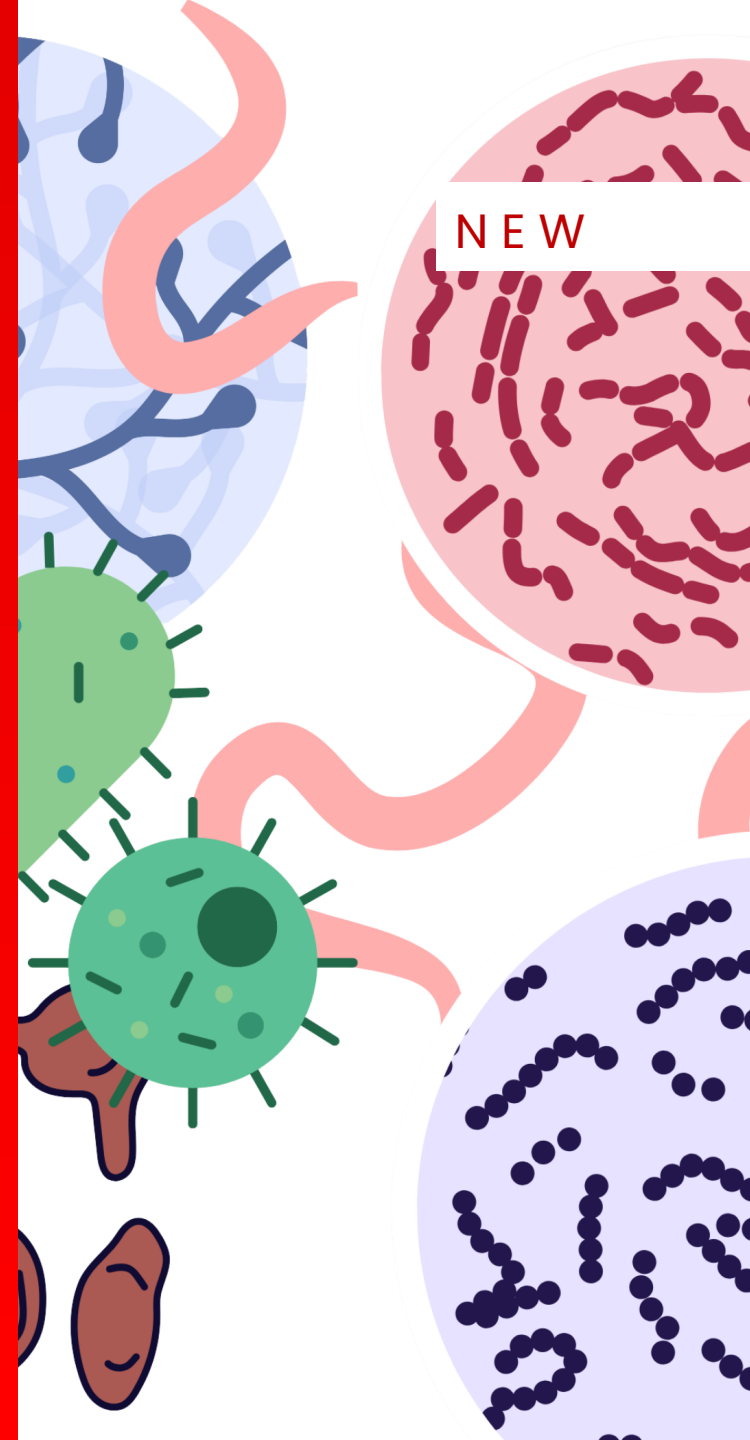
Expedite Diagnostics

Accelerating molecular results

ClassiX DNA/RNA (CXDR-96)

- One extraction chemistry
- Multiple matrices
- Manual to automated workflows

Vera Manelli, Technical Specialist



Nucleic acid extraction

Five bottlenecks that slow molecular diagnostics labs down

Too many extraction methods

Different matrices often require separate extraction procedures, and separate purchases.

Time constraints

Complex samples require more time-consuming extraction methods to achieve high purity.

Inhibitor burden

High inhibitor loads challenge downstream amplification (e.g. blood, stool, environmental matrices)

Low DNA/RNA yield

Recovery of non-degraded DNA and RNA in sufficient quantities from complex samples.

Non-automatable protocols

Manual efficiency does not translate to automated settings, with variability across users.

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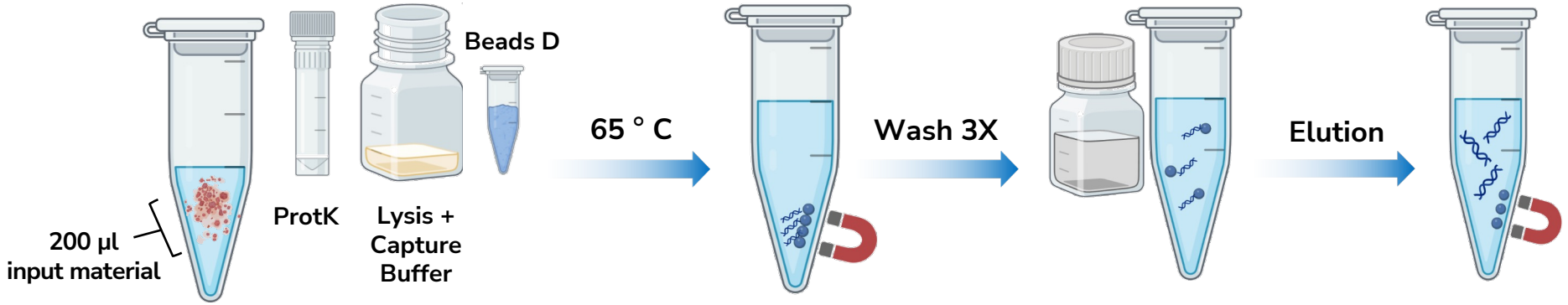
ClassiX DNA/RNA



