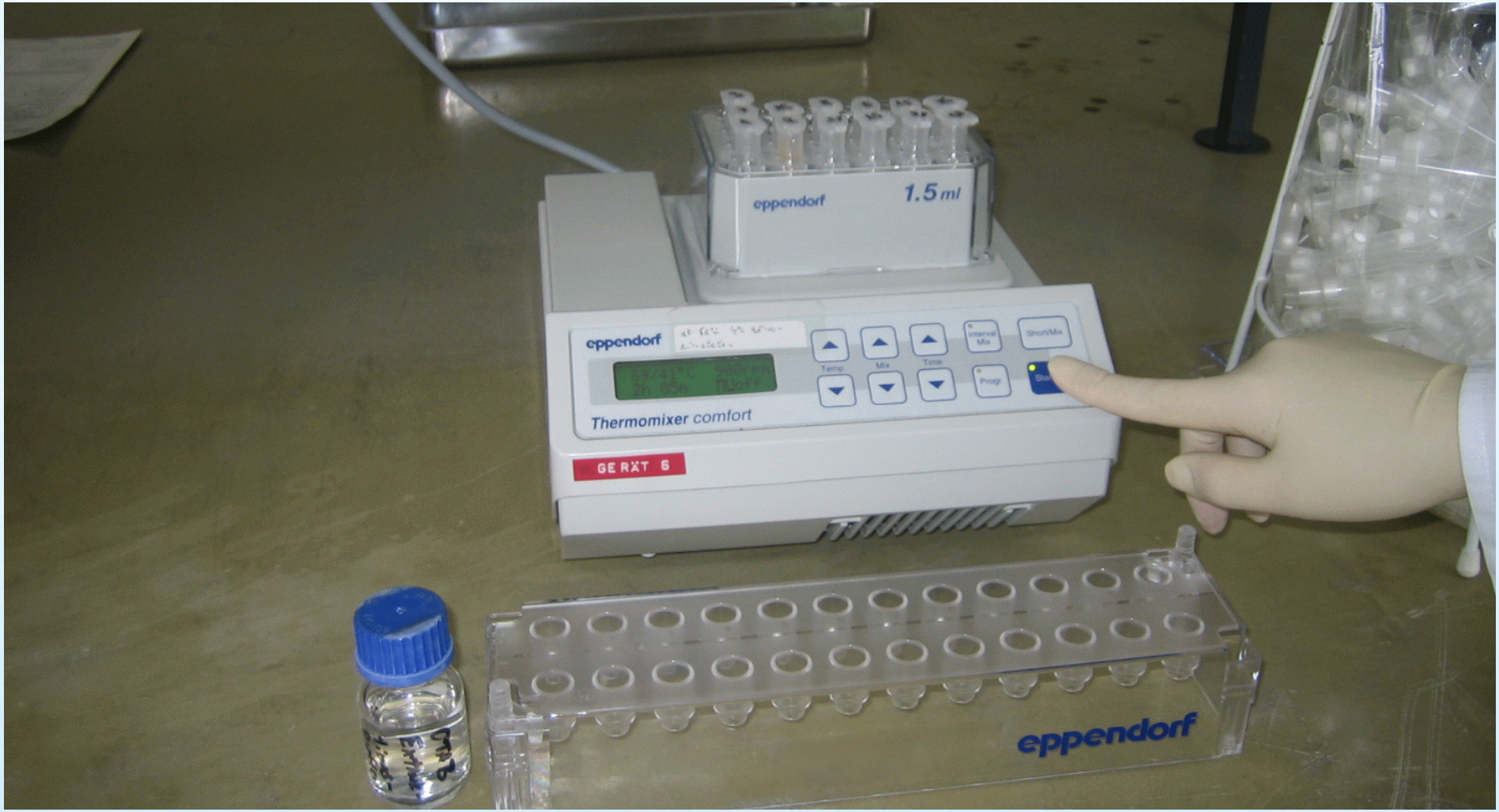
corn meal

Separation of working areas, reagents, solutions, equipment

