

**soleris™**

*Microbiology at the speed of light™*



 **NEOGEN™**  
CORPORATION



*Microbiology at the speed of light.™*



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## Neogen Corporation

Founded in 1982, Neogen Corporation (NASDAQ: NEOG) has grown to more than 400 employees in three U.S. and two international locations, and a worldwide presence. With corporate headquarters in Lansing, Mich., Neogen has additional facilities in Lexington, Ky., Randolph, Wisc., Ayr, Scotland, and Shanghai, China. Neogen's ISO 9001:2000 certification communicates to its world-wide customer base that it remains firmly committed to the quality standards customers expect and to consistently meeting those standards.

Neogen's Food Safety Division develops and markets one-stop solutions to simply, rapidly and accurately detect bacterial pathogens, mycotoxins, food allergens, genetic modifications, drug and pesticide residues, ruminant by-products and sanitation concerns in food and animal feed. In addition to the Soleris system, Neogen also offers additional microbiological solutions.

## GeneQuence® DNA hybridization assays

GeneQuence's automated DNA hybridization technology allows for the rapid and extremely accurate simultaneous processing of a large number of food samples for *Salmonella*, *Listeria* spp. and *Listeria monocytogenes*.



## Lateral flow immunochromatographic assays

Neogen's Reveal® lateral flow pathogen tests combine an immunoassay with chromatography for a rapid and accurate one-step result. Results are available 15 minutes after enrichment. The tests' unique



antibodies ensure sensitivity and specificity, and built-in visual control lines provide definitive interpretations. Tests are available for *E. coli* O157:H7, *Listeria* spp., *Salmonella* spp., and *Salmonella enteritidis*.

## Hydrophobic grid membrane filtration

Neogen's NEO-GRID™ and ISO-GRID™ tests use grid membrane filtration to capture target organisms on a hydrophobic membrane, which is then placed on an organism-specific agar plate. Target organisms are then detected and/or enumerated following an incubation. Tests are available for a wide variety of bacterial pathogens, and yeast and fungi.

## Acumedia dehydrated culture media

Acumedia, a Neogen subsidiary since 2000, has been a premier manufacturer of dehydrated culture media since 1978. Acumedia has proven expertise in media formulation, ranging from custom blends to fill the needs of a small research lab, to high-volume production for industrial use.





*Microbiology at the speed of light.™*



**The Problem, DEFINED**

Traditional microbiological testing methods have proven to be a time-consuming bottleneck for many food processors. This is because most standard methods require the preparation of samples, lengthy incubation, and subsequent counting or interpretation of results.

**Product quality**

- Spoilage organisms result in millions of dollars in lost sales

**Time constraints**

- Cost-effective food production requires efficient safety testing with the lowest false positive ratio

**Budget constraints**

- Competition and consolidation require a universal cost effective testing program

**The Solution, REFINED**

Soleris' rapid microbiology provides reliable results faster—impacting your operation in a variety of ways.

**Speed**

- Same-shift results
- Early, automated alert to problems with “real-time” availability of results

**Simplicity**

- Simplified workflow
- Fast sample preparation
- Easy to use, even by non-microbiologists

**Easy Data Analysis**

- Reporting in a variety of formats
- Automated data collecting and sample tracking
- Remote viewing of results

**Soleris reduces testing time**

Test Type	Typical Specification Levels	Traditional Methods Time to Results	Soleris Total Test Time to Negative or Below Specification Results	Soleris Early Alert Time for Positive Results
Total Viable Count (TVC)	<10,000	48 hours	18 hours	6 to 8 hours
Coliforms	<100	24 hours	14 hours	6 to 10 hours
<i>E. coli</i>	negative	24 hours	20 hours	6 to 10 hours
Yeast & Mold	<100	5 days	72 hours	30 to 48 hours
Lactic Acid Bacteria	<100	3 to 5 days	48 hours	30 to 35 hours

# Classic Microbiology Meets Automation

## How it Works

From samples to results. From results to knowledge. Optical technology—and Soleris™ vials—help get you there faster, with less sample handling, less labor, and less chance for error.