How it runs in the lab

- Magnetic bead-based protocol
- 30 min extraction time
- Detergent-free elution buffer
- Room-temperature storage (15-25°C)
- Centrifugation-free protocol

What ClassiX DNA/RNA delivers

- DNA and RNA extraction
- Compatible with multiple matrices
- Compatibility with both manual and automated workflows

Research use only – IVDR coming soon

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ClassiX DNA/RNA Validation

Validated platforms

- SwiftXtractor SL (Xpedite)
- Auto-Pure (Allsheng)
- Nimbus/Starlet (Hamilton)
- KingFisher (ThermoFisher)
- GeneXplorer (Chroma)
- Singu20 (Singuway)
- MagnetaPure 32 (Macherey-Nagel)

Validated sample types

- Whole blood
- Serum / plasma
- Urine
- Rectal swab
- Stool
- Vaginal swab
- Throat swab
- Nasopharyngeal swab
- Semen
- Wastewater

**Swabs in UTM/VTM/Saline/PBS/eNAT/...*

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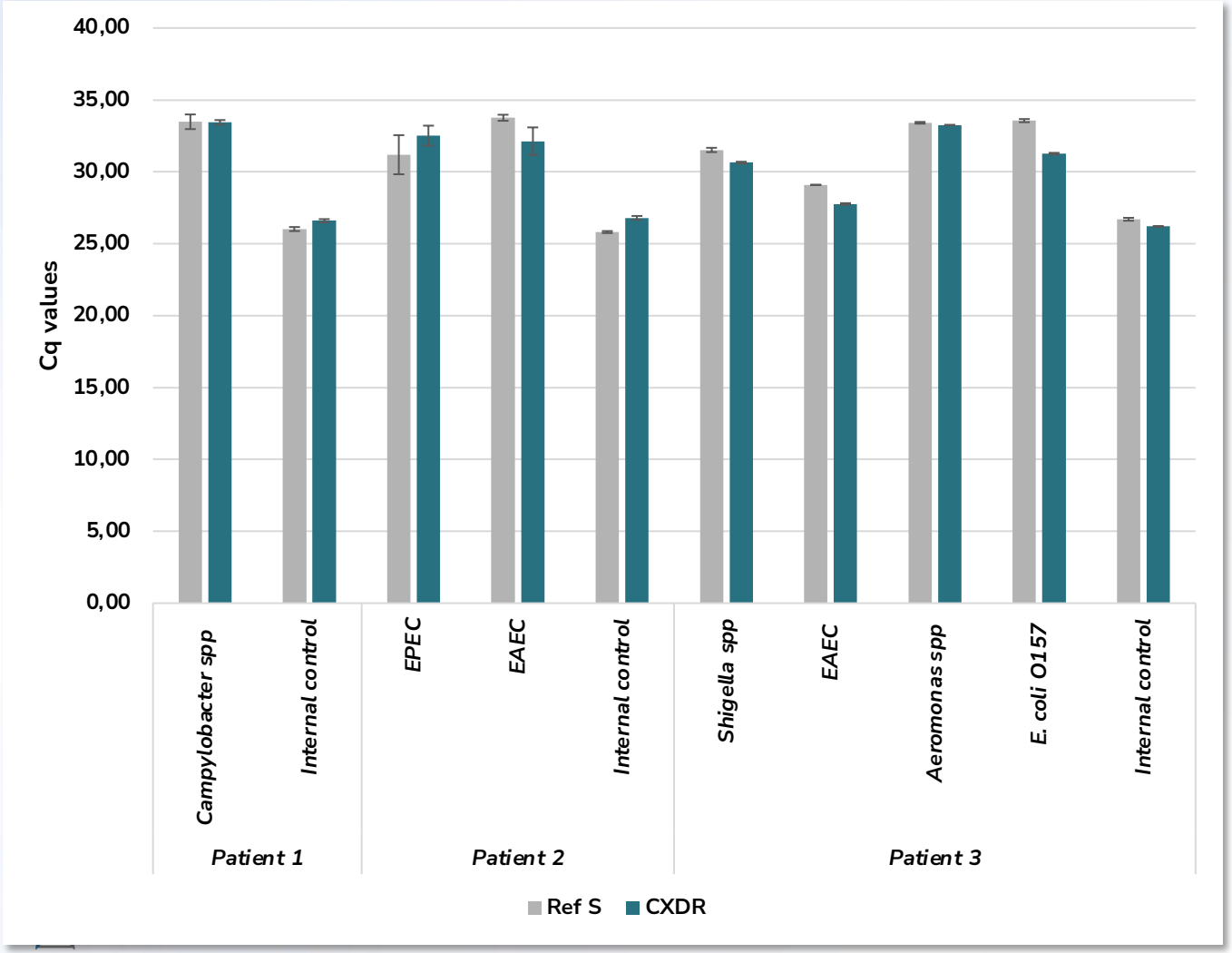
Bacteria in clinical fecal swabs

Comparison of ClassiX DNA-RNA with the laboratory's reference extraction



Lower Cq values indicate more amplifiable target

- 200 µL clinical fecal-swab input
- Automated extraction on the MagnetaPure 32.
- Benchmarking via qPCR assay

