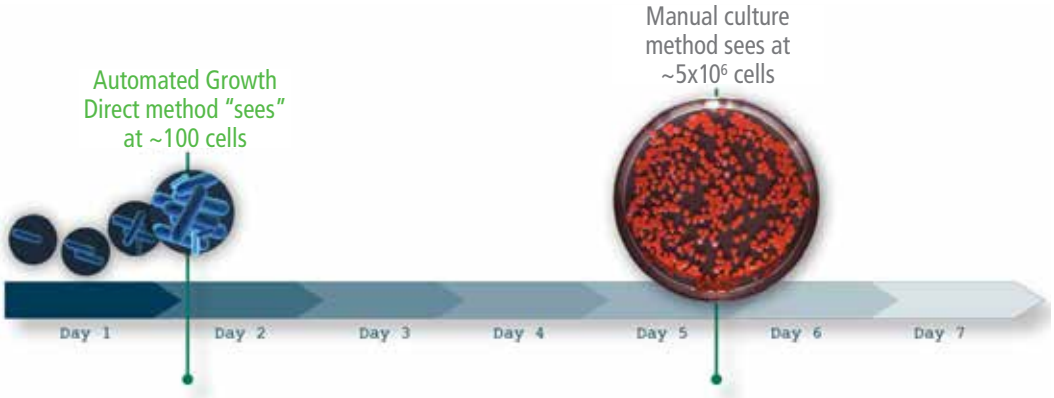
One Detection Technology.
Three Applications.
One Automated Platform.

GrowthDirect
EM • Sterility • Bioburden

Proven Technology in Use at FDA Regulated Sites

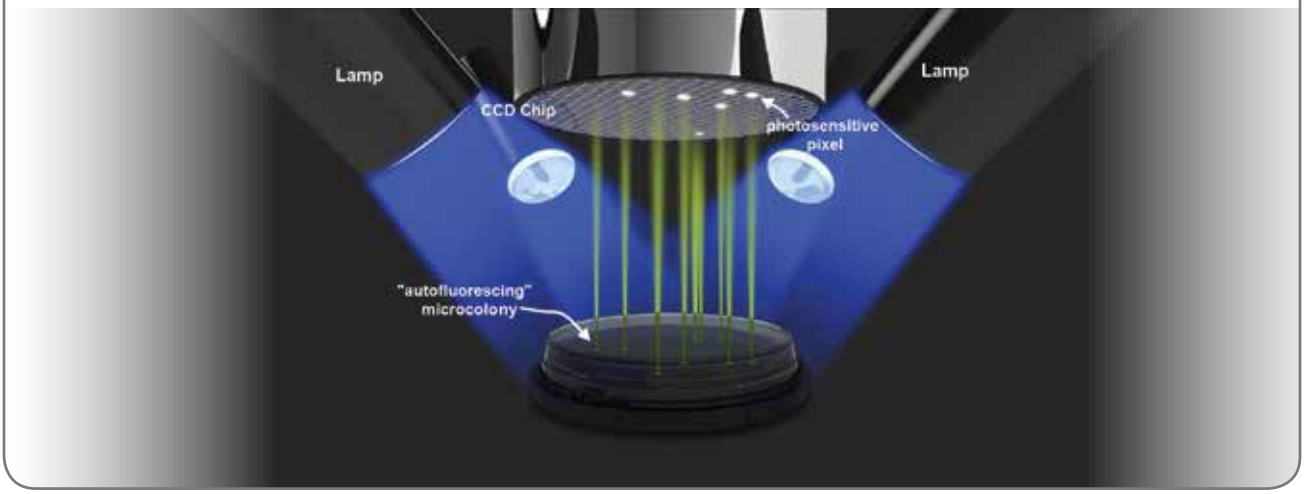
The Growth Direct™ System revolutionizes microbial testing for quality control in the manufacture of pharmaceuticals, personal care products and medical devices. The method has been validated and is in use at sites regulated by the FDA and European regional authorities.

The Growth Direct™ Technology uses the natural autofluorescence of living cells and a highly sensitive camera to "see" growth faster than the human eye. In addition, the method is able to detect contamination starting within hours.



