



ASSOCIATES OF  
**CAPE COD**  
INCORPORATED

*Specialists in Endotoxin and Glucan Detection*

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# TURBIDIMETRIC ENDOTOXIN DETECTION SYSTEMS

Validation Support • Technical Service  
Training • Assay • Detection • Analysis

## **The Complete Solution - Sensitivity, Flexibility and Compliance in Turbidimetric Endotoxin Testing**

Combining Assay, Detection, Analysis, with world class Technical Service, Training, and Validation Support, Associates of Cape Cod, Inc. offers diverse options for conducting endotoxin testing.

# THE COMPLETE SENSITIVITY, FLEXIBILITY AND COMPLIANCE

*The Associates of Cape Cod, Inc. (ACC) Turbidimetric Endotoxin Detection System includes Pyrotell®-T, the Pyros Kinetix® Flex Incubating Kinetic tube reader and user-friendly 21 CFR Part 11 Compliant Pyros® EQS Endotoxin Quantitation Software. The system allows for fully USP BET<sup>1</sup> compliant endotoxin tests, high sensitivity and an economical sample to LAL ratio providing a broad range of options for conducting endotoxin testing.*

*Other options include the BioTek® ELx808 IU™ Plate Reader and Gen5™ Secure Software that provides the flexibility to collect and analyze data for microplate users. Gen5 Secure Software is customized, 21 CFR Part 11 compliant software for the ELx808™ Incubating Microplate Reader. Gen5's interface provides easy access to all major functions of the software including reading parameters, plate layout, data reduction, on-line help wizards, tutorials and Associates of Cape Cod, Inc.'s endotoxin specific assay protocols.*

## TURBIDIMETRIC ENDOTOXIN DETECTION SYSTEMS

# SOLUTION IN TURBIDIMETRIC ENDOTOXIN TESTING

## Assay

### Pyrotell®-T - Turbidimetric Endotoxin Testing

Associates of Cape Cod Inc. Pyrotell-T Turbidimetric reagent formulation is a versatile and cost effective solution for the determination of endotoxin. Pyrotell-T can be used with the Pyros Kinetix® Flex tube reader and incubating microplate readers. It can be used for a wide variety of sample types, ranging from water testing to samples requiring high sensitivity, such as intrathecal products and those requiring high dilutions to overcome interference.

## Detection

### Pyros Kinetix® Flex – for Turbidimetric assays

The Pyros Kinetix® Flex<sup>2</sup> is an optical tube reader that enables turbidimetric and Chromogenic assays to be run in compliance with the USP, EP, and JP bacterial endotoxins test chapters<sup>1</sup>. The Pyros Kinetix Flex tube reader is available in three configurations: 32, 64 or 96 eight mm wells. Each well has a sensor that detects changes in the optical density of a sample. The test in each well is independently actuated, which assures accurate timing and allows the operator to add more samples while an assay is in progress.

### BioTek® ELx808 IU™ Plate Reader

The ELx808 IU™, manufactured by BioTek® Instruments, is an incubating absorbance microplate reader that provides the ability to collect and analyze data.

## Analysis

### Pyros® EQS

Endotoxin Quantitation Software Pyros EQS is intuitive, easy-to-use software that is designed specifically for endotoxin testing and can be used with the Pyros Kinetix Flex tube reader. Pyros EQS is a sophisticated 21 CFR Part 11 compliant, software solution that provides efficient, accurate analysis and reporting.



### Gen5™ Secure Software

Gen5 Secure Software is customized, 21 CFR Part 11 compliant software for the ELx808™ Incubating Microplate Reader. Gen5's interface provides access to all major functions of the software including reading parameters, plate layout, data reduction, on-line help wizards, tutorials and ACC's endotoxin specific assay protocols.

## Technical Service, Training, and Validation Support

ACC offers its customers extensive technical support. Our Technical Service and representatives in the field are experienced professionals who provide customer assistance for the full range of ACC products and services. Assistance with selecting a test method or reagent is always available by telephone, email, and in person, through workshops, on-site training, or on-site support. Customers who have questions about individual products, test methods, instrumentation, and/or software are invited to call our staff.

### Reference

<sup>1</sup>Bacterial Endotoxins Test. Chapter <85>. United States Pharmacopeial Convention, Rockville, MD, USA, 2010.