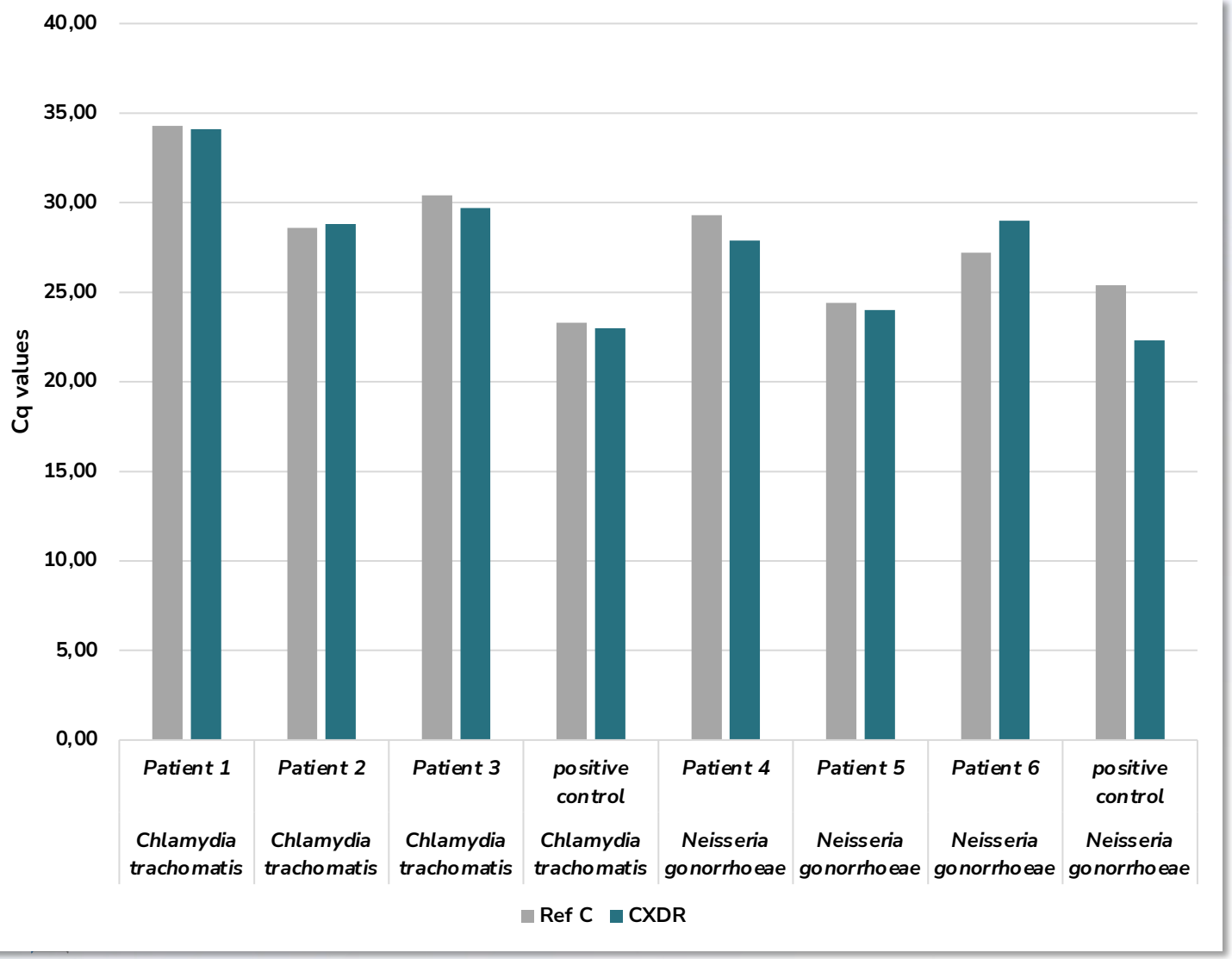
Result:

Both workflows detected all targets represented in the three samples.