The heart of the Soleris system is its ready-to-use vial. The unique vial technology measures microbial growth by monitoring pH changes and other biochemical reactions. Here's how:

- Samples of up to 5 mL are added to the vials prefilled with microbial growth medium
- Soleris monitors changes in the chemical characteristics of the medium, and reagents change color as metabolic processes occur
- Optical changes are monitored every six minutes in the vial's semifluid zone, which is separated from the sample to eliminate interference
- Changes in color, expressed as optical units, are sensed by the photo detector and recorded in the computer
- The higher the number of organisms, the faster the detection time

## Soleris Direct Vial

The Soleris direct vial is based upon the well-known process that bacteria feed on sugars, convert those sugars into acids and lower the pH of their culture media.

A critical level of bacterial growth will cause the pH indicator to change color, and cause the Soleris system to record a positive result for that sample.

- **No QC needed:** Vials are provided with specific Certificates of Analysis
- **Store on your shelf:** Vials are stable at room temperature for up to 12 months
- **Consistency:** Because of no matrix effects, Soleris can be used on even the most difficult test samples
- **Increased sensitivity:** Broth culture is more sensitive than growing on a solid surface



## Soleris Vial-in-Vial

The unique Soleris Vial-in-Vial (ViV) was designed to better detect those organisms that are hard to recover, or require very long time to results. The inner vial contains a specific culture media or sterile sponges. The inner vial is inoculated with a test sample, and placed into a standard Soleris vial that holds an indicator dye. As organisms grow within the inner vial, they produce carbon dioxide gas that interacts with the indicator dye and produces a clear positive result.

- **No matrix effects:** By separating organism growth from the detection zone, false positives are significantly reduced
- **Capture more organisms:** ViV broth enrichment is more sensitive
- **More flexibility:** ViV is applicable for a large range of potential uses
- **Sterility analysis:** Soleris ViV VHT/ESL Assay allows for rapid testing of products subjected to UHT or ESL processes



### Simple Protocols, Easy Workflow

Rapid microbiology using the Soleris system (formerly BioSys) enables you to screen raw materials or finished products for early detection of contamination—ensuring higher quality, longer shelf life, and greater value for your brands. Soleris uses optical assay technology to accurately detect and enumerate a variety of microorganisms in raw materials, at critical control points, on product lines, or in finished products. The automated Soleris system uses simple methodology, familiar principles, and automation of classic microbiology protocols. The system is as easy as 1-2-3.

Test data is automatically recorded and analyzed so trends and statistical information are available when needed. Soleris' Windows®-based software system makes it easy to generate a variety of reports and trend analyses. Best of all, the system often provides reliable answers within the same work shift—so you can confidently release products faster.



*"It's a big benefit, especially for products that need to be held until testing is complete. We can reduce the hold time from five days to two, while assuring that safe, high quality products are going out the door."*

Lori Ledenbach  
Associate Principle Scientist  
Kraft Foods Research and Development Center  
in Glenview, Ill.



**1. Inoculate ready-to-use vial**



**2. Place the vial into the Soleris incubator**



**3. Record sample identification into computer**

# Is Soleris Right for You?

If you answer yes to any of the following questions, your company will benefit from faster results.

- Do you hold product/inventory for microbiology testing results?
- Do you have commodities that are difficult to test?
- Do you manufacture a product that has a short shelf life?
- Do you take corrective action based upon general microbiology results?
- Would an early alert to "out of spec" products improve your operation?
- Would you save money by bringing your microbiology testing in-house?