<sup>2</sup>Pyros®, Pyros Kinetix® Flex, Pyrotell®-T and Glucashield® are trademarks of Associates of Cape Cod, Inc. All other trademarks mentioned are the property of their respective owners.

# ASSAY



## Pyrotell®-T Turbidimetric Endotoxin Testing

Pyrotell-T is used to quantify endotoxin in kinetic turbidimetric LAL assay. Pyrotell-T can be used with the Pyros Kinetix® Flex tube reader and incubating microplate readers. When used with the Pyros Kinetix Flex tube reader, Pyrotell-T is a highly economic, flexible and sensitive LAL assay.

It can be used for a wide variety of tests, ranging from water testing to samples requiring high sensitivity, such as intrathecal products and those requiring high dilutions to overcome interference.

### Sensitivity

When used in a Pyros Kinetix Flex tube reader, the maximum sensitivity is 0.001 EU/mL. The unique formulation of Pyrotell-T allows a wide selection of standard curves to be used, giving the user flexibility, speed, and ease in performing assays.

### Sample to LAL Ratio

The ratio of sample to LAL is determined by personal preference and sample chemistry (interference patterns). Reconstituted Pyrotell-T LAL reagent is used at a ratio of 1:1 or 4:1 and a LAL volume of 100 µL/well (48 tests/vial) or 50 µL/well (96 tests/vial).

### Performing the Test

The Pyrotell-T sample mixture is incubated in an optical reader at 37±1°C and read at wavelengths depending on the instrumentation and user choice. The time of incubation is dependent on the lowest standard concentration in the standard curve. Software is used to construct the standard curve and calculate the endotoxin concentrations.

### Reconstitution

Pyrotell-T may be reconstituted with 5 mL of LAL Reagent Water (LRW), Pyrosol® buffer, or Glucashield® buffer, depending on the demands of the sample being tested. Pyrosol buffer provides extra pH buffering capacity. Glucashield buffer, a (1→3)-β-D-Glucan inhibiting buffer, is used to render the assay endotoxin specific.

### Stability

Once reconstituted, Pyrotell-T is stable for 24 hours, if stored at 2–8°C. Pyrotell-T may be frozen once and will retain activity for as long as 3 months if stored at or below -20°C.

TURBIDIMETRIC  
REAGENTS

## Packaging

Pyrotell-T is available in multi-test vials. Each vial contains reagent for approximately 96 tests (when used with the Pyros Kinetix Flex tube reader and 4:1 sample to LAL ratio) or 48 tests (when used with 1:1 ratio and/ or in a microplate reader). It is recommended for use with the 0.5 µg/ vial Control Standard Endotoxin (CSE, E0005-1). Certificates of Analysis, specific to the Pyrotell-T and CSE lot, can be obtained from ACC or online.

## Pyros Kinetix® Flex – Turbidimetric assays

*Designed with flexibility and efficiency in mind, the PK Flex provides flexible options for conducting endotoxin testing.*

The Pyros Kinetix® Flex and Pyros® EQS 21 CFR Part 11 compliant Software combine to provide a complete system for efficient, accurate endotoxin testing.

### Features & Benefits

- Precise Temperature Control: Incubator temperature is held to 37°C ± 0.5°C
- Solid State Design: Low instrument maintenance
- Two Wavelength Settings
- Uses Low Cost Depyrogenated Disposables Accessories
- Broad Sensitivity Range: No other system is more sensitive; Pyrotell®-T lysate when used in a Pyros Kinetix tube reader, the maximum sensitivity is 0.001 EU/mL, which is 5 times more sensitive than any other LAL assays.
- Increased Efficiency: The ability for end-users to add samples to an existing assay in order to efficiently utilize all wells. Software provides



quantitative sample results while assay continues to run

- Flexible Testing: Variable volumes and ratios can be utilized, ability to maximize product MVD (Maximum Valid Dilution)
- Reduced Lysate Usage: As little as 50 µL per test

### System Specifications

**Capacity:** 32, 64 or 96 reaction test tubes

**Power Requirement:**  
 100 to 240 VAC @ 50 / 60 Hz

**Light Source:** LED

### Dimensions & Weight:

- PKF32 - 9.25" x 10" x 3.125" / 6 lbs 15 oz
- PKF64 - 9.25" x 14" x 3.125" / 11 lbs 5 oz
- PKF96 - 9.25" x 18" x 3.125" / 15 lbs 14.5 oz

**Temperature Range:** 37°C ± 0.5°C

### Warranties, Parts and Service

For details on extended warranties, repairs and recalibrations, contact your supplying office or for services outside the US, contact your local distributor.



