

# Standardization of Extraction: Enabling comparable GMO analysis across the EU

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APPLIED  
TESTING



## QIAGEN – What we do

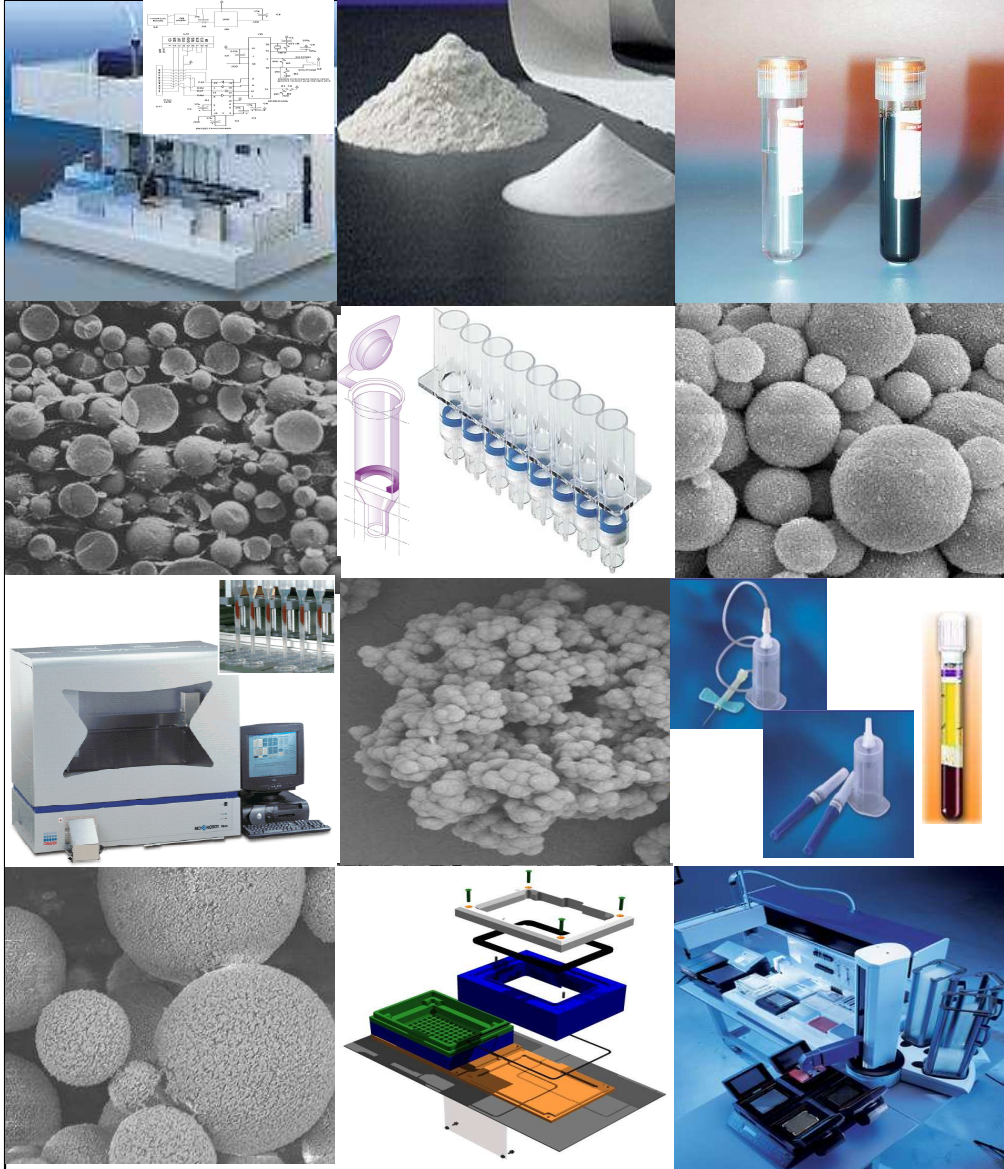
Why standardization is key

- Standardization for GMO Analysis

How we standardize pre-analytical processing

- Products
- Integration of process steps
- Automation of workflows
- Validation and quality control of products