Growth Direct method detects autofluorescing micro-colonies:
- Detection beginning within hours
- No labels or reagents
- Automated counting and reporting

Visual detection by human eye:
- Detection after 3-7 days
- Manual reading/recording/reporting



Validation is Straightforward

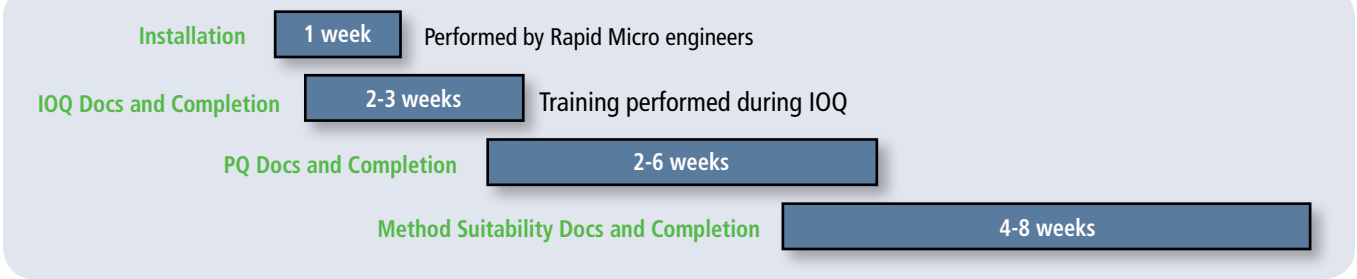
Testing with the Growth Direct™ System does not require the use of any reagents. The method is based on standard EP/USP media for growth based viability*. In addition, results are reported in CFU's, not "fluorescent events" or RLU's that can be difficult to relate to CFU's.

As a result, the Growth Direct™ System is defined as "Automated Compendial" by guidance documents such as the PDA Technical Report 33, "Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods" and as such do not need to demonstrate certain method validation requirements.

Validation of the Growth Direct System requires the following:

- Proof that the camera images and the software algorithms count equivalent numbers of micro-colonies on the membrane surface compared to a trained microbiologist.
- Performance qualification follows standard requirements in USP chapters <61>, <71>, <1227> and equivalent documents.
- For environmental monitoring, demonstration of equivalence of membrane against naked agar.
- For sterility testing, demonstration of media equivalence

Rapid Micro Biosystems' technical services team will work with you to ensure a streamlined validation process. Documents and/or personnel can be supplied by Rapid Micro Biosystems for any step in the validation process.



*Environmental Monitoring and Bioburden

Purposely Built for Highly Regulated Microbiology Quality Control Labs

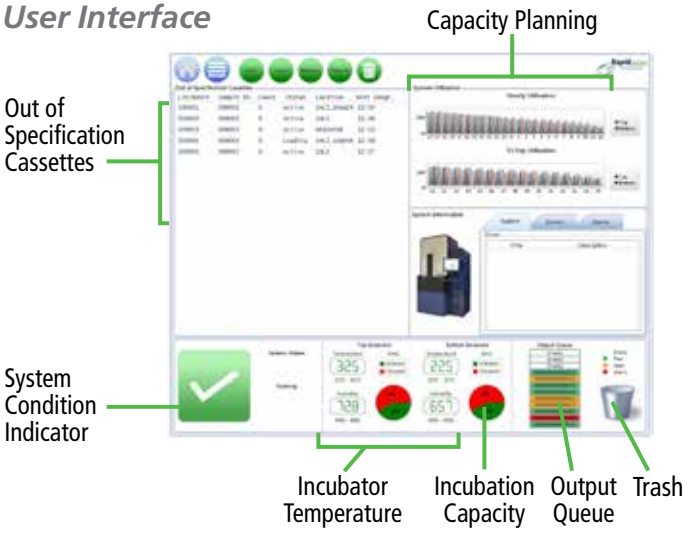
The Growth Direct™ System was specifically designed to handle the unique requirements of microbial quality control labs in manufacturing.