ClassiX DNA-RNA generated lower Cq values for 6 of the 7 pathogen comparisons

Rectal swabs

Concordant detection of STI targets



Lower Cq values indicate more amplifiable target

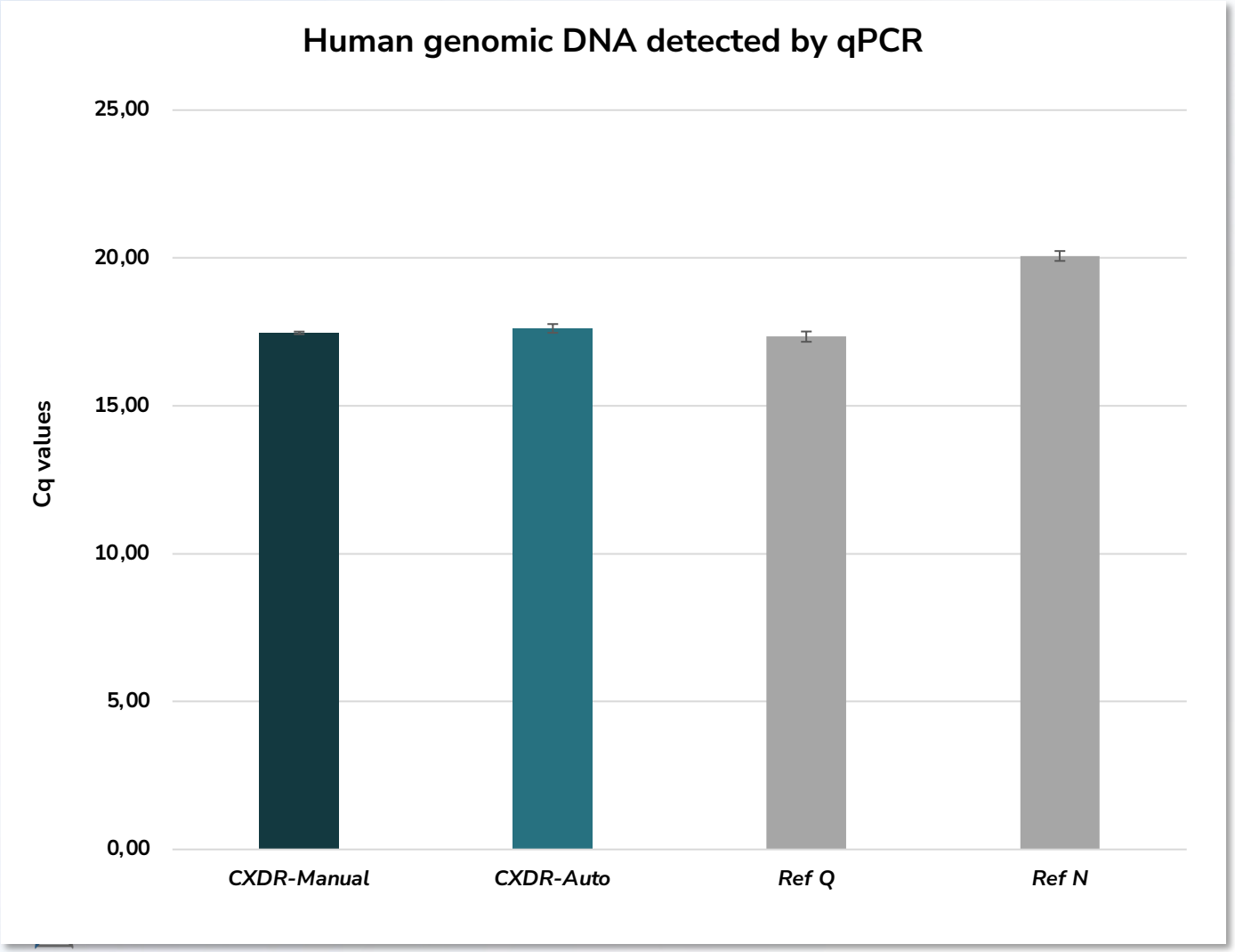
- 200 µL clinical rectal-swab input from positive patients
- **automated extraction** on GeneXplorer
- Benchmarking via qPCR

Result: The expected target was detected with both extraction workflows in all six clinical samples.

Comparable target detection with ClassiX DNA/RNA and the reference method

Whole blood

Consistent genomic DNA recovery across manual and automated ClassiX workflows



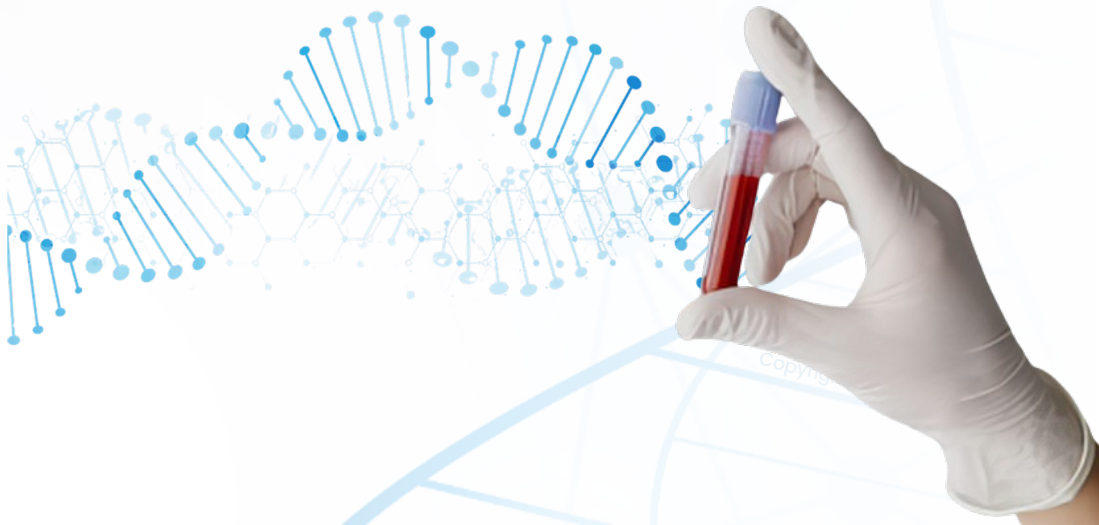
Lower Cq values indicate more amplifiable target

- 200 µL whole blood from healthy donors
- **automated extraction** on SwiftXtractor SL
- Benchmarking via qPCR

Result:

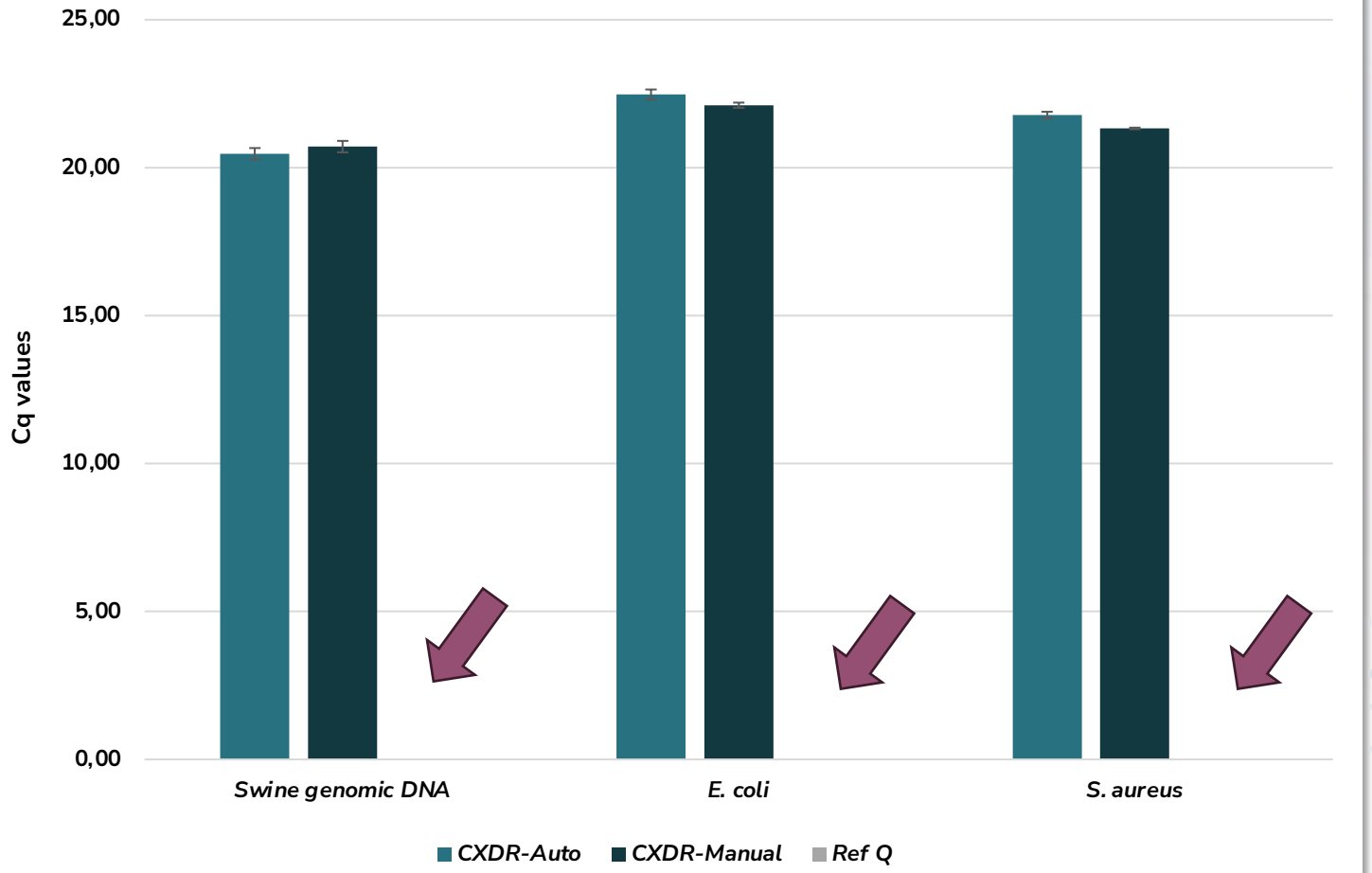
Manual and automated (SwiftXtractor SL) extraction with ClassiX DNA/RNA results were closely aligned, with a difference of 0.15 Cq.

Both ClassiX formats were comparable to Ref Q
ClassiX produced even lower Cq values than Ref N under the tested conditions



Porcine whole blood

Recovery of genomic and bacterial targets

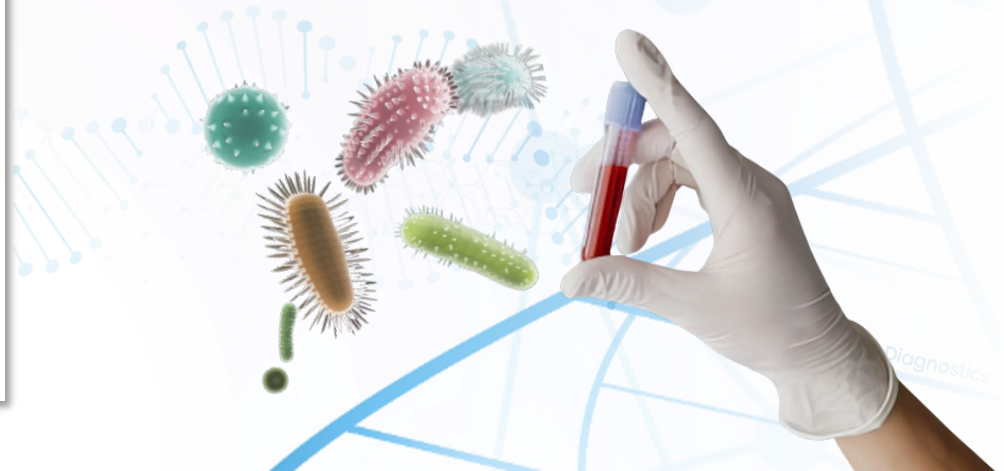


Lower Cq values indicate more amplifiable target

- 200 µL porcine whole blood input
- Porcine genomic DNA and spiked *E. coli (gram -)* and *S. aureus (gram +)*
- *ClassiX DNA/RNA Manual extraction vs automated extraction (SwiftXtractor SL) – vs manual Ref.Q kit*
- *Benchmarking via qPCR*