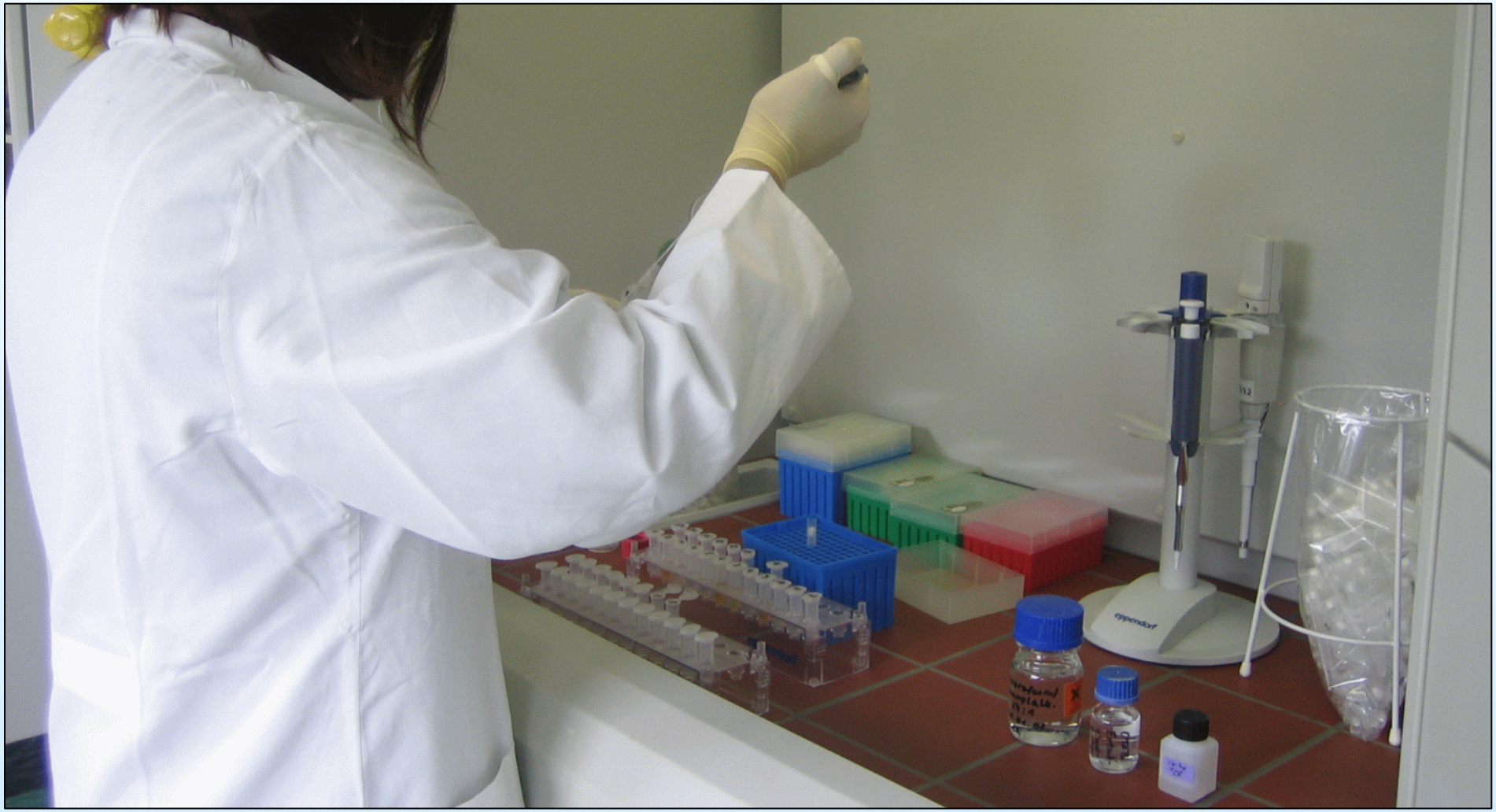


Manual extraction, addition of extraction puffer

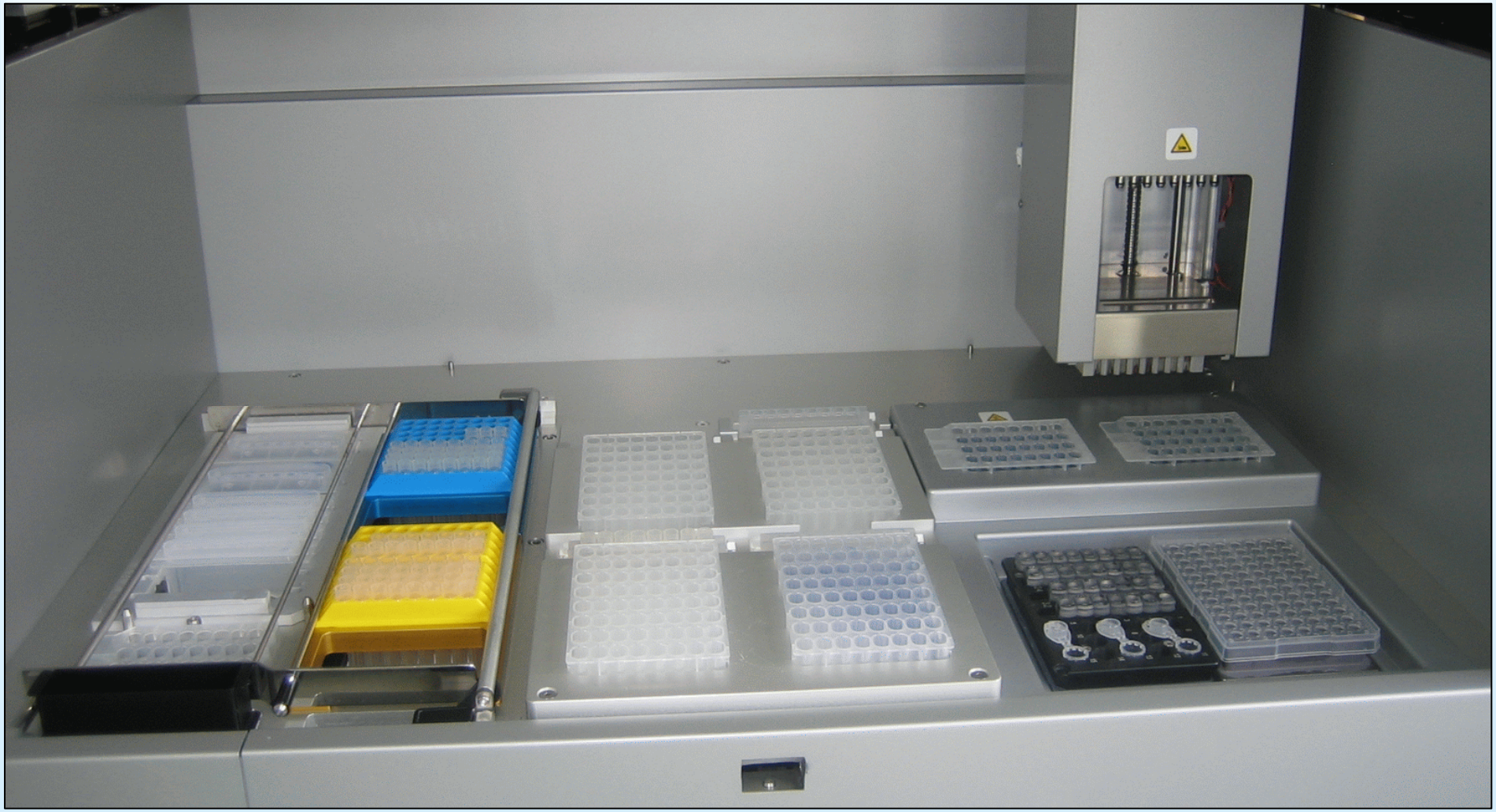