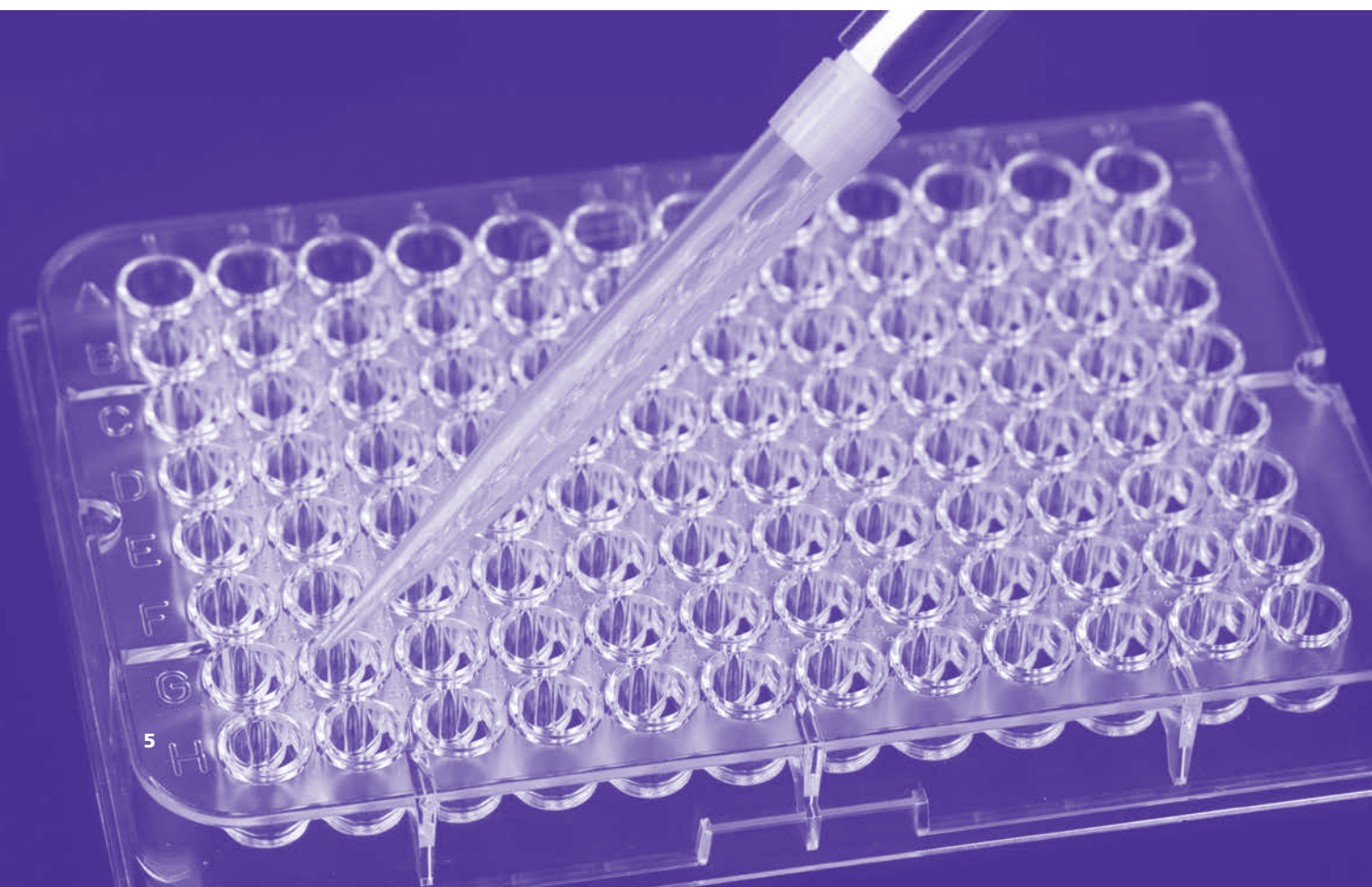
## **ELx808 IU™ Absorbance 96 Well Microplate Reader**