DNA extraction data



## QIAGEN Technologies

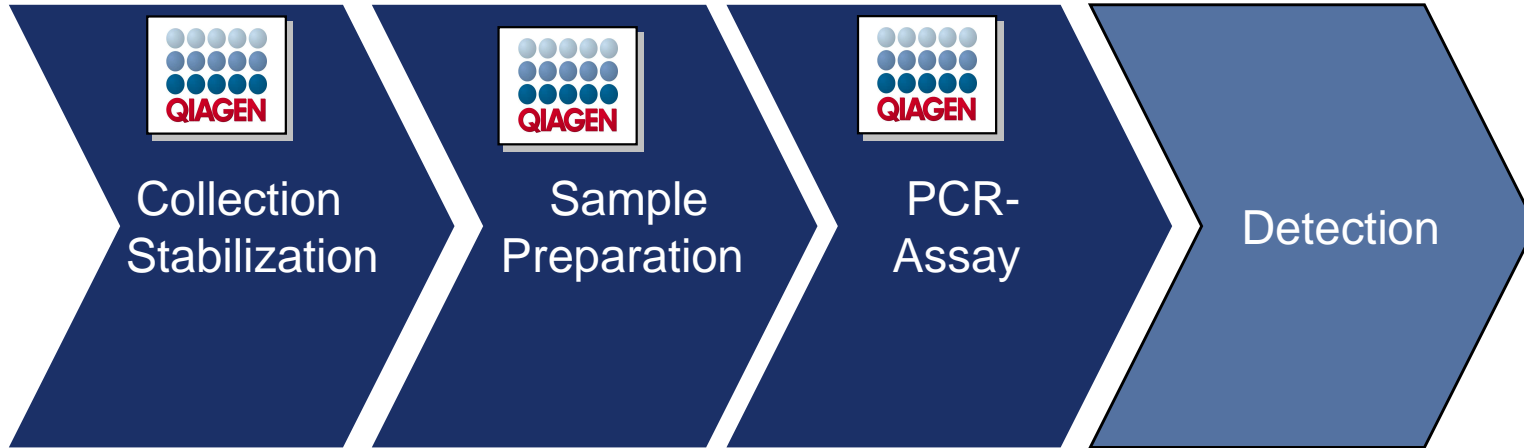
Chromatography, Filtration, Magnetic bead, Thin membrane, Hybrid capture, siRNA, PCR, Transfection, Whole genome amplification, haplotype-specific extraction etc., etc., etc.

## Engineering - Automation

- Hardware design perfection
- Software development platforms
- Electronic engineering

## Comprehensive Intellectual Property Estate

- Over 321 patents
- Over 252 pending applications
- Over 500 patents under license



