Pall Corporation

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Pallchek™ Rapid Microbiology System

Description

Highly sensitive, cost-effective and easy-to-use rapid testing to pharmaceutical standards

The Pallchek™ Rapid Microbiology System is the first of its type to be used in an approved protocol for microbiological applications in FDA and EMEA registered drug manufacturing processes, using the ATP bioluminescence technique. The Pallchek system can be used as a much faster alternative to conventional microbiological quality control methods, or may be used to supplement existing methods. It is also a much lower cost, more convenient option than all other rapid microbiological test methods, with equivalent or better sensitivity.

Simple To Use

The Pallchek system is portable and easy to use. Its simple interface and operation requires a minimal level of training and operator skills in order to perform testing. Operators can be trained in less than a day. Easy-to-follow protocols are available for various sample matrices, and sample preparation steps are similar to current methods thereby facilitating quicker validation.

Fast Results

The Pallchek system can also significantly reduce the time needed to obtain test results compared to traditional microbiology testing. For example, typical sterile sample results can take up to 14 days to obtain with culture methods. The same results can be obtained in 24-48 hours with the Pallchek system. The system's ease of use further enhances the speed to result, as the actual detection time is less than one minute, in three easy steps.

Cost Savings

The Pallchek system is a simple and affordable tool for the monitoring of microbial contamination. Acquisition and implementation is cost effective compared to comparative systems. Cost savings using the Pallchek system for faster product release and associated cost savings are well established. The system can help you incorporate important aspects of Process Analytical Technologies (PAT) initiatives that are driving more timely acquisition of key data about your manufacturing systems.

Features

- Sensitivity to 1 CFU, using an enrichment step with culture media
- Reproducible test results in minutes
- Portable and simple to use
- Considerable operating cost and time savings
- Easy and low cost installation
- Comprehensive validation and IQ/OQ support package available

Further Reading

Technical Poster: 'Determination of Threshold Values for Qualitative Rapid Microbiological Methods Using Non-Conventional Measurement Units'

Technical Poster: 'A Statistical Method for Determination of a Threshold Value during Validation of an ATP-based Bioluminescence Assay' [1]

Technical Article: 'Using ATP bioluminescence for Microbiological Measurements in Pharmaceutical Manufacturing'

Technical Article: 'Rapid Steam Sterilization Biovalidation using biological indicators and the Pallchek Luminometer'

Technical Article: 'Rapid Sterility Testing Using ATP Bioluminescence-Based Pallchek™ Rapid Microbiology System'

Publication: 'Concurrent Evaluation of both Compendial and Rapid Methods (ATP Bioluminescence) for Monitoring Water Quality in Pharmaceutical Manufacturing' [2]

Publication: 'Comparaison des méthodes traditionnelles et de l'ATP bioluminescence'[3]

Publication: 'Rapid Microbiology: A Cultural Approach'[4]

Publication: : 'Microbiologia rapida: un approccio culturale'[4]

[1] *Presented at PDA's 4th Annual Global Conference on Pharmaceutical Microbiology, October 2009*
[2] *Originally published in European Pharmaceutical Review, Volume 14, Issue 3, May 2009 (Russell Publishing)*
[2] *Originally published in Salles Propres, October 2009*
[4] *Authored by Marco Sanvito, Pall Corporation; originally published in Italian in ASCCA News #4, the journal of Italy's Association for Study and Control Of Environmental Contamination (October/December 2012) and reproduced with the author's permission*

Application

Presence/Absence Testing

- Microbial Limit Tests of clean and preserved products (USP<61>/EP <2.6.12>
- Environmental monitoring for ISO 14644-1 Class 5 & 7 areas for surface
- Testing and monitoring of WFI systems
- Product monitoring of terminally sterilized products
- Validation of sterilization using biological indicators
- Cleaning and sanitization control
- Buffers and fermentation media
- Aseptic media fills

Enumeration

- Validation of the efficacy of disinfectant and other cleaning agents
- Antimicrobial and preservatives effectiveness test (USP<51>/EP 5.1.3)
- Enumeration of ATCC and 'wild type' cultures used other important areas of use include monitoring of fermentation and cell culture operations in bioprocessing and monitoring of bioburden and environment in all cosmetic, toiletry, food and beverage sectors, as well as University and R&D laboratories

The Pallchek system is suitable for the following applications:

- Early release of finished product
- Environmental monitoring
- Raw material and process monitoring
- Microbial Limit Tests
- Testing of Water For Injection systems
- Terminally sterilized products
- Sterilization validation testing of biological indicators
- Antimicrobial effectiveness test