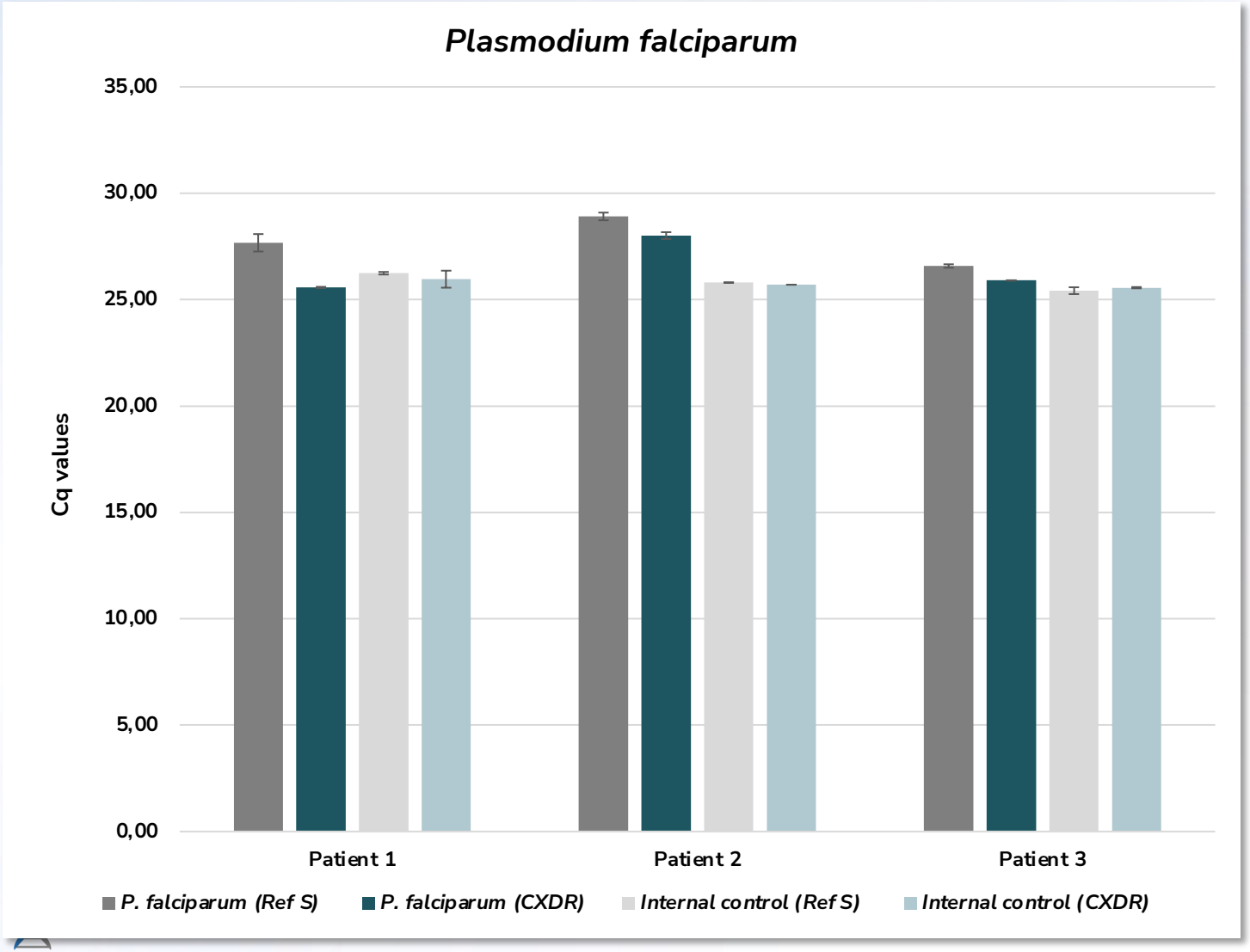
Result:

Manual and automated ClassiX results differed by less than 0.5 Cq for every target
No detectable signal in Ref Q



Whole blood

External site evaluation of clinical malaria samples



Lower Cq values indicate more amplifiable target

- Input sample: 200ul whole blood in EDTA tubes
- ClassiX DNA/RNA was automated on MagnetaPure 32 vs automated extraction from a standard reference method (Ref S)
- Benchmarking via qPCR

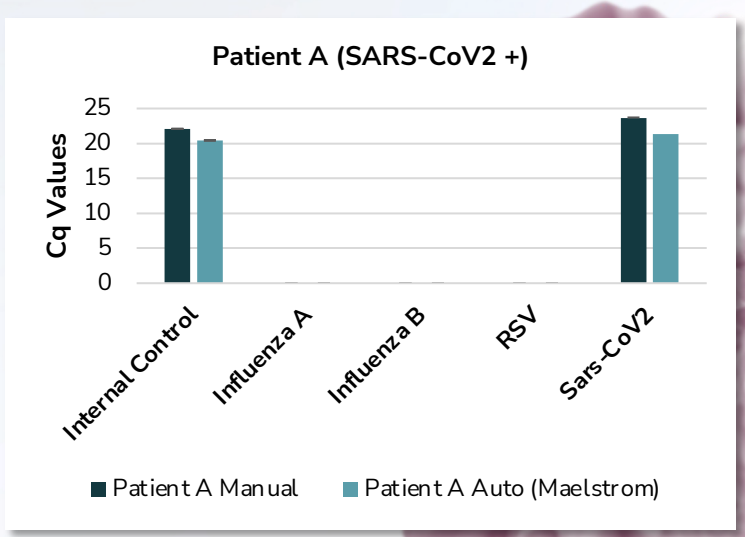
Result:

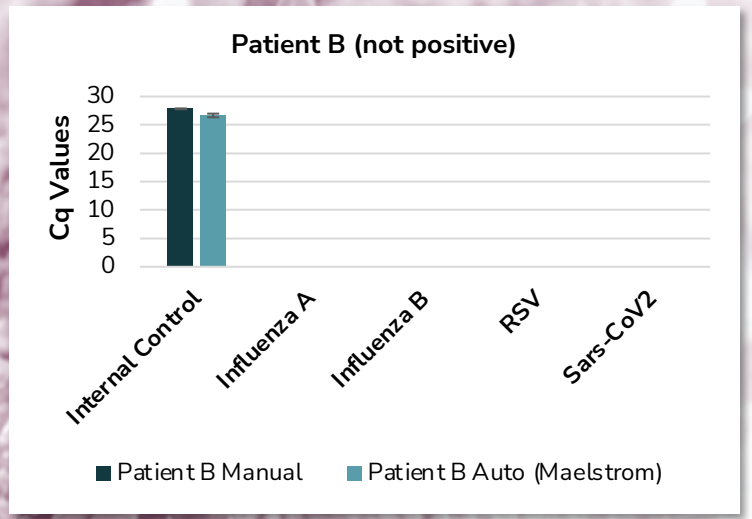
ClassiX produced a lower mean Cq in all three comparisons

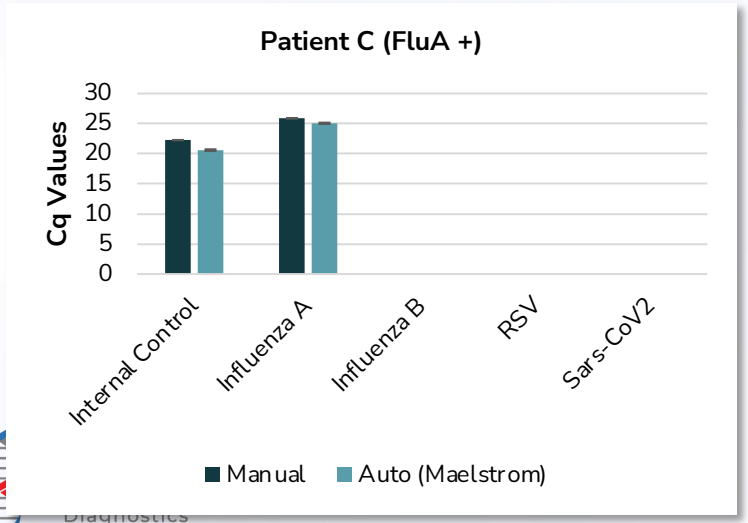
ClassiX Manual vs Auto extraction

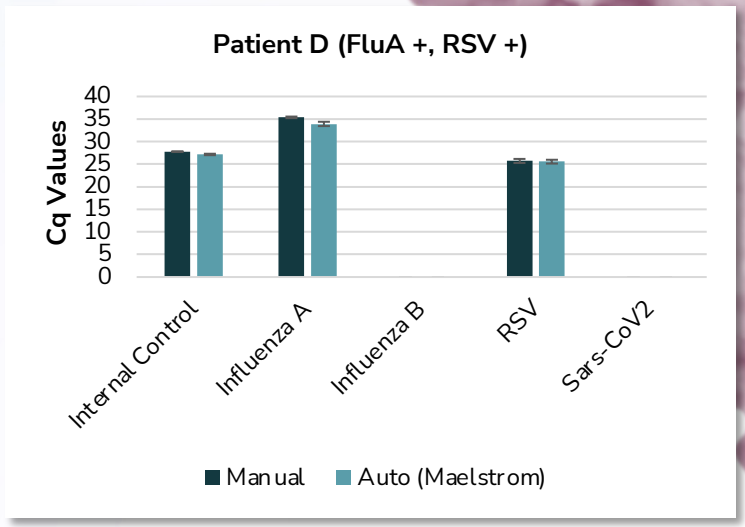
Virus detection in clinical respiratory samples

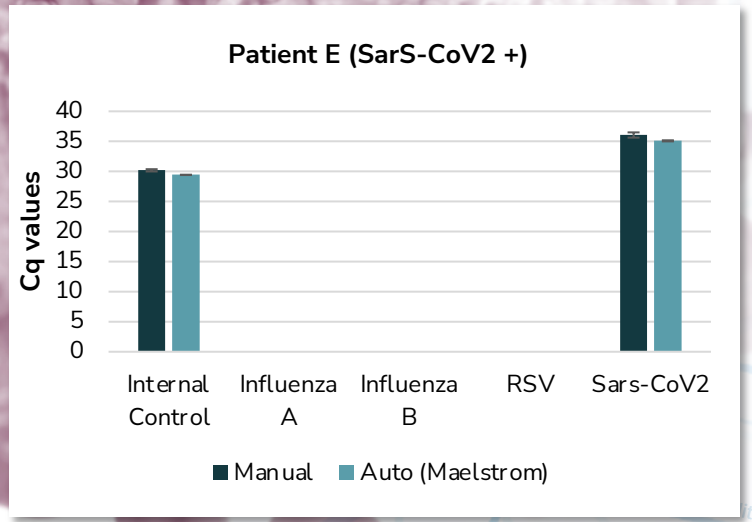
ID Nr.	Sample type
Patient A	VTM/UTM (Swab)
Patient B	Saline/PBS (Swab)
Patient C	VTM/UTM (Swab)
Patient D	VTM/UTM (Swab)
Patient E	Saline/PBS (Swab)