Manual extraction, incubation step



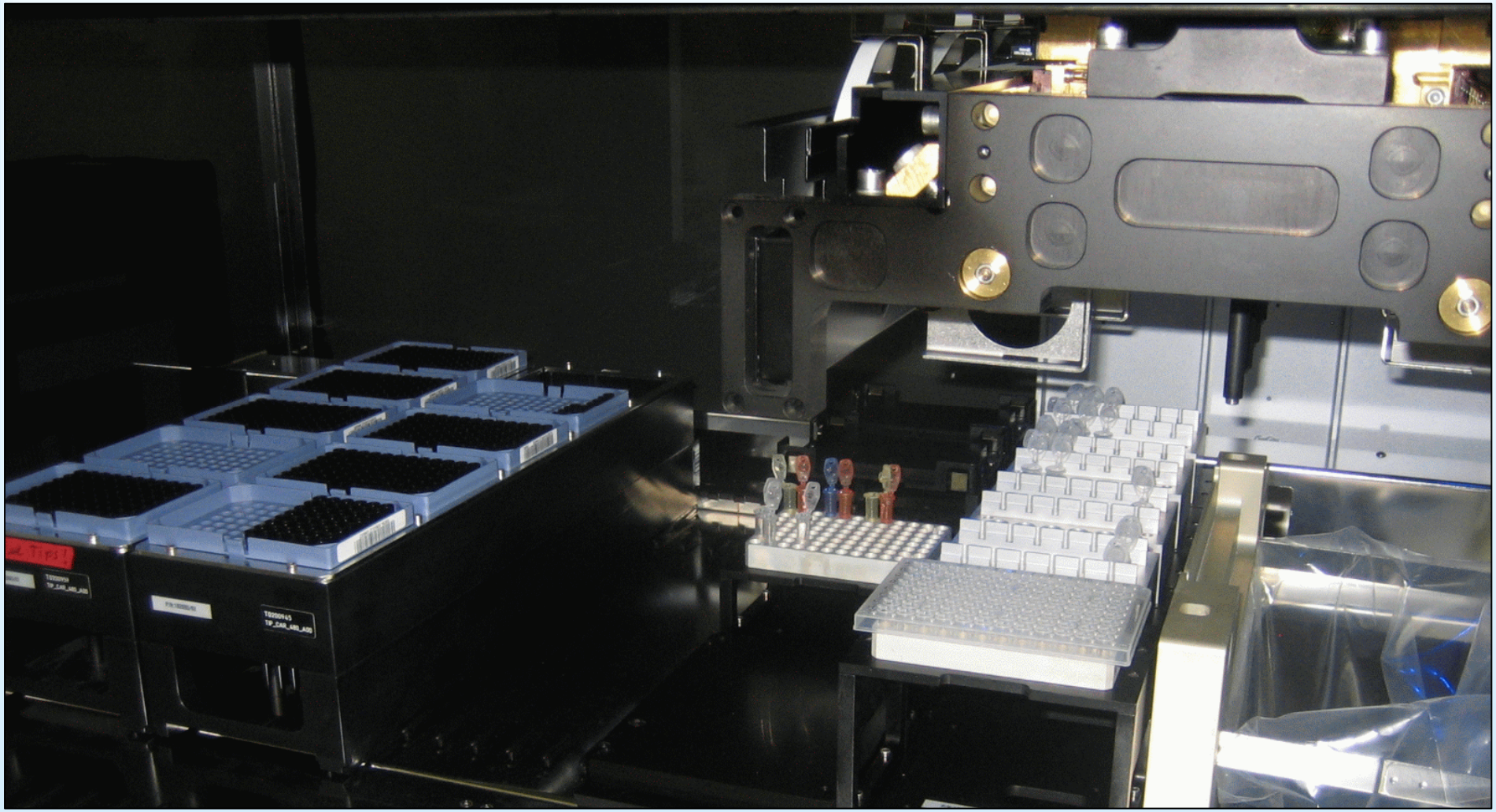
Manual extraction, handling of organic solvents