## So many benefits. So little time.

Soleris rapid microbiology provides reliable results faster—impacting your operation in a variety of ways:

### Improved efficiency and throughput

- Expedite screening of ingredients and raw materials
- Earlier alerts of contamination (hours, not days) allows immediate corrective action
- Faster clearance of raw materials and finished products reduces warehousing and refrigerated storage requirements, thereby lowering inventory costs

### Greater confidence and brand value

- Reliable rapid detection improves decision-making and confidence
- Earlier release extends shelf life and product value
- Greater operational efficiency and product quality result in higher profits

### Reduced labor materials

- Hands-on technical time reduced by as much as 95%
- Media storage and preparation eliminated
- Protocols simplified
- Automatic preparation reports eliminates transcription and related human errors

## Faster test results = speed = cost savings

### Example return on investment for Soleris rapid microbiology adoption

- Company makes an initial investment of \$84,300 (100 Yeast and Mold tests per day)
- Company showed a net increase in laboratory testing costs = \$0.88 per test
- Company showed a net decrease in operating costs = \$145,448
- Internal rate of return = 166%  
*Payback period of less than 1 year*
- Savings via reduced warehousing and inventory costs, lower rework levels and fewer recalled products

Example Return on Investment for Soleris	
<b>Cost differences in operations</b>	
Savings in annual cost of test-related overheads	<b>\$145,448</b>
<b>Cost differences in the laboratory</b>	
Cost increase per test	<b>\$0.88</b>
Cost increase per year	<b>\$5,230</b>
<b>Financial justification</b>	
Total annual savings	<b>\$140,218</b>
Payback time	7.21 months
Internal rate of return (based on 10 years lifetime)	<b>166%</b>

## Soleris Microbiological Assays

### Available Test Vials

- Total viable count
- *Enterobacteriaceae*
- Coliforms
- *E. coli*
- Lactic acid bacteria
- Yeast
- Yeast and mold
- *Staphylococcus*
- *Pseudomonas*
- UHT/ESL testing

### Applications for:

- Spoilage flora analysis
- Sterility testing
- Raw materials
- Finished products
- Shelf-life prediction
- Challenge testing/  
product development
- Membrane filtrations
- Environmental monitoring



## Specification Monitoring Method

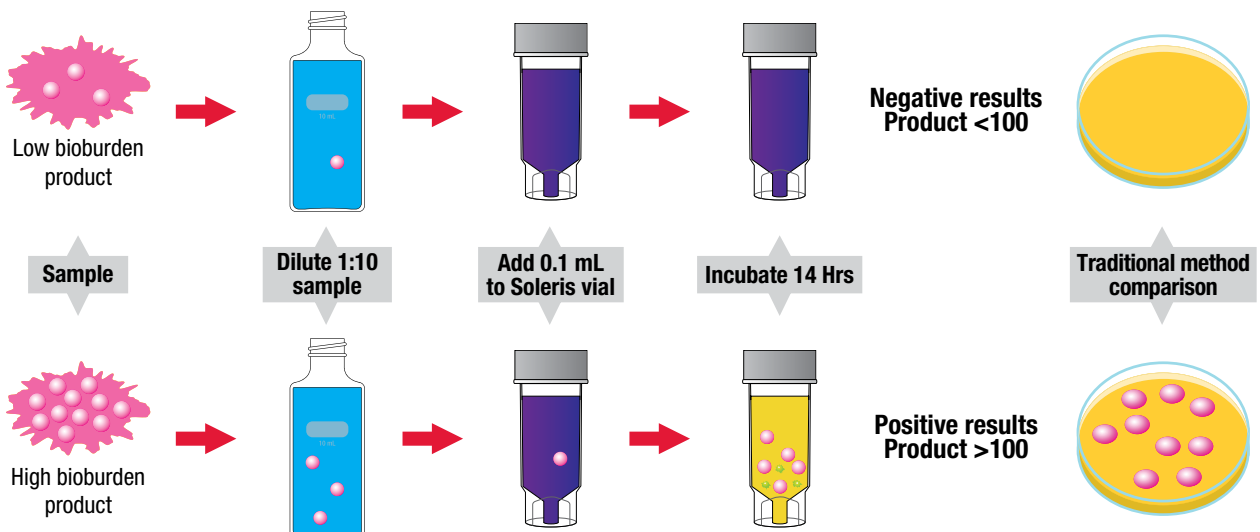
Soleris vials can detect from a minimum of a single organism up to  $1 \times 10^7$  bacteria. This large dynamic range allows for a myriad of result formats:

- Presence/absence
- Dilute to specification
- Calibration/quantification (specific applications)

One unique example of how to exploit this sensitivity is by using our unique **Specification Monitoring** indicator analysis method.

