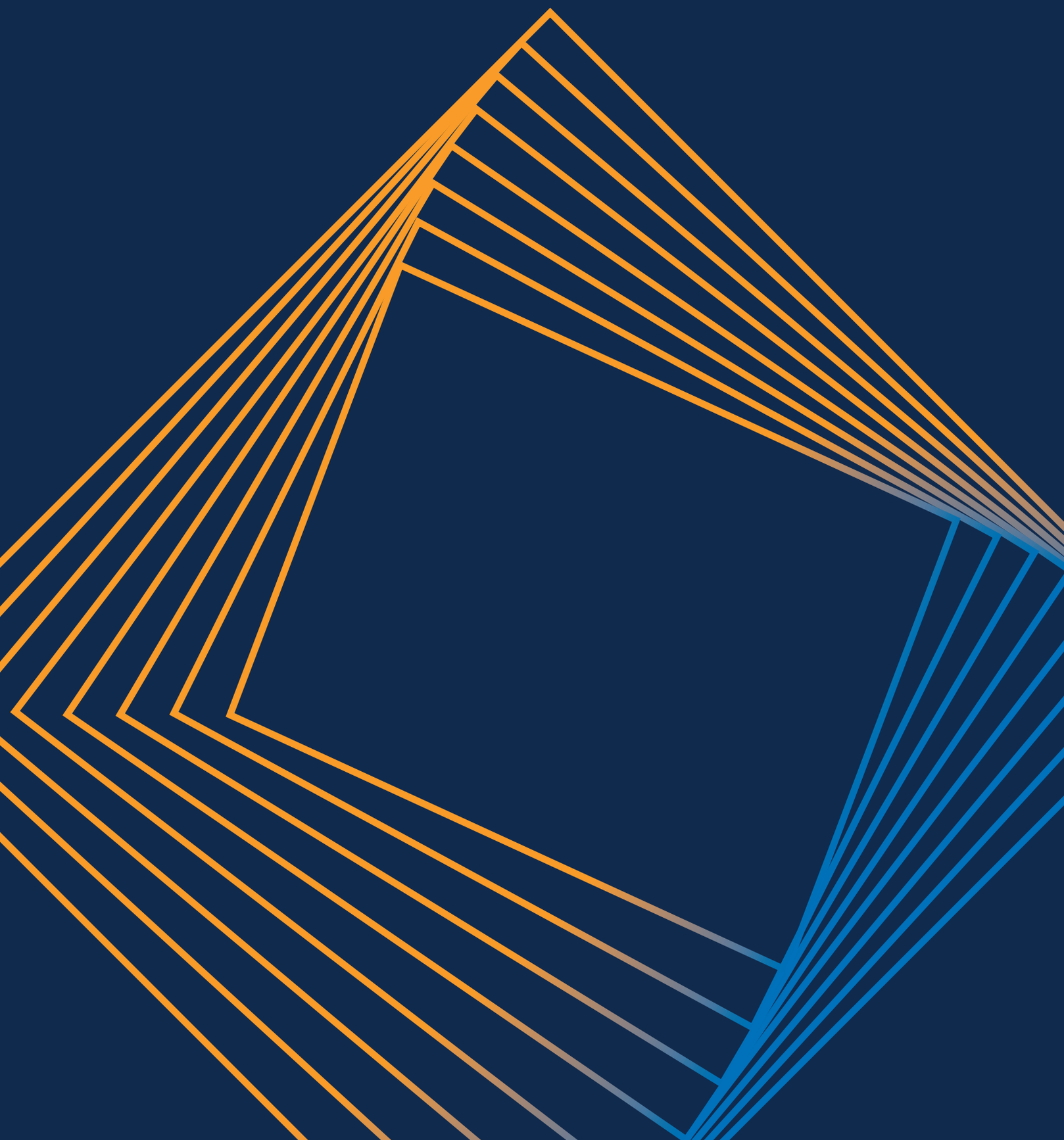
Enzyme Indicators

PROTAK SCIENTIFIC

for vH2O2 Decontamination Validation

Faster, Smarter, Safer

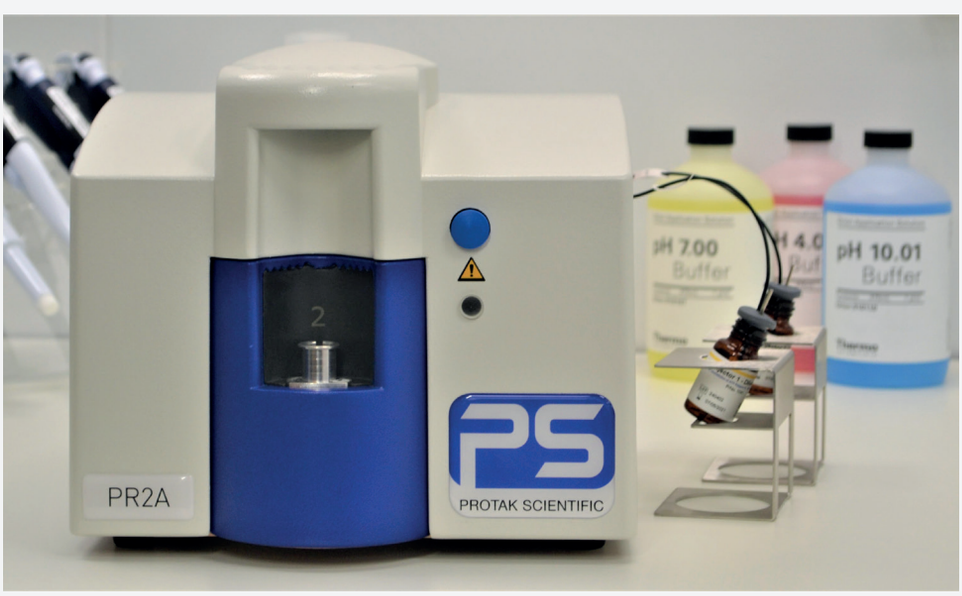


Protak Scientific is the world's only manufacturer of Enzyme Indicators (EI's)

Developed over the last fifteen years as a rapid microbial method (RMM) of measuring the efficacy, distribution, and performance of cold process decontaminations such as hydrogen peroxide (vH2O2, VHP, HVP, iHP) Ethylene Oxide etc.

As a direct alternative to traditional biological indicators.

EI's are inexpensive and carry a low risk for adoption and swiftly return the initial investment with significantly improved quality control and validation. This in turn advances decontamination validation and can remove "run to fail" from a process.



The Enzyme Indicator

Instant

- Takes just 60 seconds
- No Incubation
- No delay
- Immediate results

Real numbers

- Quantifiable data
- Quantitate numerical scale