Innovative  
Collection Devices



The  
Gold Standard



Design of test &  
consumables



Runs on all major  
detection platforms



Quality In = Quality Out

QIAGEN – What we do

## Why standardization is key

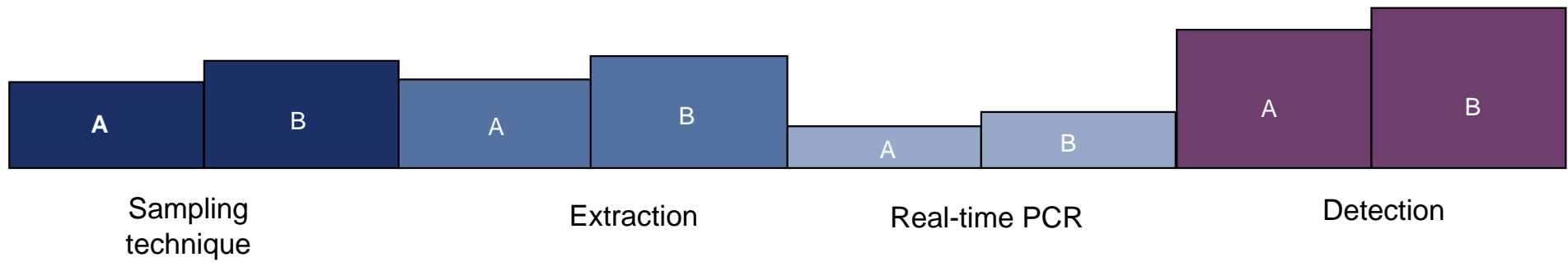
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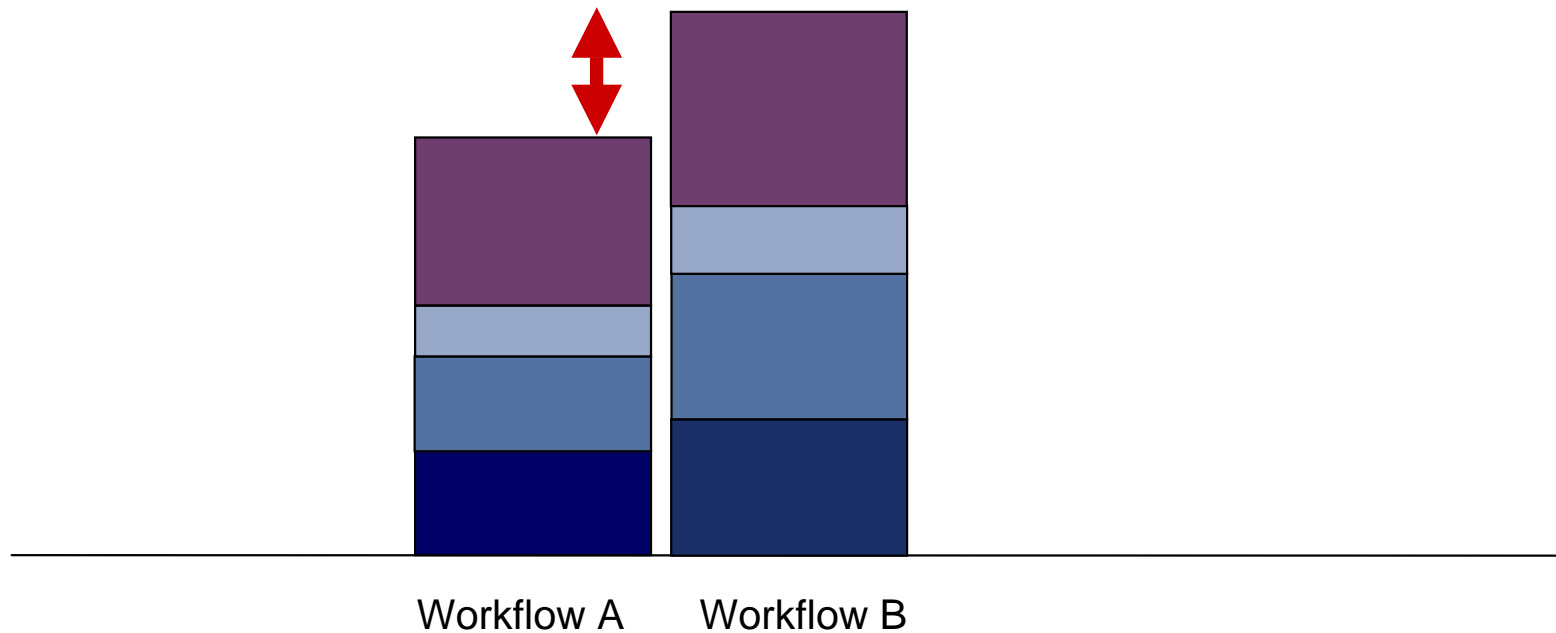
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Statistically insignificant variabilities in each of step of Workflow A and B



Can lead to a significant result differences





Food/feed sample results are compared:

- Between individual lab technicians
- Among laboratories of the same site
- Between sites of the same organization
- Between organizations
- Between countries

Non-sample type deviations can be due to:

