



## **Rapid Methods from Oxoid, Thermo Fisher Scientific - Microbiology**

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# Agenda

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- Introduction and background
- Rapid methods from Oxoid, Thermo Fisher Scientific-Microbiology
- Precis™ methods
  - Listeria Precis method
  - Salmonella Precis method
- Validation Issues
- Conclusions

# Background – Why we validate

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- EU food safety regulations (EU2073/2003 and EU1441/2007) place strict controls on Salmonella (absent/25 g) and Listeria (absent or 100 CFU/g depending on food) and EU2160/2003 control of Salmonella in poultry and pigs
- Designed to improve public health
- Harmonise requirements
- Set test requirements on food manufacturers and producers for microbial quality of foods for sale to public
  
- Performance claims
- Set customer expectations
  - Rapid compared to reference method
  - Performance of product
  - Independent validation

# Rapid Methods from Oxoid, Thermo Fisher Scientific

- Listeria Precis
- Salmonella Precis
- Oxoid Listeria Rapid Test (OLRT)
- Oxoid Salmonella Rapid Test (OSRT)
- *Brilliance*<sup>TM</sup> Staph 24 Agar
- Western European, Canadian and Australian distributor of DuPont Qualicon BAX<sup>®</sup> System –molecular identification method
- Range of dehydrated and prepared media and confirmation methods for many applications



# Before rapid methods: ISO methods

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- *Salmonella* spp. and *Listeria* spp. both major causes of food poisoning
- ISO methods for both organisms are lengthy
  - *L. monocytogenes* (detection) ISO 11290-1 4-7 days
  - Salmonella ISO 6579 5-6 days
  - require multiple culture media
  - large number of manipulations per sample
  - multiple confirmation tests

# Precis Methods

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- Single broth
  - ONE Broth™ based on highly nutritious medium
  - Selective properties allow:
    - inhibition of competing organisms while maintaining favourable conditions for target organism –cleans up background flora
    - recovery of target organism, even when stressed or present at low numbers
    - no cross contamination problems
- Single chromogenic plate
  - Definitive positive obtained
- Rapid confirmation
- Simple
- Cost effective
- No capital outlay or service contracts
- Validated by AFNOR to ISO 16140:2003

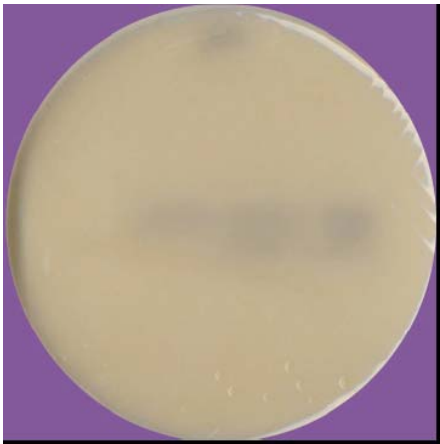
# Listeria Precis Method

- Validated to ISO 16140:2003 by AFNOR for all human foods and environmental samples
  - Detection limit 0.1-3 CFU/g
  - Relative accuracy 92.1%
  - Relative specificity 93.4% (not 100% due to confirmed supplementary positives)
  - Relative sensitivity 90.6%
- Traditional culture of 1 broth and 1 plate
- 24 hour enrichment
- Single sample transfer - broth to plate
- Simple confirmation method – O.B.I.S mono (ID0600M)
- Time to result – 2 days