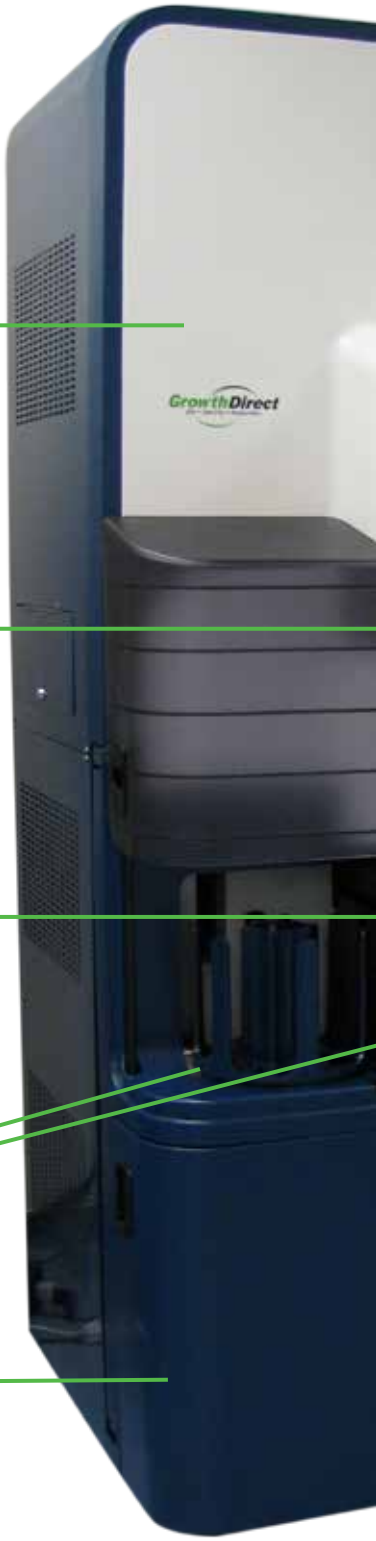
- System reads cassettes every 4 hours and immediately reports results
- Preset alert limits notify out of specification (OOS) result immediately via e-mail, allowing users to make decisions and take remediation steps right away
- High capacity incubators allow for large test volumes
- Technology supports various test protocols simultaneously including:
  - Incubation time and temperature
  - Transfers between incubators for serial incubation
- System can be operated as a stand alone instrument or interfaced to LIMS
- The Growth Direct™ Multitest System can support multiple applications concurrently (Environmental Monitoring, Bioburden, and Sterility)

Built for High Throughput

Test Conditions	Enviromental Monitoring	Bioburden Testing	Sterility Testing
If your Current Testing Time (Days) is:	5	7	14
And Number of Temperatures is:	1	1	2
Representative Test Time with the Growth Direct™ System (Days) will be:	2.5	3.5	7
Average Samples Per Day (7 days/Week):	280	175	20

User Interface





External Surfaces
- Disinfectant and chemical resistant

Cassette Elevator
- Loads cassettes into 1 of 2 incubators

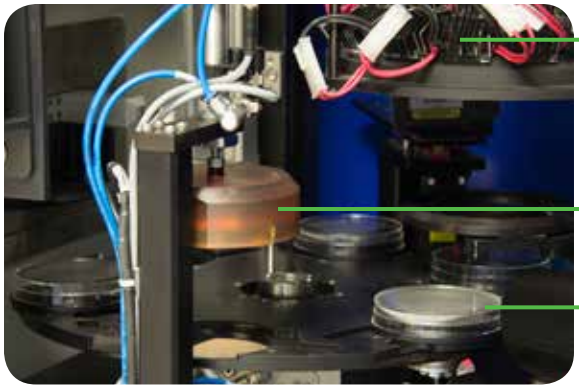
Positive Cassette Retrieval
- Up to 10 cassettes retrieved at 1 time

Input Queue

- 2 removable carousels
- 60 EM cassettes/carousel
- < 20 minute load time
- 36 Sterility cassettes/ carousel

Trash Disposal
- Holds 110 cassettes

Imaging Chamber



Imager

Condensation removal

Precise orientation station

Instrument Internal View

User Interface

- Touch Screen
- Software 21CFR Part 11 Compliant

Bar Code Printer & Scanner

- Scans/reads 1D or 2D barcodes

Incubators

- 1 or 2 Temperatures
- Incubator holds 350 Environmental Monitoring or Bioburden Tests
- Incubator holds 140 Sterility Tests

ORDERING INFORMATION			
Part Number	**Description**	**Applications Supported**	**System Capacity**
S700-GD2	Growth Direct™ System Configured for Sterility Testing. Includes anaerobic indicator monitoring.	Sterility	560
E700-GD2	Growth Direct™ System Configured for Environmental Monitoring and Bioburden Testing. Includes simple trending analysis.	Environmental Monitoring, Bioburden Testing	700
B700-GD2	Growth Direct™ System Multi-Test Configured for all applications. Includes customized incubation racking and software configured to match testing workload.	Environmental Monitoring, Bioburden Testing, Sterility	560-700

One Instrument, Multiple Testing Applications

Environmental Monitoring

The Growth Direct™ System for Environmental Monitoring revolutionizes the analysis of samples by automating the high volume testing typically found in the combination of air, surface and personnel monitoring.