Automatic extraction



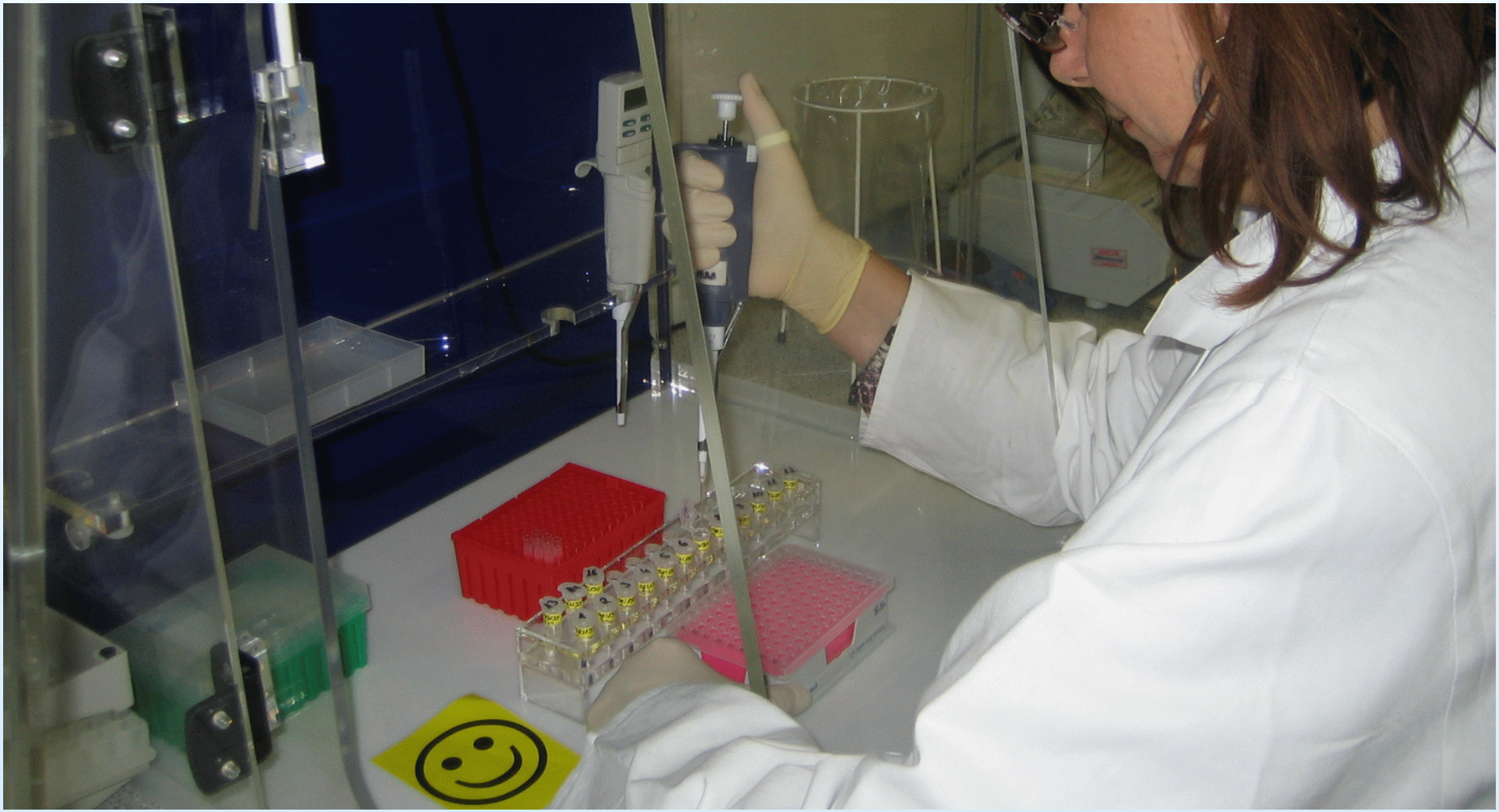
PCR-set up by automatic robot



Manual mastermix setup

Dedicated working area (false handling)

Dedicated working area (right handling :-)