References

Rapid Micro Project in Chiesi Pharmaceuticals Group: development and validation of an alternative method for the release of non-sterile and sterile Products, Bosi M, Fantuzzi A, 6th Annual PDA Global Microbiology Meeting, Bethesda, MD, October 2011

Rapid Sterility Testing Using ATP Bioluminescence Based Pallchek™ Rapid Microbiology System. Denoya, C., Reyes, J., Ganatra, M. and Eshete D. Chapter 17, 433-461. In Rapid Sterility Testing. Ed. Jeanne Moldenhauer, PDA, Bethesda, MD, and DHI publishing LLC, IL - October 2011

A Rapid Microbiological Assay to Monitor the Effectiveness of a Vaccine Injector Sanitization Following a Microbial Challenge Procedure. Denoya, C., Reyes, J., Dawson, E., Sessoms, D., Baumstein, M. and Shabushnig. J. American Pharmaceutical Review, American Pharmaceutical Review, 13(4) May/Jun, pages 54-61 - June 2010

Chicken Egg Vaccine Injector Manufacturing: A Bioluminescence-based assay to monitor effectiveness of instrument sanitization after microbial challenge procedure, Denoya C, Reyes, J., Dawson E, Sessoms D, Baumstein M, and Shabushnig J. Annual Meeting of the Parenteral Drug Association, Orlando, USA - March 2010

Concurrent Evaluation of both Compendial and Rapid Methods (ATP Bioluminescence) for Monitoring Water Quality in Pharmaceutical Manufacturing. Bagur, E. European Pharmaceutical Review, Issue 3, 2009

Pallchek Rapid Microbiology Method in the preservative efficacy test screening studies, Roberto Cecchini, Paola Barzi, Yannic Bartsch, Maria Berretta, Giorgio Bagatti, Mariagrazia Terlizzese, Merck Serono, Merck KgA poster at PDA Conference on Rapid Microbiology Methods: Successful Implementation Strategies, Berlin Germany - February 2009

Technical Assessment of a Bioluminescence-based Rapid Microbiological Method (RMM) for detection of microbial contaminants in pharmaceutical samples, Claudio Denoya, Pfizer presentation at PDA Conference on Rapid Microbiology Methods: Successful Implementation Strategies, Berlin, Germany - February, 2009

Technical Assessment of a Bioluminescence-based Rapid Microbiological Method (RMM) for detection of microbial contaminants in pharmaceutical samples, Claudio Denoya, Jennifer Reyes, Amelia TaitKamradt, Pfizer poster at 3rd PDA annual microbiology meeting, Chicago, USA - October 2008

Key Aspects of Validation and Implementation of Rapid Microbiology Methods for In-process Monitoring, Ornella Finocchiaro, Merck Serono, presented at Rapid Micro User Group (RMUG) 6th Annual Conference, California, USA – May 2008

Evaluation and Implementation of an ATP Bioluminescence Method for Rapid Bioburden Testing in Biotech Manufacturing, Tom Woods, Genentech, and Maitry Ganatra, Pall Life Sciences, presented at Rapid Micro User Group (RMUG) 6th Annual Conference, California, USA – May 2008

The Application of ATP Bioluminescence for Preservative Efficacy Screening, Mateja Kramer, LEK Pharmaceuticals and Vojko Kmetec, University of Ljubljana, Slovenia, presented at PDA Annual Meeting, Nevada, USA – March 2007

Rapid Microbiology Methods (RMM) for Monitoring of Pharmacological Process, Ornella Finocchiaro, Eleonora Giudice, Carl Jane, Nadia Torre, Francesco Antonetti, Merck Serono, and Christina Bruntner, Pall Corporation, presented at PDA's 'Rapid Microbiology Methods: Make Them Work, Get Them Approved' meeting, Verona, Italy – February 2007

Using ATP Bioluminescence for Microbiological Measurements in Pharmaceutical Manufacturing, Lucia Ceresa and Peter Ball, Pall Life Sciences, Encyclopedia of Rapid Microbiological Methods Volume II, edited by Michael J. Miller, PDA/DHI Books – January 2006

Pall System, Lucia Ceresa, Pall Life Sciences, Encyclopedia of Rapid Microbiological Methods Volume II, edited by Michael J. Miller, PDA/DHI Books – January 2006

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ATP Bioluminescence To Control The Activity Of Antimicrobial Agents, Julien Labbe, Allergan, Salles Propres No. 32 – July 2004

Validation under the regulatory requirement of an ATP bioluminescence rapid detection method for releasing products, Gilberto Dalmaso, GlaxoSmithKline, Italy, presented at IVT Microbiology Event Of The Year, Virginia, USA – June 2004

Anti-Microbial Kinetics: Method by ATP Bioluminescence, Julien Labbe, Allergan, presented at PDA Annual Meeting, Basel, Switzerland – February 2004

