CMD

The αBET™ endotoxin testing system

Rapid, cost-effective, compliant testing at point-of-need



Your endotoxin testing partner

Founded in Cardiff (UK) in 2014

ISO 9001 and ISO/IEC 17025 accredited organisation

Long-standing collaboration with FUJIFILM Wako Chemicals USA

Manufacture and supply of the aBET™ system

State-of-the art contract endotoxin testing facility

- Routine sample analysis
- Method development and validation
- Low endotoxin recovery studies



UKAS TESTING 23137

bsi ISO 9001 Quality Management Systems CERTIFIED FS 749484



The CMD αBET™ Endotoxin Testing System

Fully integrated, flexible endotoxin testing system

Excellent performance whilst using a fraction of FDA-licensed turbidimetric LAL reagent

Fully quantitative results provided in a matter of minutes (10 - 0.001 EU/mL)

Minimal user input needed beyond introduction of sample

On-board FDA 21 CFR Part 11 ready software package ensures data integrity, allowing users to perform Pharmacopoeial compliant tests

Uniquely tolerant of sample matrix colour / opacity meaning a wide range of samples can be tested on the system e.g., biopharma products, nanoparticle formulations, cell culture media

Compliance, confidence and flexibility

The CMD αBET™ system uses FUJIFILM Wako's FDA-licensed PYROSTAR™ ES-F turbidimetric reagent:

- No cross-reactivity with (1,3)-b-D-glucan
- Quantitative testing over the range of 0.001 to 10 EU/mL from a single consumable and reagent combination



Users can choose to run the system in several key modes:

1. **Compliant Test:** Users guided through Pharmacopoeial compliant assay (calibration plus spiked / unspiked samples)
2. **Lysate Verification:** Extended calibration to verify lysate performance
3. **Calibrated Test:** Uses an archived calibration to generate quantitative results most rapidly
4. **Non-calibrated Test:** Random sample testing, results provided as 'times' cf. 'concentrations'