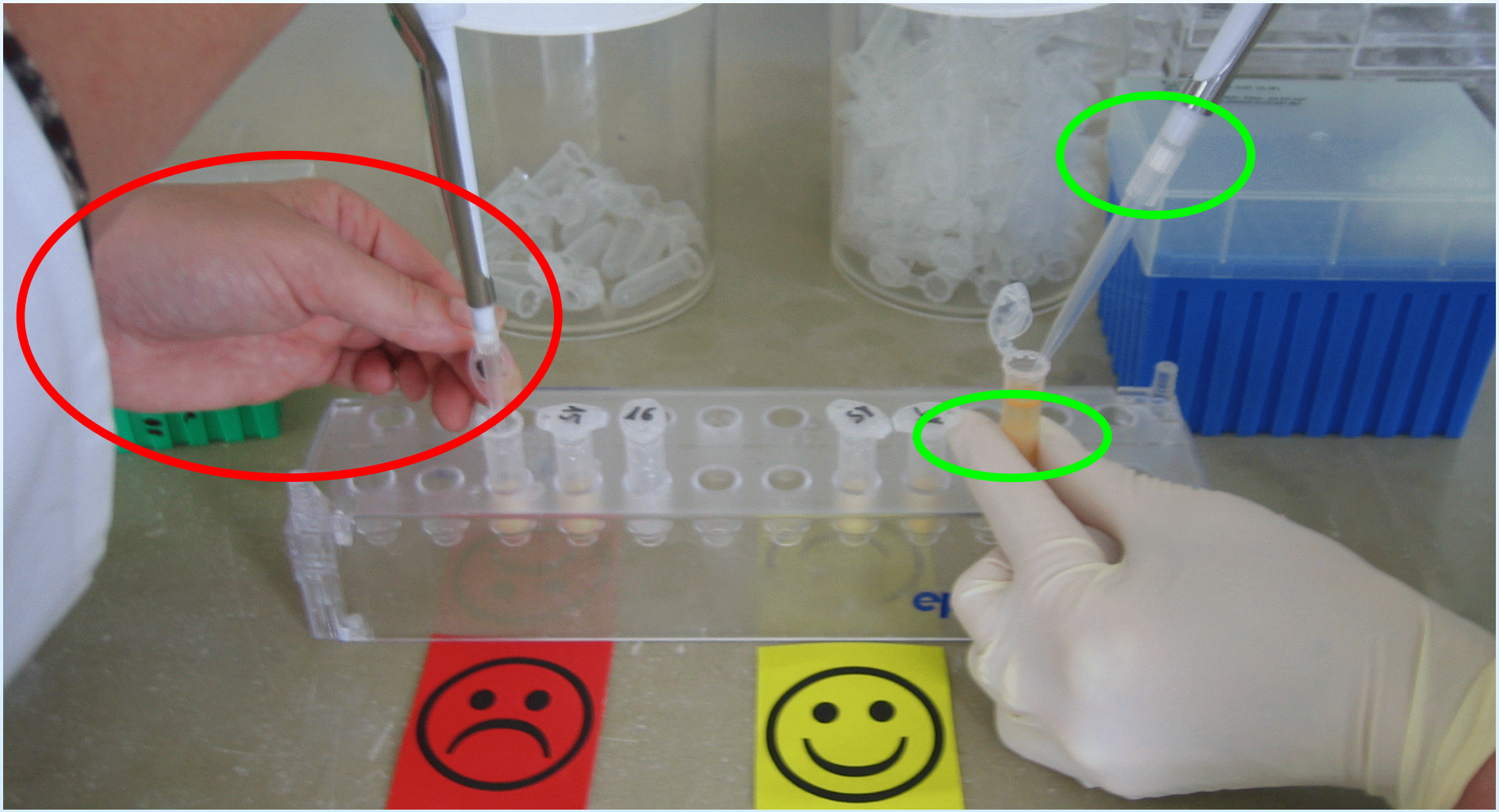


Remember some personnel accreditation criteria

Personnel

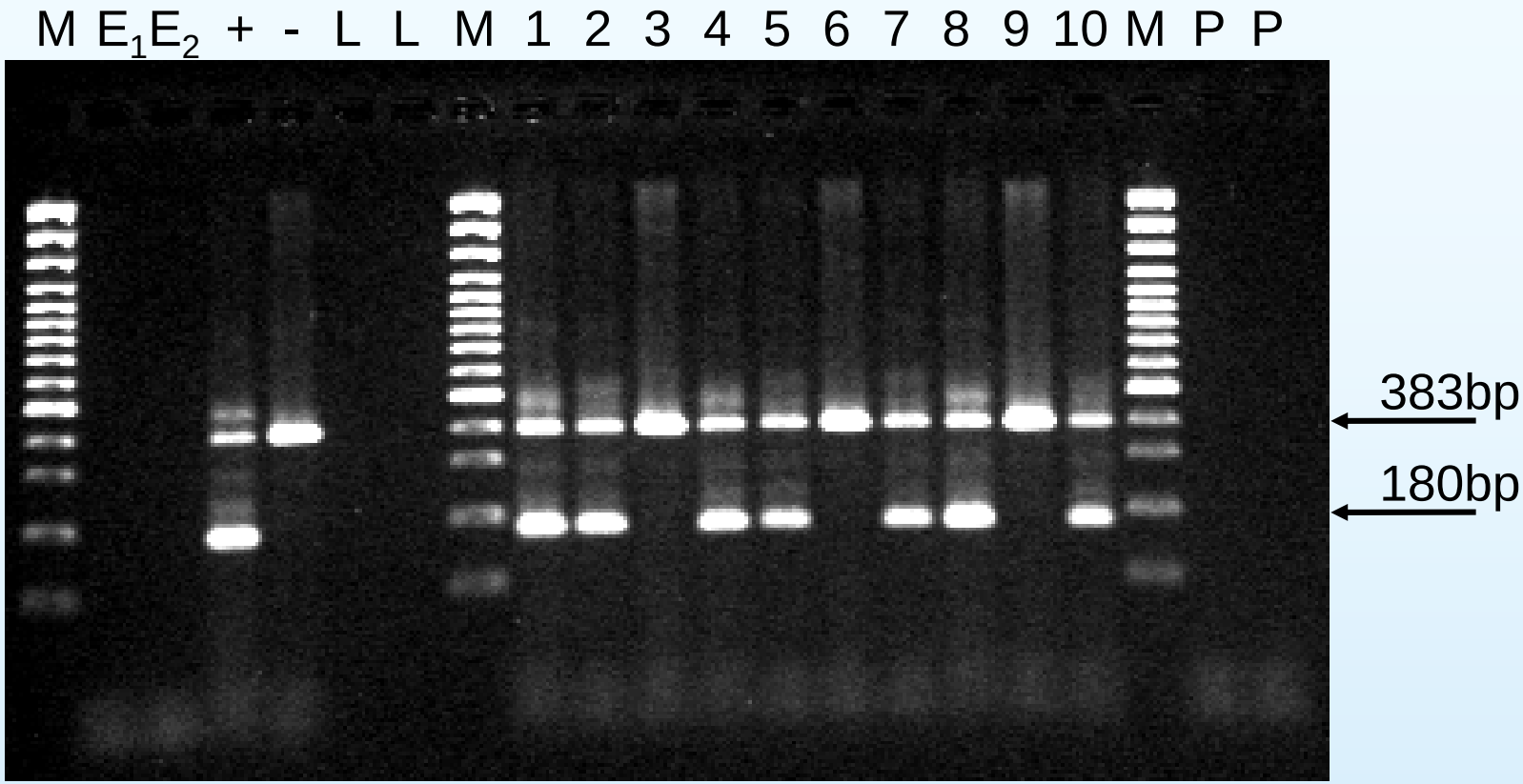
- professional competence,
- education,
- training,
- experience,
- dated authorization and
- confirmation of competence