- Specification level is not zero
- Multiple applications for raw materials and finished products

Nearly all product specifications report as less than cutoff value (i.e.,  $<100$  or  $<100,000$ ). Our method allows you to quickly know if you are above or below a specification. By using our customized dilution table you can make a simple dilution and add a specified amount to the Soleris Vial or Vial-in-Vial. If the product tested is above your specification, this will lead to a positive result, and you will know within hours, not days.

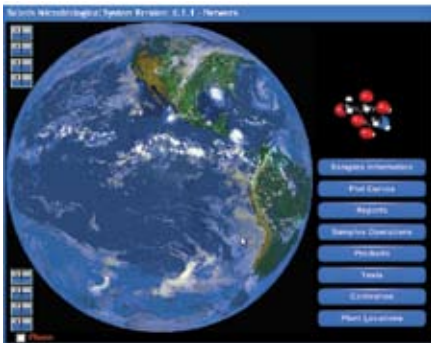


# Automated Data Collection and Analysis

## Soleris software, central to the simplicity

One of the most significant features of the Soleris system is its software, specially designed to provide the following functions:

- Controlling the Soleris instruments (up to 8)
- Real time data analysis of the optical data received from the instruments
- Automatic monitoring samples for compliance to specifications in real time
- Providing early alarms for contaminated samples
- Communicating the results and alarms over networks and phone lines
- Generating various reports including graphical trend analyses
- Configurable to individual customers' Laboratory Information Management Systems (LIMS)



The Soleris software, embedded in a Windows-based PC collects the optical data of the test vials (up to 1024) every 6 minutes. The dynamic pattern of each test vial is analyzed in real time to provide instantaneous determinations of presence and concentrations of active microorganisms. All results are automatically archived in a history file to provide audit trails and generate reports and trend analyses.

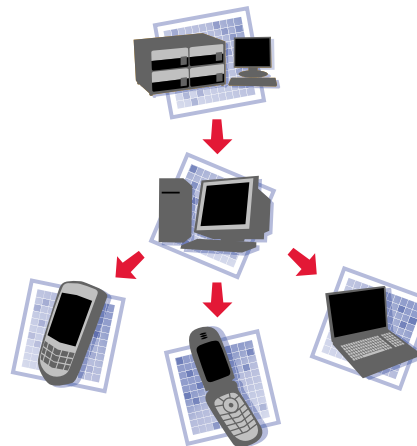
## Soleris software dashboard

The relevant data of each test vial can be effectively displayed with a few mouse strokes. Choosing a specific location (vial) in the individual incubator, a popup window provides the information of the sample code, the product, the associated test, entry data and time, status and remaining run time.



## Remote Data Viewing—React to problem results FASTER!

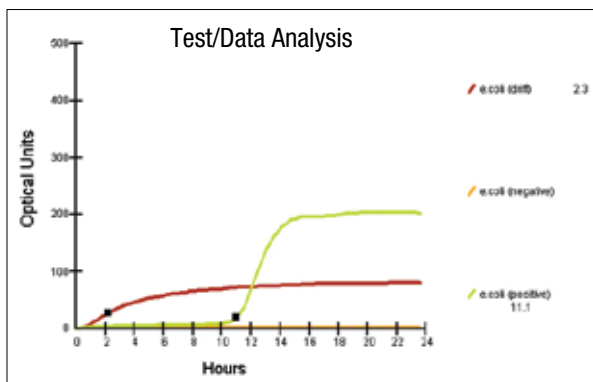
The Soleris software has the ability to alert users remotely via multiple channels. Real time alerts of positive (above specification) results can be immediately transmitted by the Soleris Remote Data Viewing package to users via telephone or electronic mail.