The ELx808 IU™, manufactured by BioTek® Instruments, is an incubating absorbance microplate reader that provides the ability to collect and analyze data. The ELx808 IU™ comes equipped with an on-board diagnostic self-test to confirm and document reader performance. All calculations are performed automatically. The ELx808 IU™ utilizes fast kinetics to measure in intervals

as short as 6 seconds. A 4-Zone™ Temperature Control system and unique heated track/carrier design provide for minimal evaporation and edge effect. The ELx808 IU™ incorporates a staggered optical design to eliminate channel-to-channel cross talk. The unique formulation of Pyrotell-T lysate allows a wide range of standard curves to be used, giving the user flexibility, speed, and ease in performing assays. When used in a microplate reader, the maximum sensitivity is 0.005 EU/mL.

### **Features of the ELx808IU™ Plate Reader**

- Programmable and variable shaking speed
- End-point, kinetic and well-scanning capabilities
- On-board data analysis, including curve-fitting
- Precise reporting
- Can be used for a wide range of applications



# ANALYSIS

## Pyros® EQS – Endotoxin Quantitation Software

### Features & Benefits


- Designed to be 21 CFR Part 11 Compliant: Meets regulatory compliance requirements of the FDA
- Oracle® Database: Unlimited data storage with the industry standard in pharmaceutical databases. Secure storage and back-up utilizing Oracle supplied functionality
- Choice of network client-server or stand-alone workstation configuration: Flexibility to meet the needs of small to very large laboratory configurations
- Enhanced Reporting Options, including the ability to export to MS Word®, Excel®, Crystal Reports® and Adobe® PDF file formats: Variety of template formats for ease of reporting
- Runs Multiple Standard Curves: Ability to run endotoxin potency determinations
- Flexible Operation: Background data collection permits other applications to run while collecting data. Data collection continues locally, even if network connection to database is lost
- Enhanced for use with Pyros Kinetix® Flex: Broad Sensitivity Range: As low as 0.001 EU/mL Individually timed reactions; allows for continuous addition of samples during operation
- Easy user-friendly installation: Auto-installs any pre-requisite applications



Pyros EQS writes to an Oracle® database, the industry standard in data security. It has multiple access levels for improved security, detailed audit trails, and built-in trending by date range, technician, sample type and LAL lot. The software provides enhanced reporting options, flexible operation modes and incorporates electronic signatures, as well as a supervisor sign-off on completed tests. The application also offers two choices for calculating Coefficient of Variations (CVs), and a summarized Pass/Fail Report. Pyros EQS is LIMS compatible through multiple export options.

Software Validation Protocols provide the end user with a comprehensive set of integrated documents to guide them through the system validation process. A Validation Plan outlines the tasks and documentation required to perform the validation. A Requirements Specification, the foundation of the validation process, clearly delineates the system's required functions and expected performance. Detailed instructions guide users step-by-step through the IQ/OQ, and PQ processes. Stress Test procedures are included as well as Change Control and Maintenance guides.





# ENDOTOXIN QUANTITATION SOFTWARE

## Gen5™ Secure Software

### Incubating Microplate Reader Software

Designed by engineers focused on microplate instrument technology, Gen5 works the way you do. Gen5\* Secure Software is customized, 21 CFR Part 11 compliant software for the ELx808™ Incubating Microplate Reader. Gen5's contemporary interface provides easy access to all major functions of the software including reading parameters, plate layout, data reduction, on-line help wizards, tutorials and ACC's endotoxin specific assay protocols.

*\*Trademark of Bio-Tek Instruments, Inc.*

# TECHNICAL SERVICE, TRAINING, AND VALIDATION SUPPORT



Assistance with selecting a test method or reagent sensitivity is always available from our Technical Service Department, and representatives in the field. Our staff and distributors can help with characterization, validation or routine testing. The LAL Update®, our newsletter, includes useful technical articles and is available on our website. Our Contract Test Service regularly performs characterization and method development and can provide results by all test methods. Regardless of which method is selected, you can always be assured of the full support of ACC.