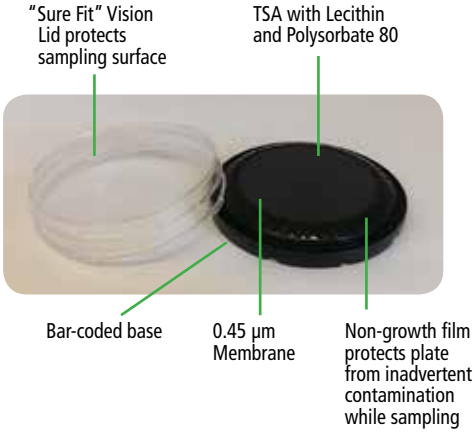
Item No.	Description
ET80-100	Environmental Monitoring cassettes, TSA with Lecithin and Polysorbate 80, 100 cassettes/case
EMVL-100	Environmental Monitoring Vision Lids, 100 lids/case
ET80HT-100	Environmental Monitoring cassettes, TSA LP80HT, 100 cassettes/case

Delivers Efficiency

The system can be located in close proximity to manufacturing and samples can be immediately loaded onto the technology straight from manufacturing. Barcodes on the cassettes track the sample and identify its protocol and handling rules.

Large Capacity

Designed with high throughput in mind, the system contains two incubators with a total incubation capacity of up to 700 environmental monitoring cassettes. Robotics concurrently load, incubate and analyze samples, providing the maximum throughput in minimal space.



Integration to LIMS

The Growth Direct™ System for Environmental Monitoring seamlessly integrates into existing laboratory information management systems, accelerating the availability of sample data beyond the lab and eliminating any keying errors associated with manual sample processing.

Actionable Reporting

The system alerts users immediately via email when samples are out of conformance, while trending analysis uncovers any developing issues.

Media Types

Media is Tryptic Soy Agar with Lecithin and Polysorbate 80.

Bioburden Testing

The Growth Direct™ Bioburden test for raw materials, in-process product, and water involves sample preparation through simple filtration. Filter placement on an agar surface is identical to the compendial method.

Cuts Testing Time in Half

The bioburden test uncovers positive results within hours of testing and provides final results in about half the time of a typical test. Results are reported in colony forming units (CFU's).

Easy to Validate

The Growth Direct™ System for Water and Bioburden is NOT an alternative method, but rather an automated version of the existing compendial method, simplifying validation.

Actionable Reporting

Configurable action and alert limits provide the user updates when samples are out of the configured specification allowing faster response to potential contamination events. Alerts can be sent to email and mobile phones.

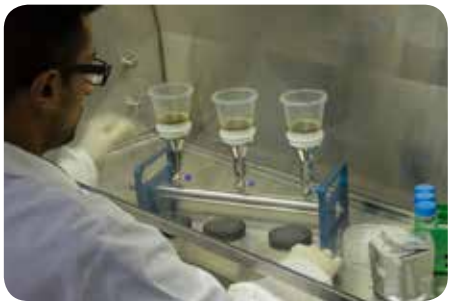
Non-Destructive

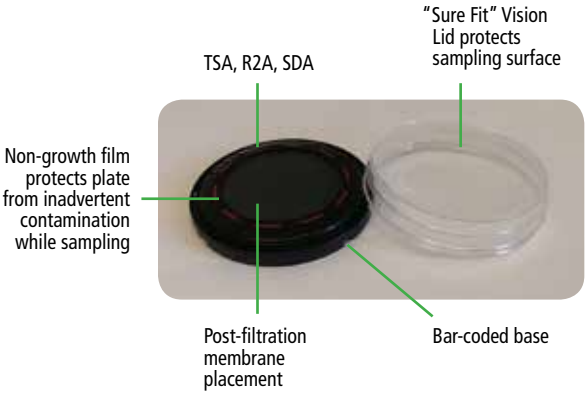
The system uses no reagents. Positive samples can continue to incubate and be sent to a microbial identification system for further analysis.