Test results can be transmitted to designated users as soon as they are activated in the computer controlling the Soleris instruments. There's no waiting for the report: You can release merchandise the moment the results are in.

## Powerful reports and trend analysis

- The Soleris software has built-in recording functions that can generate the following reports:
  - User-selected individual samples
  - Daily report showing all samples run in a chosen day
  - Weekly, monthly, and periodic reports
  - Instrument locations summary report
  - Graphical trend and histogram analyses
- Each of the printed reports can be further customized
- Graphical trend analysis is an excellent tool to display trends of individual products over specific periods of time



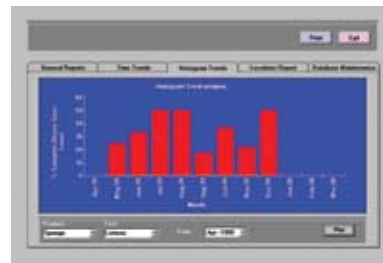
*"It's a very versatile piece of equipment."*

Dr. Carl Catrenich  
Procter & Gamble  
Corporate Microbiologist  
in Cincinnati, Ohio

## From data to actionable knowledge

The Soleris system delivers more than real-time microbiology. It also provides a complete data management system with the tools you need to make important decisions about your processes. The Soleris software package is an operator-friendly, Windows-based, lab management system. The system provides:

- Proper audit trails
- Trend analysis
- Multiple reports and report formats



## Validation Report

Product: Tech Services  
Food Sample #1

Description:

Test Code	Source/Production Lot	Specification
TVC	101	<10 cfu/g

Entry Date	Entry Time	DT (Hours)	Result	Vial Lot	Operator Name
5/6/08	1:59 pm	ND	10		sh



Test Code	Source/Production Lot	Specification
Yeast & Mold	101	<10 cfu/g

Entry Date	Entry Time	DT (Hours)	Result	Vial Lot	Operator Name
5/6/08	1:59 pm	29.5	ABOVE SPEC		sh



Test Code	Source/Production Lot	Specification
Coliform	101	<10 cfu/g

Entry Date	Entry Time	DT (Hours)	Result	Vial Lot	Operator Name
5/6/08	1:59 pm	ND	10		sh



Test Code	Source/Production Lot	Specification
E.coli	101	<10 cfu/g

Entry Date	Entry Time	DT (Hours)	Result	Vial Lot	Operator Name
5/6/08	1:58 pm	8.8	ABOVE SPEC		sh





Equipment Specifications	Soleris 32	Soleris 128
Number of samples	1 to 32	1 to 128
Number of incubators (controlled independently)	1	4
Height	16 cm (6 ¼")	42 cm (16 ½")
Width	45 cm (17 ½")	73 cm (28 ¾")
Depth	55 cm (21 ¾")	69 cm (27 ¼")
Weight	12 kg (26 lb, 8 oz)	60 kg (132 lb, 4 oz)
Ambient temperature control	15-35°C	15-35°C
Temperature control	± 0.5°C	± 0.5°C
Incubator temperature range	15-60°C	15-60°C
Ambient humidity range	<85% RHD	<85% RHD
Power supply	100/250V AC ± 10% 50/60 Hz	100/250V AC ± 10% 50/60 Hz
Power consumption (per unit, excluding PC)	120 VA, 1 amp	500 VA, 3-5.5 amps

**Expandability:**

- Up to eight instruments connected to one PC
- Any combination of the 32 and 128 sample units
- Up to 1,024 samples monitored simultaneously



# System and Components

## Instruments

Item No.	Product
BS32	Soleris 32 with computer
BS128	Soleris 128 with computer

## Supplements

Item No.	Product	Quantity
BPB-99	Butterfield's Phosphate Buffer	70 bottles
ETOH-25	Ethanol Yeast and Mold Reagent	1 x 25 mL
SI-118B	<i>Staphylococcus</i> Supplement	2 vials/100 tests
MI-114-K185	Sterility/UHT Dye Indicator	4 x 22 mL
TS-124	Tryptic Soy Broth (100 mL)	20/case
MI-114	ViV Dye Indicator	4 x 22 mL
YI-110	Yeast and Mold Supplement	4 x 10 mL