- Protocol
- Technician
- Reagents
- Instrument use

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Non-standardized technologies and protocols are risky and can lead to:

- Ambiguous results
- Incorrect determination of GMO content
- Comparisons of non-equivalents
- Failure to validate a method



Food & Feed are particularly challenging sample types

- Difficult to lyse samples
- Huge variety of materials and sample types
- DNA degradation
- Mixed DNA content
- Processing of foods introduces complexities
- Presence of inhibitors like proteins or intermediates

Standardized solutions decrease variability and increase reliability

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Extraction of GMO samples



## Proven

- 10,000+ peer-reviewed papers in 2004
- 15+ diagnostic partnerships

## Universal

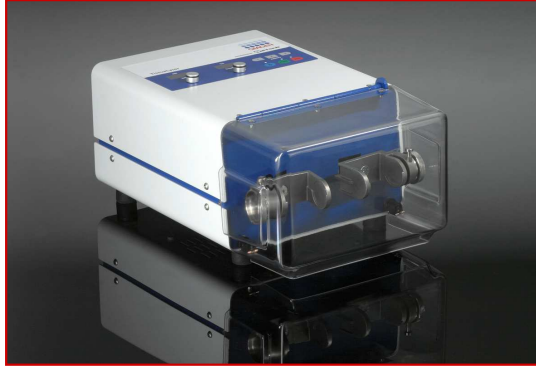
- Recommended by platform providers
- Global presence

## Optimized

- Thorough development & evaluation
- Detailed protocols and application notes

## Expert advice

- Tech Support by Ph.D Scientists



## Disruption:

- TissueLyser for fast and contamination-free disruption



## Purification:

- QIAGEN's proven separation and purification technology

**Assay**

## Detection:

- Validated downstream detection assay



# Standardization By Automation Of Workflow

## GMO/Food/Plant Sample Preparation Portfolio

Manual DNeasy Kits, QIAamp Kits



LTP Automation  
15 samples / run

BioSprint 15



High Throughput Automation  
96 samples / run

BioSprint 96



High Throughput Automation  
96 – 192 samples / run

BioRobot Universal



## Industry leading standards

- cGMP compliant (21CFR 820 & 21 CFR 200)
- IVD-D certified EN ISO 13485:2003 (EU)
- ISO certified 9001:2000
- 100 % successful track record in 3rd party audits