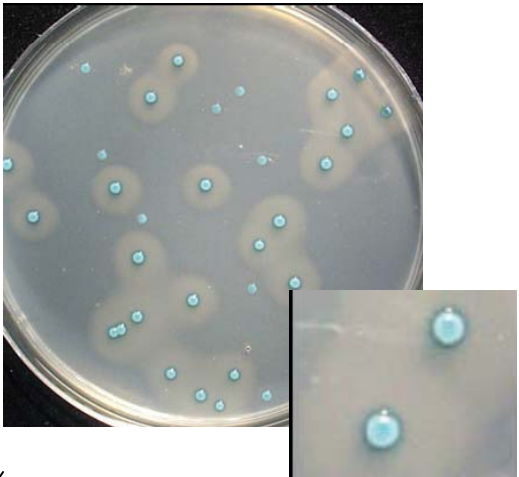
# Listeria PreciS: Detection Method



22-26 h  
30°C



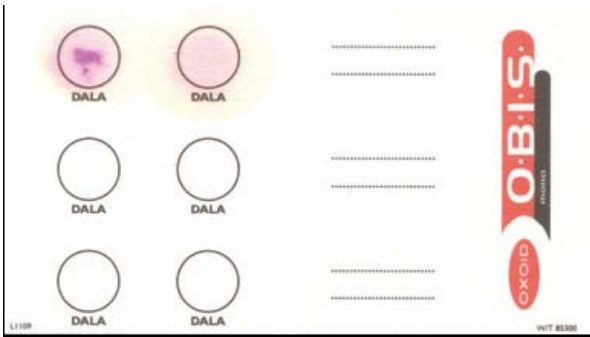
22-26 h  
37°C



25g/25ml sample +  
225ml ONE Broth  
Listeria

Plate 10µl onto single  
*Brilliance* Listeria plate

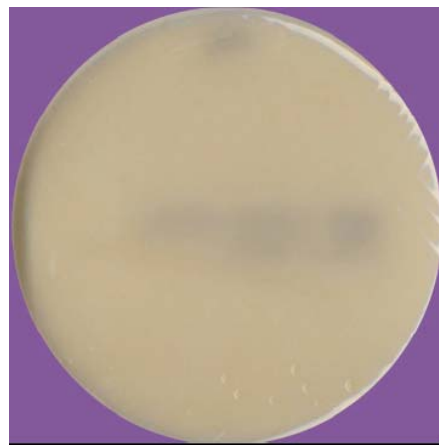
If present, confirm  
blue/green colonies with  
halos as *L.*  
*monocytogenes* with  
O.B.I.S mono



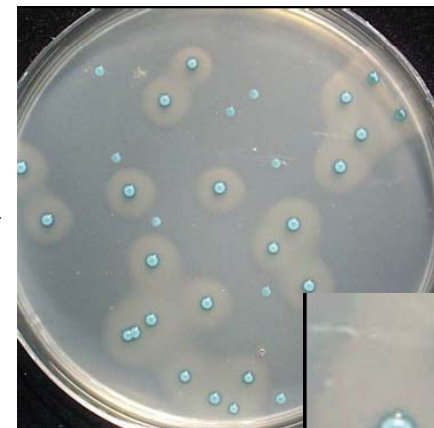
# Listeria Precip: Enumeration Method



1 h 20°C



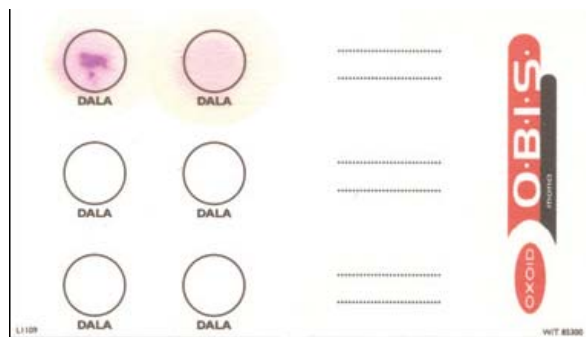
45-51 h  
37°C



25g/25ml sample +  
225ml BPW

Plate 100µl onto single  
*Brilliance* Listeria plate

Inspect plate, count and  
confirm blue/green  
colonies with halos as *L.*  
*monocytogenes* with  
O.B.I.S mono



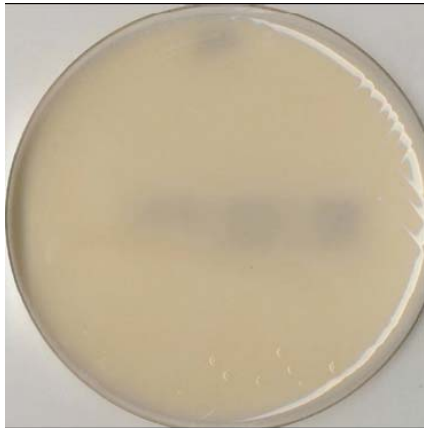
# Salmonella Precis Method

- Validated to ISO 16140:2003 by AFNOR for all human foods, animal feeds and environmental samples with exception of primary production samples
  - Detection limit 0.1-1.8 CFU/25g
  - Relative accuracy 91%
  - Relative specificity 92% (not 100% due to confirmed supplementary positives)
  - Relative sensitivity 89.9%
- Traditional culture of 1 broth and 1 plate
- 18 hour enrichment
- Single sample transfer - broth to plate
- Chromogenic Plate contains Inhibigen™ Technology
  - Reduces false presumptive positives
- Simple confirmation method – Oxoid Salmonella latex (FT0203A)
- Time to result – 2 days