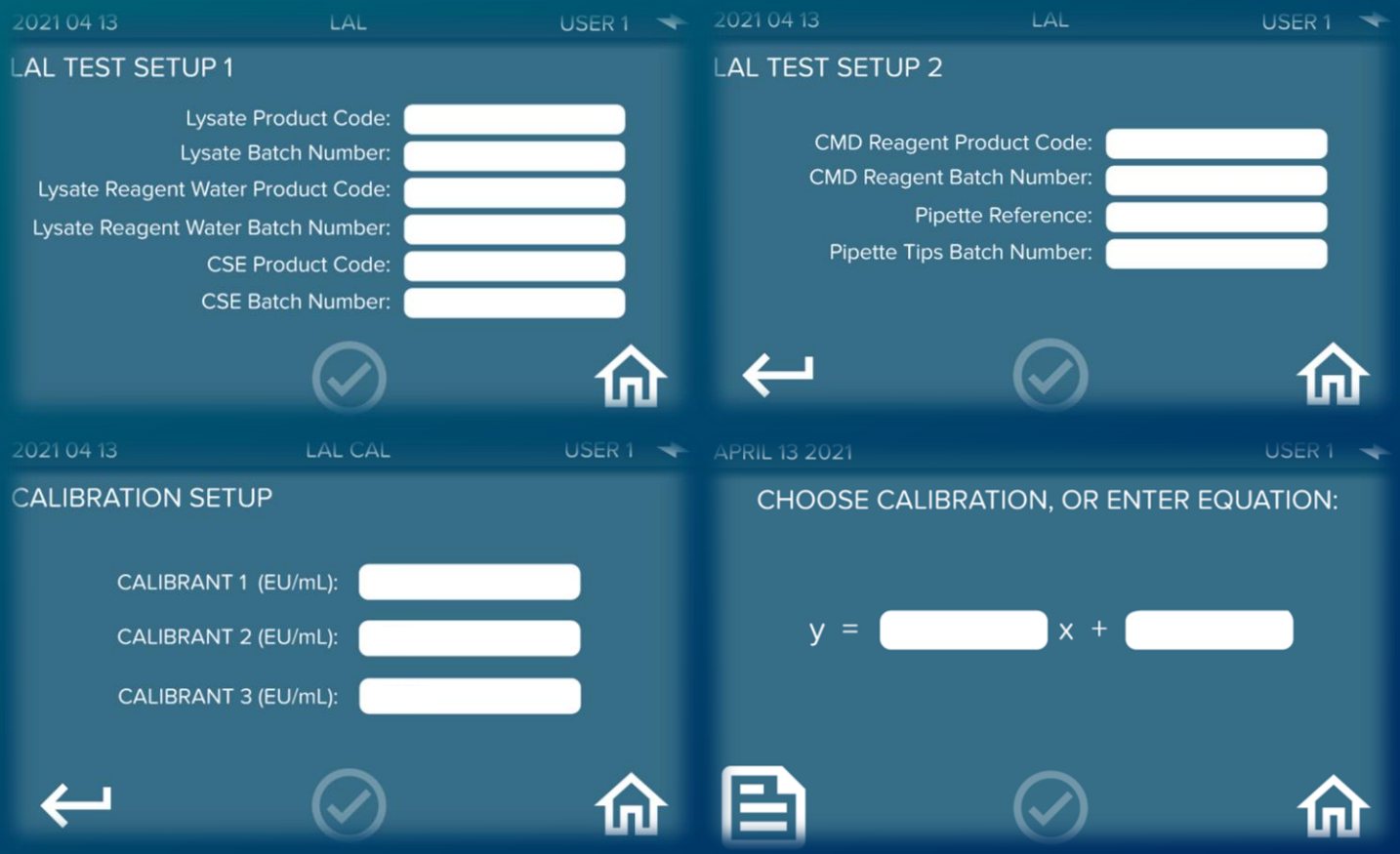


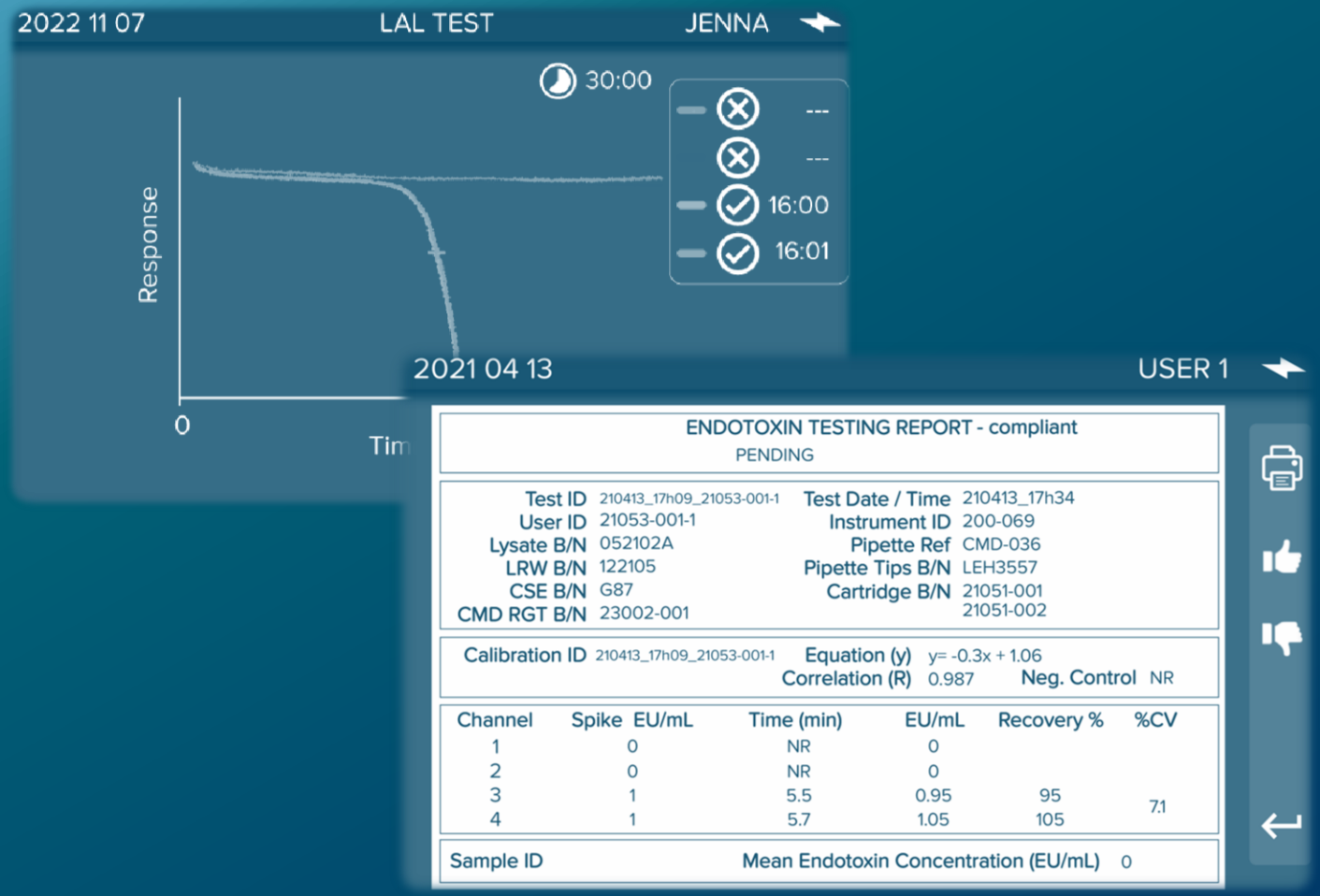
Simple and traceable

When running a compliant or calibrated test, users have the option of adding details of lysate and other reagents / accessories used for traceability

Users decide calibration range - no need for different cartridges / lysate combinations

All calibrations archived on system for future use