- Correlated to Biological Indicators

Quality

- Built in safeguards
- Continuous checking and validation of EI's
- Positive and negative controls

Digital data

- No manual interpretation
- Greatly reduced manual recording
- Simple to use

Traditional Biological Indicators

Extended wait

3, 5, 7 days? Incubation for an extended time frame. Hampers validation of new equipment, revalidation and product release.

Poor data

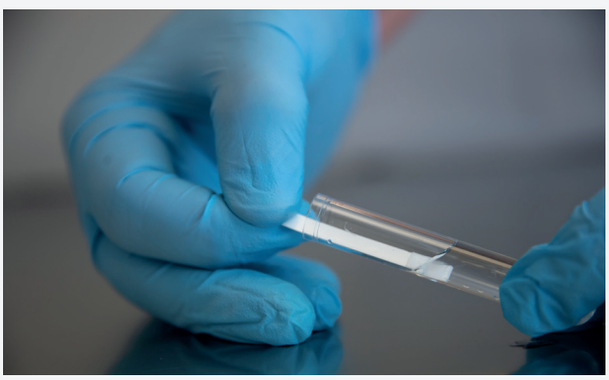
Binary results, variable resistance in batch, large variation between batches, rogue results, false positives.

Process costs

Many aspects of Biological Indicator validation place high, unnecessary costs into the manufacturing process.

Enzyme Indicator technology

60 SECONDS



1. The Process Challenge

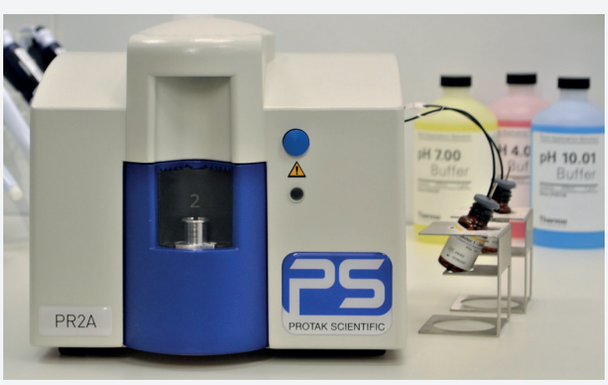
thermostable Adenylate kinase (tAK)

Engineered quantity of enzyme applied to carrier. Viability reduced through exposure to oxidization processes.