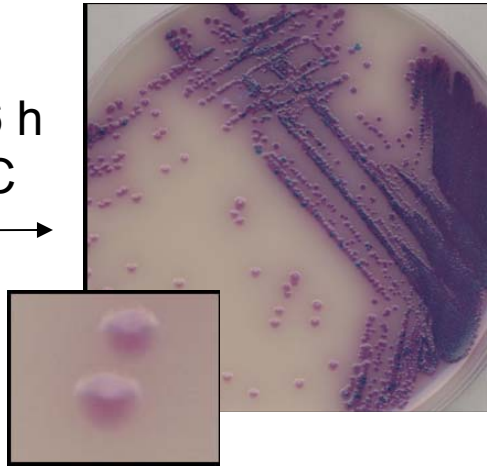
# Salmonella Precis Method



16-20 h  
42°C



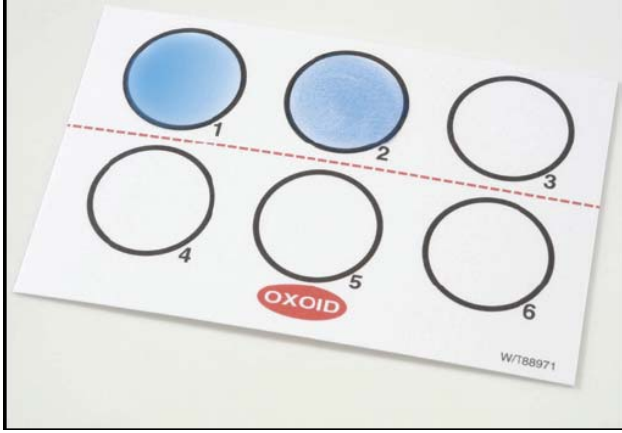
22-26 h  
37°C



25g or 25 ml sample +  
225ml ONE Broth  
Salmonella

Plate 10µl onto single  
*Brilliance* Salmonella plate

If present, confirm isolated  
purple colonies using  
Oxid Salmonella Latex  
Test.



# Validation issues



- Experience of working with MicroVal, AFNOR, NordVal and AOAC
- Co-recognition of validation bodies in all EU member states
- Combined MicroVal and AOAC-RI validation
- ISO 16140 validation demonstrates product meets EU regulations (EU2073 & EU1441)
- Facilitates customer uptake of product
- Good links with customers, generates interest early in product life cycle

# Validation issues



- More hurdles for food product validation compared to clinical products (EU98/79 non-annex II) within EU
- Validation Costs
  - Around €55,000
  - Inhibitory for products with small market potential e.g. Vibrio testing within Europe
  - Obstruction to smaller companies
- Validation Timescales not always met:
  - Recent experience: >12-18 months
  - Dependant on drive, experience and resources of expert lab
  - Problems encountered and solutions
  - Review by validation bodies

# Validation issues



- Uncertainty of ISO 16140 revision timescale
- Validation limited to narrow range of food types
  - Validated foods may not be relevant to customer
- Customers must still validate themselves

# Conclusions

- Thermo Fisher Scientific-Microbiology, provide a wide range of traditional culture media and rapid culture based methods under the Oxoid and Remel brands

remel



- Listeria and Salmonella Precis methods are quick and easy traditional culture based methods for rapid detection of two common food pathogens
- Molecular detection available using DuPont Qualicon BAX<sup>®</sup> system
- Rapid alternative methods only option for industry as reference methods slow, expensive and/or difficult
- Method validation essential for alternative methods for analytes in EU2073 & EU1441 and important for product acceptance in Europe for other analytes