Real-time data visualisation

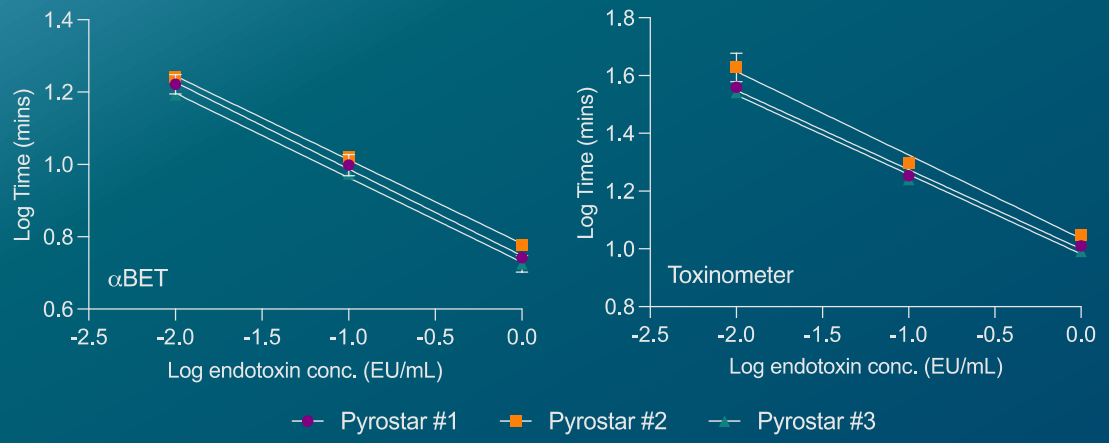
All test modes allow for RT data visualisation and result presentation

Final report can be reviewed / approved

Report provides mean endotoxin concentration of sample, as well as recovery of spike and %CV values

Report can be printed, backed up to a PC, as well as always being available within Data Records on the aBET™ system