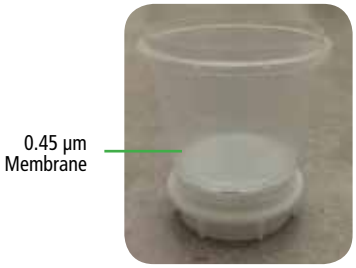
Media Types

Choices of media include R2A agar for water testing, Sabouraud Dextrose Agar for yeasts and molds, and Tryptic Soy Agar and for general product testing.

Item No.	Description
BR2A-048	Bioburden Cassettes, R2A, 48 cassettes/case
BSDA-048	Bioburden Cassettes, SDA, 48 cassettes/case
BTSA-048	Bioburden Cassettes, TSA, 48 cassettes/case
B150-048	Bioburden Filtration Funnels, 150 ml, 48 funnels/case
B250-048	Bioburden Filtration Funnels, 250 ml, 48 funnels/case
BBVL-048	Bioburden vision lids, 48 lids/case







One Instrument, Multiple Testing Applications

Sterility Testing

The Growth Direct™ Sterility test supports the aerobic and anaerobic testing of filterable samples.

Positive Results in Hours

The test provides early detection of a positive microbial contamination allowing faster response to contamination events.

7 Days Versus 14

The Growth Direct™ System for Sterility cuts testing time in half. Final results of sterility testing are available in half the time of the current test.

Closed Loop

Sample preparation is closed looped and performed in an isolator or in a clean room, similar to the existing method. The test includes both anaerobic and aerobic test cassettes.

Non-Destructive

No additional reagents are added. Samples with positive results can continue to grow.

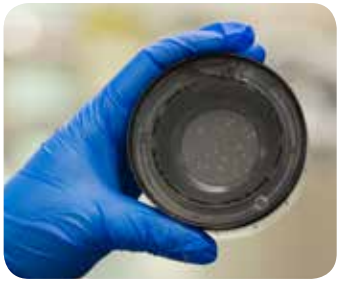
Discrete Colonies

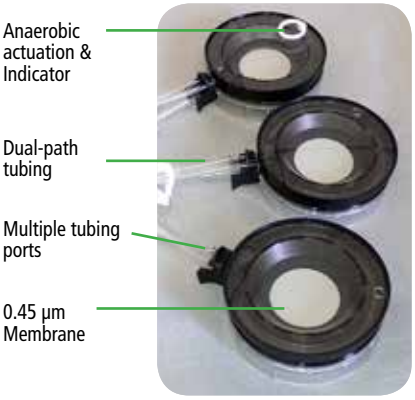
Colonies grow on the surface of the membrane and can be "picked' directly, eliminating the time and labor necessary with a subculture step.

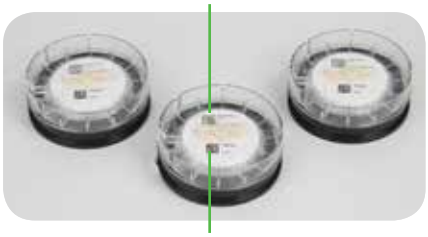
One Media Simplifies Testing

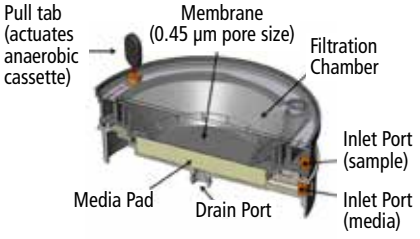
One media, modified Schaedlers Chocolate broth, a superior growth media for many microbes, is needed. Low particulate Fluid A and D rinses are available.

Item No.	Description
S302-010	Kit Includes 3 cassettes (2 aerobic, 1 anaerobic), with tubing set for Small Volume Parenterals, short needle, sterile venting. 10 kits/case
SBB1-010	Modified Schaedlers Chocolate Broth media, 330 ml/bottle. 10 bottles/case
SFLA-010	Sterility Fluid A Rinse with Septum, 500 ml bottle. 10 bottles/case
SFLD-010	Sterility Fluid D Rinse with Septum, 500 ml bottle. 10 bottles/case
S601-1US	Sterility Cassette opener, 110-120 Volts AC – US power cord
S601-2EU	Sterility Cassette opener, 220-240 Volts AC – EU power cord
S602-GD2	Sterility drain manifold, Sterile









Integration to Laboratory Information Management Systems (LIMS)

Laboratory Information Management Systems have been implemented at many companies in an effort to improve workflow, data tracking and data sharing by providing a user friendly yet powerful central data management point. Integration of LIMS with other automated systems allows for streamlining of processes, as well as reducing human errors to save time and money for the Microbiology Quality Control Lab.