2. The Assay

Luciferin / Luciferase Luminescence

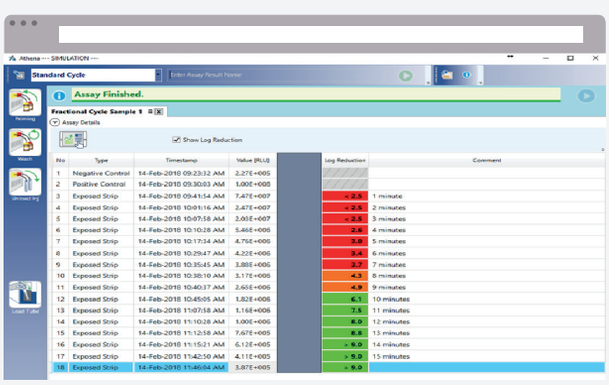
Post cycle the EI is recovered and the remaining viable tAK is used to catalyse our luminescent assay in an automated process.



3. The Reader

PR2A Luminometer

A fully automated reading platform that accurately and repeatedly measures light in RLU from enzyme driven luminescent reaction. With in built process qualification.



4. The Result

ATHENA Software Digital Delivery

Validatable, quantitatively, and immediate validated cycle efficacy reporting delivered via developed software that offers CFR 21 part 11 compliant reporting.

Significantly reduced variation

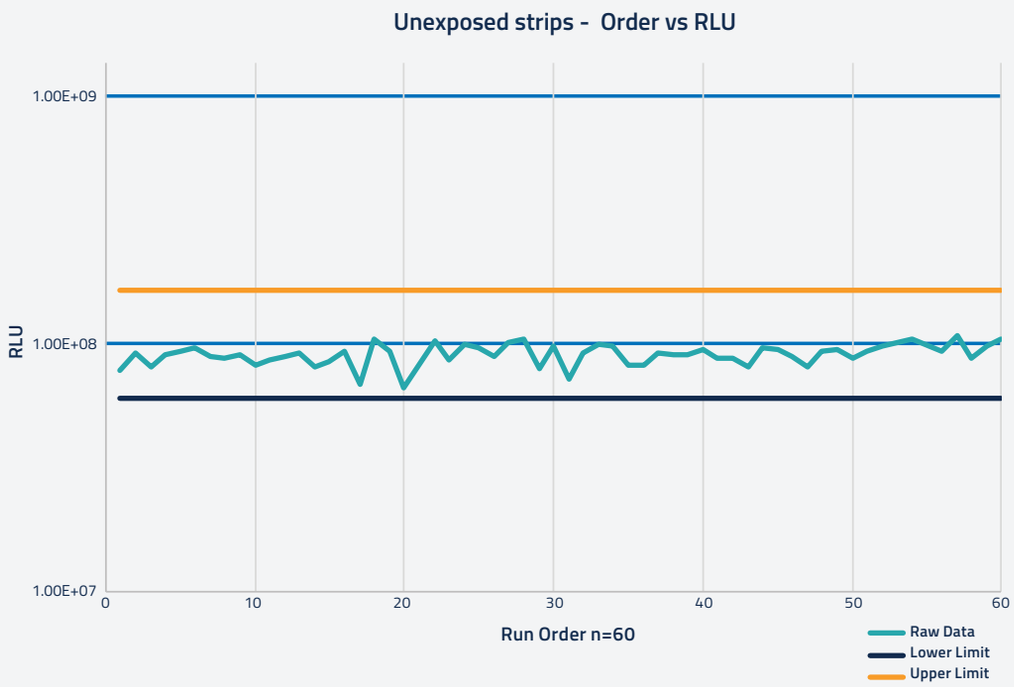
QC TEST PROCESS (DATA FROM GRAPH)

Positive: 95% of N=60 unexposed strips (95-100% Acceptable)

Mean RLU = 9.09E+007 (Acceptable Range 6.00E+007 -1.64E+008)