Cinétique d'action antimicrobienne: Méthode par ATP Bioluminescence, Pallchek, Julien Labbe, Allergan, presented at 3e Rencontres de Microbiologie (A3P), Lille, France – June 2003

Evaluation of In-vitro Synergy Between Two Antibiotics Using a Pallcheck (sic) Luminometer, K.S. Ambrus, D. Rupp, C. Anger, S. Kapadia, Allergan, presented at the Annual Meeting of the American Society for Microbiology, Florida, USA – May 2001

Performance

How It Works

The Pallchek Rapid Microbiology System consists of a portable, highly sensitive and accurate luminometer and reagent kit. It works on the basis of measurement of adenosine triphosphate (ATP) which is released from cells and converted to light using the luciferin-luciferase substrate/enzyme. The specially-formulated and validated Pall® reagent kits ensure that the light is generated in a consistent pattern, and over a significant time period, to ensure that convenient and consistent protocols can be developed. ATP bioluminescence is measured directly on the filter after sample processing.

Maximum sensitivity is achieved when measurements are made on liquid samples that have been collected using a membrane filter. This allows several advantages - concentration of any microorganisms present in the sample on the surface of the filter, and optimization in washing the filter to remove any components present in the sample which could affect recovery and potentially interfere with enzymatic reaction. Once the sample is collected on the filter membrane, the user needs to follow three simple steps: 1. Addition of extract reagent 2. Addition of Luciferin/Luciferase enzyme/substrate 3. Measurement of light.

Following a specific method, it is also possible to retain a sample portion for subsequent testing such as identification, being a non-destructive procedure. Results are displayed on a simple LCD screen and immediately printed, or can be exported to an external data storage device, according to user preference.

Additional Information

Meeting Regulatory Requirements

The validation guide for the Pallchek system (Pall publication USTR 2359) confirms attributes for the system which conform to key guidelines laid down in the regulatory guidance documents. It also includes comparability data showing such equivalence with the current compendial method for presence/absence testing. The comparability study and the statistical result evaluation approach were key factors in the success of the first applications to FDA CDER and EMEA for use of the Pallchek system to enable the release of non-sterile products and monitoring of WFI quality. Construction of the Pallchek luminometer is documented in accordance with GAMP guidelines. With respect to stored data there is a data storage function which is protected from being accessed, edited or overwritten by a locking device. If you require further information, please contact Pall.

Full supporting documentation is available, including Testing Procedures and also full service capability for individualized IQ and OQ as well as support for PQ.

Technical Support

Pall's technical support is available for:

- Feasibility studies with full report
- System demonstrations
- Operator training

- Application specific protocol development
- Phone and email support during implementation
- Installation and Operation Qualification
- Consultancy (validation strategy & PQ)

Our scientists draw on a large pool of knowledge and provide support for evaluation and qualification of appropriate procedures for rapid microbiological analysis anywhere in the world. We also operate a global network of service groups, providing calibration, maintenance and other after-sales services for the Pallchek system.

Complementary Supplies

A fully comprehensive range of accessories such as disposable filter funnels, wide-ranging membrane types and pore sizes, a portable vacuum pump and media is available to streamline your microbiology operations. Please see 'Ordering Information' for more details.

Ordering Information

The Pallchek Rapid Microbiology System consists of:

- Lightweight case with shoulder strap
- Pallchek luminometer
- Charger unit
- Testing plate
- Cable for exporting data
- CD containing Operation Manual and data capture software, plus certificate of calibration

Part Number 13673A	Suitable for use in USA (115V AC, 50/60 Hz)
Part Number 13673B	Suitable for use in Europe (230V AC, 50/60 Hz)
Part Number 13673C	Suitable for use in UK (230V AC, 50/60 Hz)

Dimensions	25 x 17 x 15.5 cm
Weight	2 kg (4.4 lb)
Display	2 lines of 16 alphanumeric characters
Power	Internal rechargeable battery
User Controls	START, MODE, SET, STOP

Accessories

Part Number	Decription	Details
7142	High Sensitivity Bioluminescent Reagent Kit (80 tests)	1 per pack
7150	High Sensitivity ATP Correlation Kit (80 tests)	1 per pack
7147	Membrane Filter and Liquid Sample Holders	100 per pack
7149	Plastic sterile spreaders, individually bagged	50 per pack
13674	220 volt Thermal Printer (EU: standard 2 round-pin plug)	1 per pack
13680	220 volt Thermal Printer (UK: 3 flat-pin plug)	1 per pack
13675	115 volt Thermal Printer	1 per pack

Spare Parts

Part	Description	Details
13679	Aluminum Test Plate	
7140	Base reading chamber Silicone seal gasket	

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