Laboratory quality data in any location



CMD αBET™ System			
Endotoxin conc. (EU/mL)	**Mean time (mins)**	**St Dev**	**% CV**
1	5.6	0.36	6.4
0.1	10.0	0.63	6.3
0.01	16.6	1.04	6.3
FUJIFILM Wako Toxinometer® tube reader			
Endotoxin conc. (EU/mL)	**Mean time (mins)**	**St Dev**	**% CV**
1	10.5	0.62	5.9
0.1	18.5	1.15	6.2
0.01	37.2	2.88	7.7

Equivalent performance to the FUJIFILM Wako Toxinometer® tube reader system in terms of accuracy / precision, but with faster time-to-result and the requirement for less lysate and sample per test.

aBET™ CV values are for endotoxin concentration, not time. Other systems allow up to 25% CV between duplicate reaction times – this equates to a CV of ~ 80% when converted to EU/mL. Concentration CV values of < 10% are readily achievable on the aBET™ system.

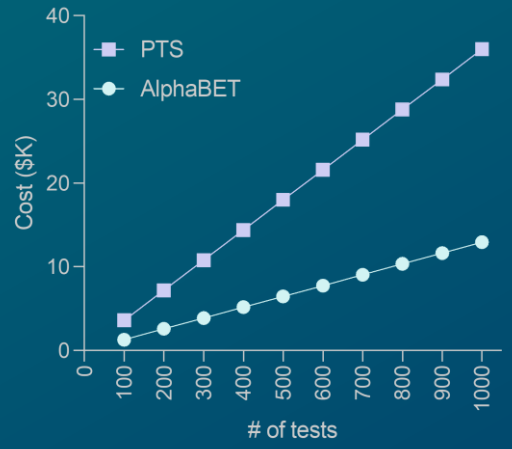
Sustainability & cost effectiveness

Switching to the αBET™ system reduces the consumption of lysate by more than 90%

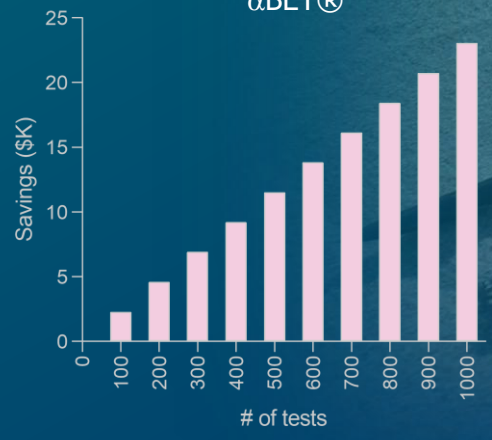
Just 14 μL of sample needed per test

Recurring costs typically 1/3rd of other cartridge-based testing systems

Cost: αBET® vs. PTS



Recurrent savings: αBET®



The CMD αBET™ Family

- ✓ **Dual-wavelength** expansion module enables recombinant cascade reagents and chromogenic LAL-based assays to be run on your αBET™ system, alongside the existing kinetic turbidimetric assays.
- ✓ **Independent random-access** ports allow users to double throughput of testing. Calibration times halved.
- ✓ **Expansion module** connects directly to the αBET™ master system via an ethernet cable.



αBET™ EM

Two cartridge
(8 test) throughput

The CMD αBET™ Family



αBET™ 4-port

Four cartridges
(16 test) throughput

The **ONLY** small footprint, fully integrated system that allows users to run **ALL** traditional LAL as well as recombinant cascade reagents

- ✓ **Dual wavelength -** Enhanced KTA using magneto-optical sensing at 850 nm plus traditional 405 nm optical detection (rCR, KTA and KCA)
- ✓ **Same small volume -** Maximum reagent volume per test: 12 µL, reduced costs
- ✓ **True random access -** Start testing when ready, run different assays across ports
- ✓ **Fully compliant -** Run calibration (3, 4 or 5-point) alongside samples
- ✓ **All calibrations archived for use in 'Calibrated Test' mode**
- ✓ **On-board FDA 21 CFR Part 11 ready software package**
- ✓ **Back-up via USB stick or ethernet cable**

Ready to improve the efficiency, sustainability and cost-effectiveness of your endotoxin testing? We can’t wait to work with you!

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