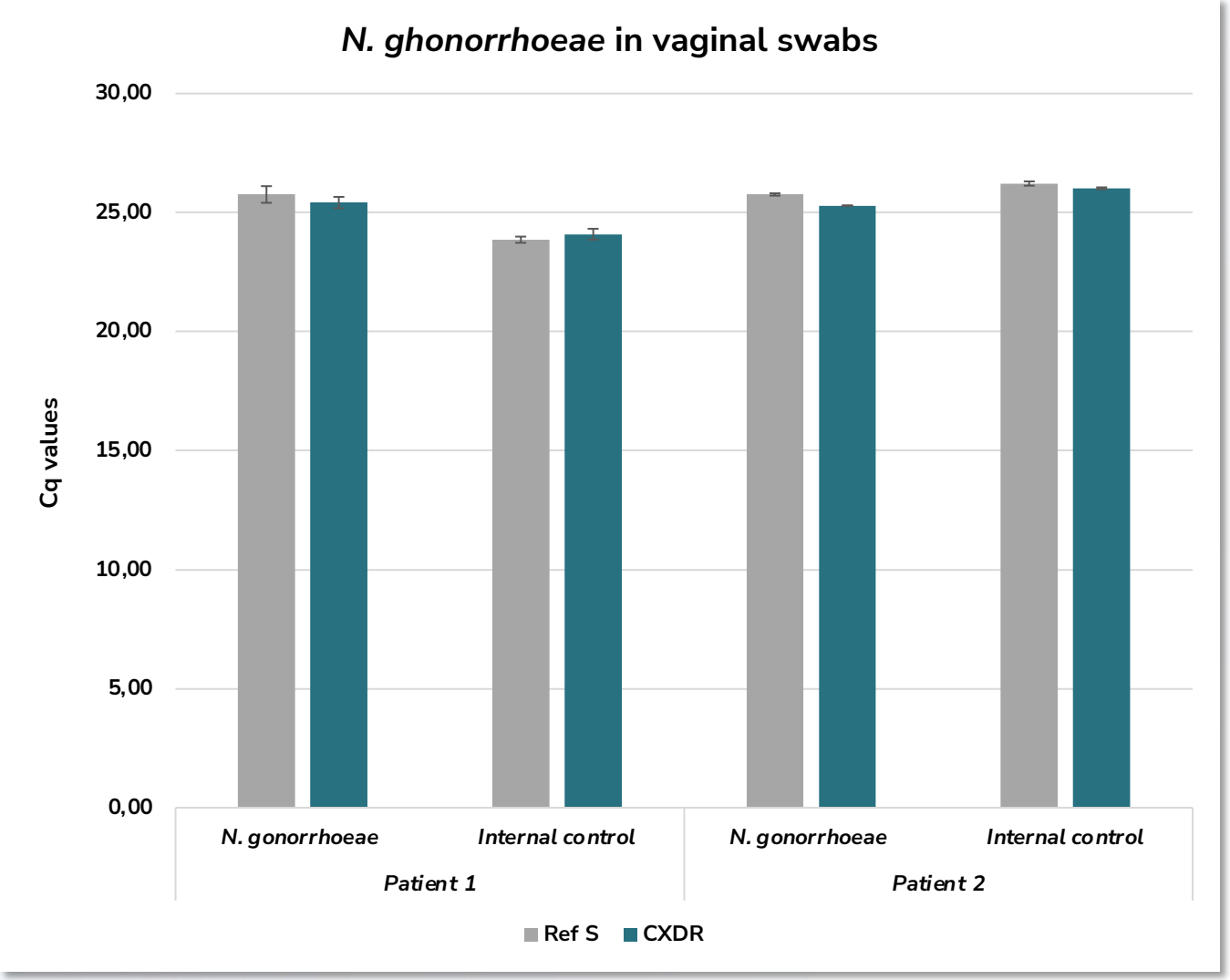






Lower Cq values indicate more amplifiable target

Vaginal swabs
Consistent *N. gonorrhoeae* detection



Lower Cq values indicate more amplifiable target

- Two *N. gonorrhoeae*-positive vaginal-swab samples
- ClassiX DNA/RNA automated on MagnetaPure 32
- Compared with the laboratory's automated reference extraction
- Target and internal control assessed by qPCR

Result:
The expected target was detected with both extraction workflows in both samples.

ClassiX and the reference method produced closely aligned Cq values for the target and internal control.

Validation highlights

Broad matrix applicability

Tested with blood, serum or plasma, urine, stool, and multiple swab-based sample types.

DNA and RNA recovery

Validation covers extraction from human/mammalian samples, bacteria, yeast and viruses.

Manual to automation translation

Manual and automated ClassiX workflows produced closely aligned results across matrices.

Performance in challenging samples

Amplifiable targets recovered from inhibitor-rich matrices including whole blood and stool.

External-site evidence

Clinical-sample evaluations showed concordant detection vs. established reference workflows.

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More info and data

Discover more resources and full validation data.

Application note

Product page

xpedite-dx.com

For any inquiries:
info@xpedite-dx.com

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