%CV = 9.90%

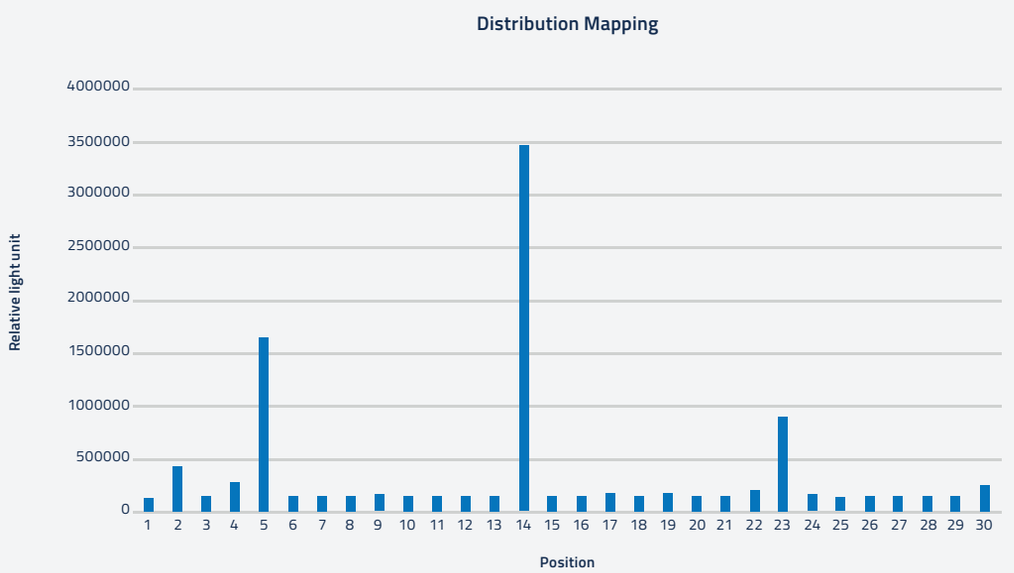
(Acceptable Range = < 15%)



Superior distribution data

DISTRIBUTION

Good distribution shown throughout most of the enclosure with clear Challenge Locations determined by low inactivation in positions 5, 14 and 23



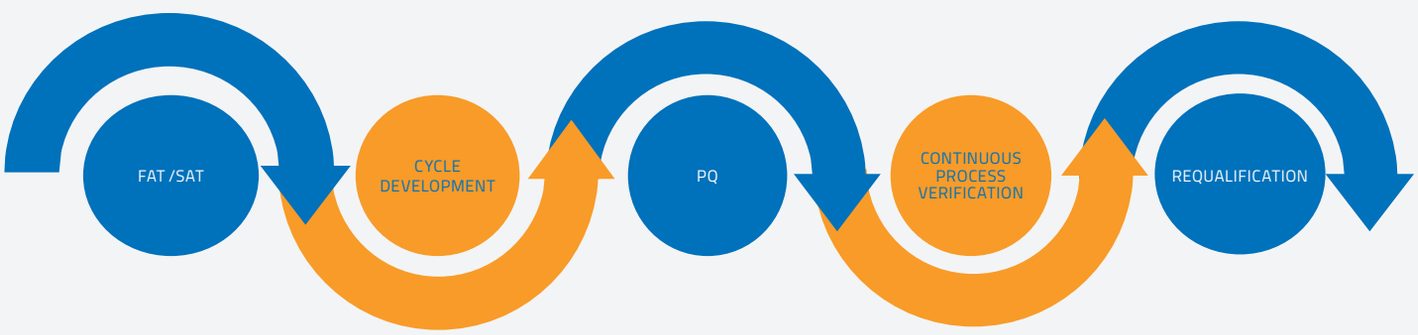
Where do EI's bring value?

Supplier Phase – Once final cycle selected:

- Fractional cycle- Correlation to BIs
- Adjustment to achieved log reduction (Athena)
- Positional x 3

Continuous process verification:

- Use of EI data gathered within validation.
- Map to challenge location (1-5 EIs)
- Safe for routine use - Biological but non-viable



- Best/Worst case for gas distribution = Challenge location definition.
- Prior to final cycle setup - only airflow and injection rate required.
- Cycle reconfirmation at SAT

- Repeat cycles x3 for all selected loads.
- Best/Worst case location placement only with EIs at other locations.
- EI Data set build

- Repeat of PQ on 6 monthly/annual frequency
- EI Data set build

EI validation delivers

Regulatory Compliance

Substantially more robust and reproducible challenge.

Process Understanding

EI's facilitate spot checks and continuous cycle qualification.

Large Financial Gains

EI technology will deliver multimillion dollar savings every year.

Continuous Validation

Engineered to deliver validation control and qualification on every read.

60 Second Results

7 day incubation reduced to 60 second read. Saving 1000's of hours per year.

Preventing Failure

Removing RUN TO FAIL from decontamination process.

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