## Global reach with subsidiaries and distributors worldwide



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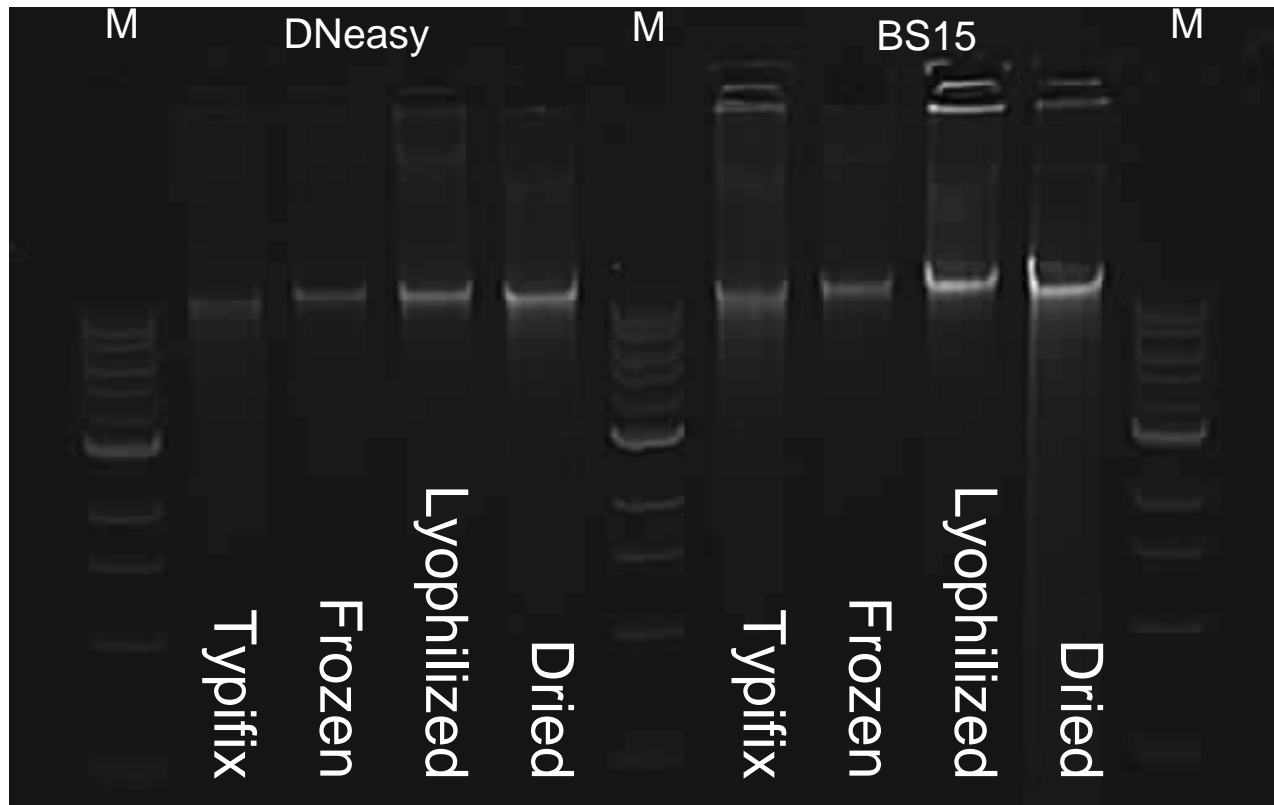


# Manual & Automated DNA isolation

## Equivalent results from identical samples

DNeasy Manual Prep

BioSprint 15 Automated Prep







# Wide Range Of Plant and GMO species DNA Isolation Using QIAGEN

DNA isolation for GMO analysis on BioSprint	DNeasy extraction of GMO in raw and processed foodstuffs	QIAamp extraction of GMO in raw and processed foodstuffs
<p>Fresh leaf / Tissue</p> <ul style="list-style-type: none"> <li>■ Maize</li> <li>■ Cotton</li> <li>■ Pine</li> <li>■ Rose</li> <li>■ Soybean Spruce</li> <li>■ Wheat</li> </ul> <p>Lyophilized Leaves</p> <ul style="list-style-type: none"> <li>■ Maize</li> <li>■ Rapeseed</li> <li>■ Sunflower</li> </ul> <p>Seeds</p> <ul style="list-style-type: none"> <li>■ Apple</li> <li>■ French bean</li> <li>■ Grape</li> <li>■ Linen</li> <li>■ Lunpine</li> <li>■ Orange</li> <li>■ Rapeseed</li> <li>■ Soybean</li> <li>■ Turnip</li> <li>■ Tomato</li> <li>■ Wheat</li> <li>■ Maize (dried seed powder)</li> </ul>	<p>Soybean</p> <ul style="list-style-type: none"> <li>■ Biscuits</li> <li>■ Soya Flour</li> <li>■ Tofu</li> <li>■ Soya protein</li> </ul> <p>Maize</p> <ul style="list-style-type: none"> <li>■ Cornflour</li> <li>■ Cornmeal</li> </ul>	<p>Soybean</p> <ul style="list-style-type: none"> <li>■ Chocolate cream</li> <li>■ Milk chocolate</li> <li>■ Nougat waffle biscuit</li> <li>■ Chocolate muesli bar</li> <li>■ Praline chocolates</li> <li>■ Chocolate biscuits</li> <li>■ Chocolate diet drink</li> <li>■ Miso paste</li> </ul> <p>Maize</p> <ul style="list-style-type: none"> <li>■ Taco shells</li> <li>■ Chocolate cereal</li> </ul>



# Standardization The Key To Success

## Proven products



## Integration of process steps



## Automation of workflows



## Validation and quality control of products



THANK YOU!