ACC offers its customers extensive technical support. Our Technical Service department is staffed with experienced professionals who provide customer assistance for the full range of ACC products and services. Technical support is available by telephone, email, and in person, through workshops, on-site training, or on-site assistance. Customers who have questions about individual products, test methods, instrumentation, and/or software are invited to call our staff.

## **Software Validation Protocols**

ACC offers Validation Protocols that provide the end user with a comprehensive set of integrated documents to guide them through the system validation process. The protocol files in Microsoft® Word format allows users to edit the documents to meet their company's specific validation requirements.

## **Reagent Transfer Protocol (RTP)**

The Reagent Transfer Protocol document (RTP) is used to validate the change from another manufacturer to ACC LAL reagents. If changing LAL reagent manufacturers, ACC offers assistance with guidance and instructions for using the Validation Protocol. This can be used as verification of the validation process. The Reagent Transfer Protocol is designed to assist users in completing validation of their switch from the current LAL reagent to an ACC product. During this process, if the user requires any assistance you will be able to obtain help and advice through the Technical Services department of ACC.

## Pyrotell®-T Multi-Test

5 mL/vial (approx.50 tests/vial)

- T0051-5 5 pack (250 tests)  
 T0051-25 25 pack (1250 tests)

## Pyrosol® LAL Reconstitution Buffer

- #BC051-5 Pyrosol Buffer without pH indicator,  
 5.5 mL/vial 5 Pack  
 #BC051-25 Pyrosol Buffer without pH indicator,  
 5.5 mL/vial 25 Pack  
 #BC554-1 Pyrosol Buffer without pH indicator,  
 55 mL/vial

## Pyros Kinetix® Flex

- PKF32 Pyros Kinetix Flex 32-well (includes  
 instrument, software and validation)  
 PKF64 Pyros Kinetix Flex 64-well (includes  
 instrument, software and validation)  
 PKF96 Pyros Kinetix Flex 96-well (includes  
 instrument, software and validation)

## Microplate Reader

- PPS04 ELx808 Incubating Microplate Reader,  
 (software sold separately)  
 ELXP Universal Test Plate for ELx808 reader

## SOFTWARE PRODUCTS

### Pyros Kinetix® Software

- PEQS11 Pyros EQS Software and Manual  
 (21 CFR Part 11 Compliant)  
 PEQS Pyros EQS Software and Manual  
 (without compliance features)  
 PEQS11-VAL-PKF Pyros EQS Software Validation  
 Package (PK Flex)  
 PEQS-OR One year renewal for Oracle® database  
 support in Pyros® EQS software

### Microplate Reader Software

- Gen5 Gen5™ Secure Software  
 5320500 Gen5™ installation qualification pkg.  
 PQPE Product Qualification Package, ELx808

## Accessory Products

### LAL Reagent Water (LRW)

LRW is intended for reconstitution of LAL reagents and CSE, and to dilute samples and standards for LAL assays. LRW is not for human or animal injection. LRW contains less than 0.001 EU/mL endotoxin and less than 1.56 pg/mL glucan.

- W0051-10 5.5 mL/bottle, 10 bottles/pack  
 W020P 20 mL/bottle, 10 bottles/pack  
 W0504 50 mL/bottle  
 W050P 50 mL/bottle, 5 bottles/pack  
 W1004 100 mL/bottle  
 W100P 100 mL/bottle, 4 bottles/pack  
 WP0501 50 mL/Plastic bottle  
 WP050C 50 mL/Plastic bottle, 30 bottles/pack  
 WP1001 100 mL/Plastic bottle  
 WP100C mL/Plastic bottle, 30 bottles/pack  
 WP5001 500 mL/Plastic bottle  
 WP500C 500 mL/Plastic bottle, 12 bottles/pack  
 WP10001 1L/Plastic bottle  
 WP1000C 1L/Plastic bottle, 12 bottles/pack