## Confirmation Kits

Item No.	Product	Quantity
BGB-127	Brilliant Green Bile Broth	10 x 5 mL
KO-122	Kovac's Reagent	25 mL
LM-126	<i>Lactobacillus</i> MRS Broth	10 x 5 mL
TT-123	Tryptone (Indole) Broth	10 x 2 mL

## Vials

Item No.	Product	Quantity
CC-BP9	Coliform Buffered Medium	100 vials
CC-BP9-PRO	Coliform Buffered Medium, low pH	100 vials
CC-102	Coliform Medium (CC), 5 mL	100 vials
CC-109	Coliform Medium (CC), 9 mL	100 vials
EC-104	<i>E. coli</i> Medium (EC)	100 vials
MT-101	Empty Outer Vials	100 vials
EB-BP9	Enterobacteraceae Buffered Medium	100 vials
EB-105	<i>Enterobacteraceae</i> Medium (ENT)	100 vials
LB-1111	Lactic Acid Medium Red	100 vials
LB-1112	Lactic Acid Medium Green	100 vials
SM-118	<i>Staphylococcus</i> Medium	100 vials
NB-100	Total Viable Count (TVC)	100 vials
VIV-140	Vial in Vial, Lactic Acid Medium	100 vials
VIV-125	Vial in Vial, <i>Pseudomonas</i>	100 vials
VIV-132	Vial in Vial, Sterility/UHT	100 vials
YCA-106A	Yeast Acid Food Medium	100 vials
YC-106	Yeast Dairy Medium	100 vials
MA-113	Yeast and Mold Vial	100 vials



## Preventative Maintenance and Service Options

Since Soleris has very few moving parts, the instrument should continue to perform trouble-free for years if a simple annual routine maintenance program is followed.

The integrity of Soleris assays can be compromised if the temperature and light sources are not maintained within the specification limits, or the operating system driving the Soleris instrument is not properly maintained. A little preventative maintenance can stop potential Soleris performance issues before they start.

### Service Options:

1. **SS-100: Full Preventative Maintenance**, includes parts, labor, software upgrade\* and extended warranty of Soleris instrument

Service includes annual maintenance on machine, any necessary upgrades, and temperature calibration of each drawer. Extended warranty covers the Soleris instrument for one additional year. (The computer, monitor, and printer are not included with the extended warranty.) Certification of service will be provided at the time of maintenance.

In the event the unit cannot be repaired, a replacement instrument will be provided within five business days, and the new unit warranty will supersede the extended warranty program.

2. **SS-101: Preventative Maintenance**, includes calibration, any parts needed, and software upgrade\*

Service includes preventative maintenance and calibration only. Any replacement parts or upgrades will be included. Service includes annual inspection and maintenance on machine, any necessary software upgrades, computer maintenance and temperature calibration for each drawer. Does not include an extended warranty. Certification of services will be provided.

3. **SS-102: Preventative Maintenance**, includes calibration only

Service includes preventative maintenance and calibration only. Any parts that need to be replaced will require additional charges (approximately \$500 to \$1,000). Service includes annual check and maintenance on machine, computer maintenance and temperature calibration for each drawer. Certification of services will be provided.

4. **SS-103: Instrument Calibration Only**

SERVICE DOES NOT INCLUDE preventative maintenance, and includes a maximum of three units per service fee. Any parts needed to be replaced will require an additional charge. Certification of calibration services will be provided.

5. **TL-163: 32 Sensor and 1 or 4 drawer Temperature Logger**



Temperature logger unit allows for temperature calibration of all four drawers of a Soleris 128 or the one drawer of a Soleris 32 system. Includes a serial connector cable and Excel spreadsheet designed for easy data analysis.

*\*Software upgrade will only be performed if computer system is compatible with new software system.*

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