Reduce Manual Work:

Integration to LIMS reduces the following manual tasks:

- Hand writing additional information (incubation start date/ time) on plates using markers.
- Interpretation of another operator's hand writing
- Upkeep of paper documentation
- Manual transcription of data into LIMs

Reduce Investigations related to ranscription errors

With the Growth Direct System™ interfaced with LIMS, the time required to enter, review, correct and file results are drastically reduced. In addition, the need for correction of data is reduced, and costly investigations related to transcription errors are eliminated.

Information available to the enterprise

With integration between LIMS and the Growth Direct™ System, test results are available to LIMS users as soon as the assay completes, improving decision making.

Item No.	Description
GDOC-LIM	2 way LIMS connectivity software

Two-Way LIMS Integration

Services Suite

Site Visit Pre-installation

To ensure successful installation and operation of the Growth Direct™ System, Rapid Micro Biosystems works with your facilities team and will conduct a pre-installation site visit to ensure that delivery and assembly of the technology occurs with no issue, and that the needed infrastructure is in place to begin qualification as quickly as possible.

Feasibility Studies Optimized Processes

Prior to purchase of the Growth Direct™ System the Rapid Micro Biosystems technical team can assess your product samples to make sure that they are compatible with the Growth Direct™ Technology. These assessments are performed by on-staff microbiologists and results are published as an application report.

A member of the Rapid Micro Biosystems team can meet with you to discuss your current processes and offer strategies to simplify and accelerate the processing of samples even before they are loaded into the Growth Direct™ System.

QA Document Support

Rapid Micro Biosystems is able to meet with your Quality Assurance team to discuss documentation requirements and processes that must be completed internally to ensure a smooth and expedient validation process. Rapid Micro Biosystems provides document packages for the validation process that can be reviewed with your Quality Assurance team.

Return on Investment Development

Rapid Micro Biosystems can work with you on the development of a compelling ROI for justification of the Growth Direct™ System.

Network Connectivity

To ensure a successful connection to the network the Growth Direct™ System has a dedicated menu page to enable the IT team to link the Growth Direct™ System to the host network.

Bi-Directional LIMS Integration

The Growth Direct™ System can be integrated to a LIMS system to enable bi-directional interface with the system software. Results can be retrieved from the operator's desk terminal or sample test lists downloaded remotely to the system for analysis.

The data on the Growth Direct™ System can be dropped to a number of different LIMS systems and other networked programs e.g. EM trending databases. The Growth Direct™ System creates a standard export file in .xml or CSV format that can be parsed by the networked program to pull relevant data.

Reference Computer

To streamline the validation process, Rapid Micro Biosystems can provide a reference computer for your company's IT group to work with to prepare for the addition of the Growth Direct™ System to the company's network. The reference computer is an exact replica of the software and technology that drives the Growth Direct™ System.

Remote Access

Rapid Micro Biosystems is able to work with your IT team to enable secure, remote access by the Rapid Micro Biosystems service team to the Growth Direct™ System to monitor performance.

System Software Menu Page

Support Options to Meet Your Business' Needs

Rapid detection, improved efficiency, and reduced investigations are critical to your business' success. Rapid Micro Biosystems' Support Services deliver tailored services to help you maintain and maximize the performance of your Growth Direct™ System. Our engineers provide proactive and preventive support using advanced tools to help you ensure system availability, reduce risk, and accelerate ROI. Support includes preventive maintenance visits, upgrade support, training, and other critical services. Choose from different levels of support services that would best suit your business' needs.

	Level A	Level B	Level C
Number of preventive maintenance visits per year	2	2	2
Turnaround time on interventions	24 hours	48 hours	72 hours
Number of interventions included	All interventions covered (including parts & labor and travel costs)	All interventions covered (including parts & labor and travel costs)	All interventions covered (including parts & labor and travel costs)
Upgrade support	Software upgrade + requalification documents provided	Software upgrade + requalification documents provided	Software upgrade provided
Training	Basic system training	Basic system training	Basic system training
Applications support	2 weeks	1 week	Not included
Incubator services	Incubator Clean and Annual Incubator Temperature Mapping		

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