### Pyrotubes®

- TK100-10 8 x 75 mm borosilicate glass for  
 Pyros Kinetix® Flex 50 tubes/pack,  
 10 packs/carton  
 TB050 10 x 75 mm borosilicate glass for  
 turbidimetric method 50 tubes/pack  
 TB240-5 12 x 75 mm borosilicate glass  
 (for dilutions only)  
 42 tubes/pack, 5 packs/carton  
 TB013-5 13 x 100 mm borosilicate glass  
 (for dilutions only)  
 18 tubes/pack, 5 packs/carton

### Pyroplates®

- CA961 96-well microplate, 1 each

### Precision Pipette Tips

- PPT25 250 µL tips, 96 tips/box, 10 boxes/pack  
 PPT10 1000 µL tips, 96 tips/box, 8 boxes/pack

### Glucashield® (1→3)-β-D-Glucan Inhibiting Buffer

Glucashield buffer is used to reconstitute LAL and render the reagent insensitive to (1→3)-β-D-Glucan interference by effectively blocking the Factor G pathway of the endotoxin clotting cascade. For use with Pyrotell Multi-Test Vials, Pyrotell-T, Pyrochrome® and Chromo-LAL.

|          |  |
|----------|--|
| GB051-5  | Glucashield Buffer 5.5 mL/vial (5 pack)  |
| GB051-25 | Glucashield Buffer 5.5 mL/vial (25 pack) |

### Control Standard Endotoxin,

#### Escherichia coli O113:H10

|         |                      |
|---------|----------------------|
| E0005-1 | 0.5 µg/vial (1 vial) |
| E0005-5 | 0.5 µg/vial (5 pack) |
| E0125-1 | 125 µg/vial (1 vial) |
| E0125-5 | 125 µg/vial (5 pack) |
| EC010-5 | 10 ng/vial (5 pack)  |

**Racks** - All are acrylic test tube racks that fit 8 x 75 mm test tubes

|       |   |
|-------|---|
| TTR32 | PK Flex test tube rack (numbered 1-32)  |
| TTR64 | PK Flex test tube rack (numbered 33-64) |
| TTR96 | PK Flex test tube rack (numbered 65-96) |

### Warranties, Parts & Services

Extended Warranties - 1 Year Agreement

|         |   |
|---------|---|
| WPKX32  | Pyros Kinetix® Flex 32-well format (on-site calibration included) |
| WPKX64  | Pyros Kinetix® Flex 64 well format (on-site calibration included) |
| WPKX96  | Pyros Kinetix® Flex 96 well format (on-site calibration included) |
| PEQS-OS | On-site Pyros® EQS service (per day, plus travel expenses)        |

### Parts

|          |   |
|----------|---|
| PN002223 | PK Flex Serial Cable  |
| PN002224 | PK Flex USB   |
| PN002225 | Twin PK Flex Serial Cable   |
| PN002226 | Twin PK Flex USB  |
| PT008    | Lamp for ELX808   |
| ELX540   | 540 nm Filter, ELx808 microplate reader for diazo endpoint assays |

### Calibrations

(performed at ACC Facility)

|       |                                    |
|-------|------------------------------------|
| CAL02 | Calibration for Pyros Kinetix      |
| CAL06 | Calibration for Pyros Kinetix Flex |

### Calibrations

(performed at customer site - continental US)

|       |  |
|-------|--|
| CAL03 | On-site Calibration for Pyros Kinetix      |
| CAL07 | On-site Calibration for Pyros Kinetix Flex |
| CALRU | Rush On-site Calibration                   |

### Validations

(performed at customer site - continental US)

|          |   |
|----------|---|
| PEQS-VAL | Pyros EQS: On-site Validation for Pyros Kinetix or Pyros Kinetix Flex |
|----------|---|

### Private Workshops

|        |  |
|--------|--|
| WKSP01 | On-site One Day LAL Workshop (per workshop, up to 5 attendees)   |
| WKSP02 | On-site Two Day LAL Workshop (per workshop, up to 5 attendees)   |
| WKSP03 | On-site Three Day LAL Workshop (per workshop, up to 5 attendees) |
| WSEQ01 | Workshop Equipment Rental (per workshop)                         |
| WSCT01 | Additional Workshop Trainer (per day)                            |

### LAL Consulting

|        |                                       |
|--------|---------------------------------------|
| CSOS01 | On-site Consulting Services (per day) |
| SCOS01 | On-site Service Call (per day)        |