Handling of solutions



Material handling

Extraction controls, positive controls, inhibition controls, negative controls

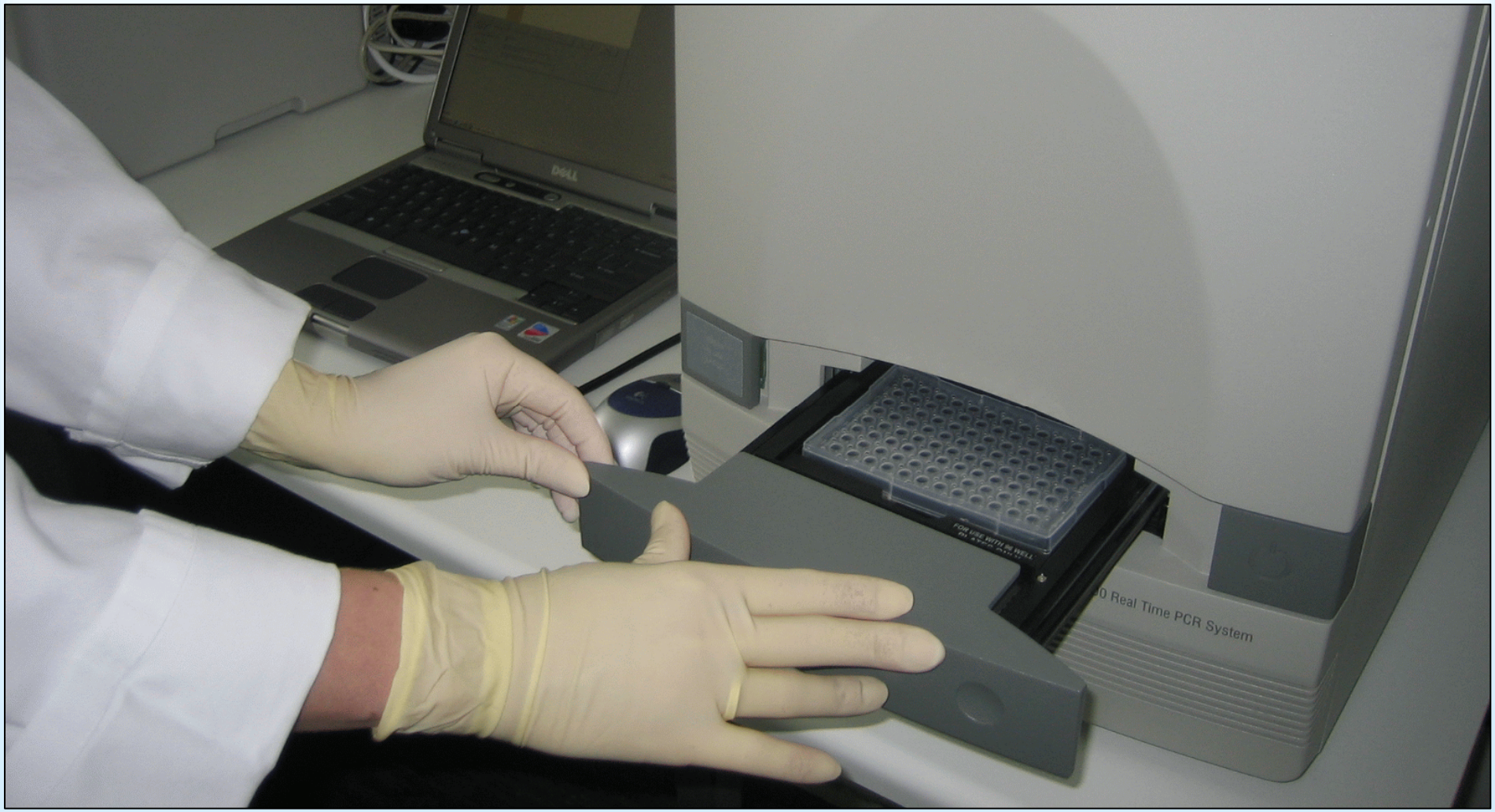


E1, E2 = extraction controls;
+ = positive extraction control;
- = negative extraction control;

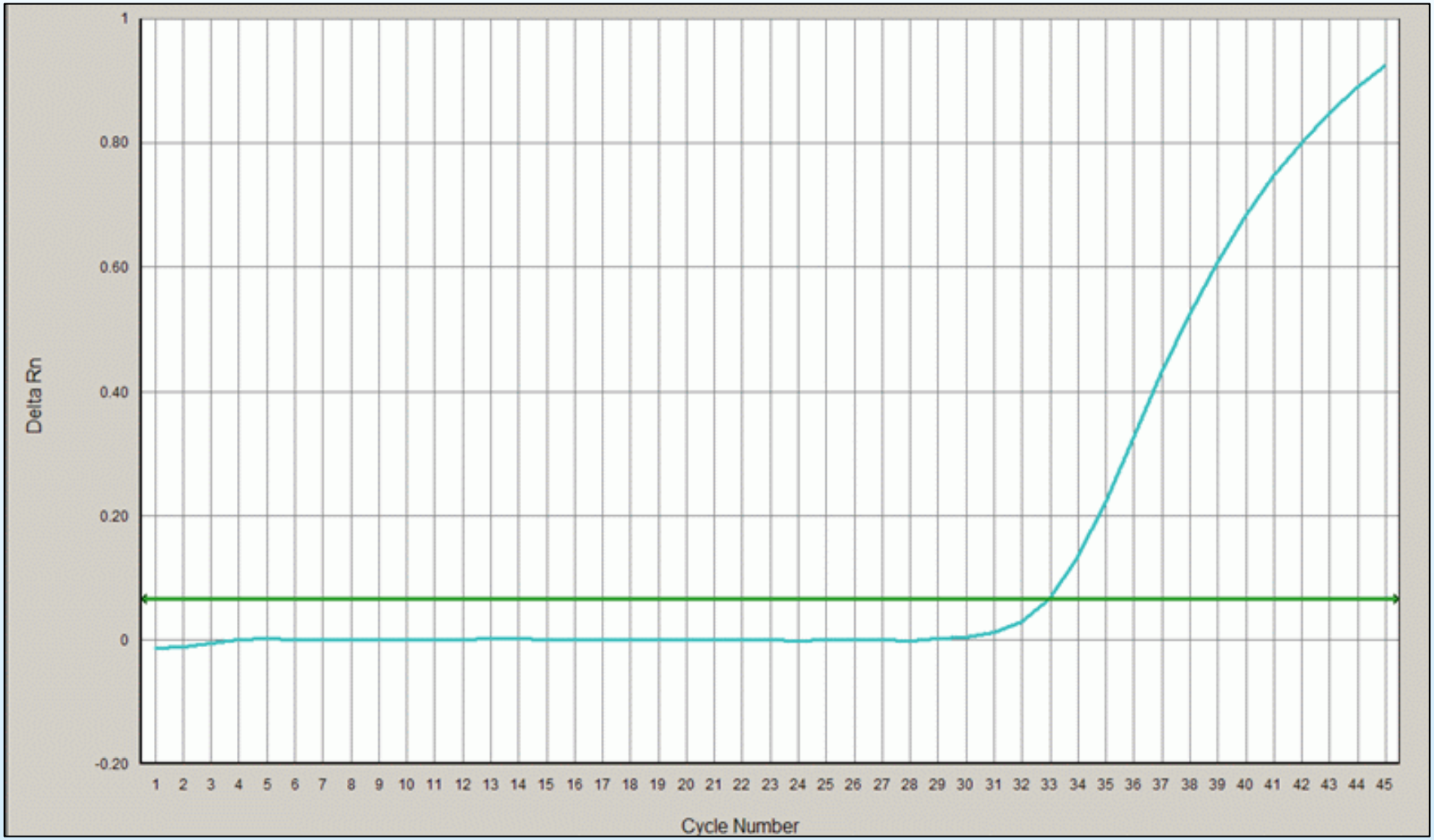
L = empty lane;
1-10 = samples;

M = DNA Length standard;
P = negative PCR control

real time PCR system



Positive control reactions



Controls (ISO EN 22174)

	negative process control[a]	positive process control[a]	negative extraction control[b]	internal/external amplification control[c]	positive PCR control[d]	negative PCR control[d]
sample treatment	↓	↓				
nucleic acid extraction	↓	↓	↓			
amplification	↓	↓	↓	↓	↓	↓
detection	↓	↓	↓	↓	↓	↓

[a] The frequency of use shall be determined as part of the laboratory quality assurance program.
[b] The control is not necessary when the negative process control is performed.
[c] The internal or external amplification control shall be performed with every PCR reaction.
[d] This control is necessary for every batch of samples in a cycler run.
↓ Procedures covered by this control.

Reference materials

irm
Institute for Reference Materials and Measurements

ERM
European Reference Materials

CERTIFICATE OF ANALYSIS

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ERM®-BF413b

DRIED MAIZE POWDER 1261

	Mass fraction	
	Certified value [1] [g / kg]	Uncertainty [2] [g / kg]
MON 810 maize content	1.00	0.26

1) *The certified value is based on the mass fraction of dried non-GMO powder and dried GMO powder mixed and corrected for the water content. The value is traceable to the International System of Units (SI).*
2) *Estimated expanded uncertainty U with a coverage factor k = 2, corresponding to a level of confidence of about 95 %, as defined in the Guide to the Expression of Uncertainty in Measurement (GUM), ISO, 1995. Uncertainty contributions arising from characterisation as well as from homogeneity and stability assessment were taken into consideration.*

EN ISO/IEC 17025, 5.9

- Quality control
  - Regular use of certified reference materials and/or internal quality control using secondary reference materials
  - Participation in interlaboratory comparison or proficiency-testing programmes
  - Replicate tests or calibrations using the same or different methods
  - Correlation of results for different characteristics of an item

Summary

Accreditation needs technical competence

- ✓ - in the laboratory
- ✓ - of the assessors

ISO 17025 offers flexibility

Vote for

- accreditation and assessment of testing laboratories, if applicable, not only related to individual methods;
- criteria approach, if applicable
- Not only one way to get a result.