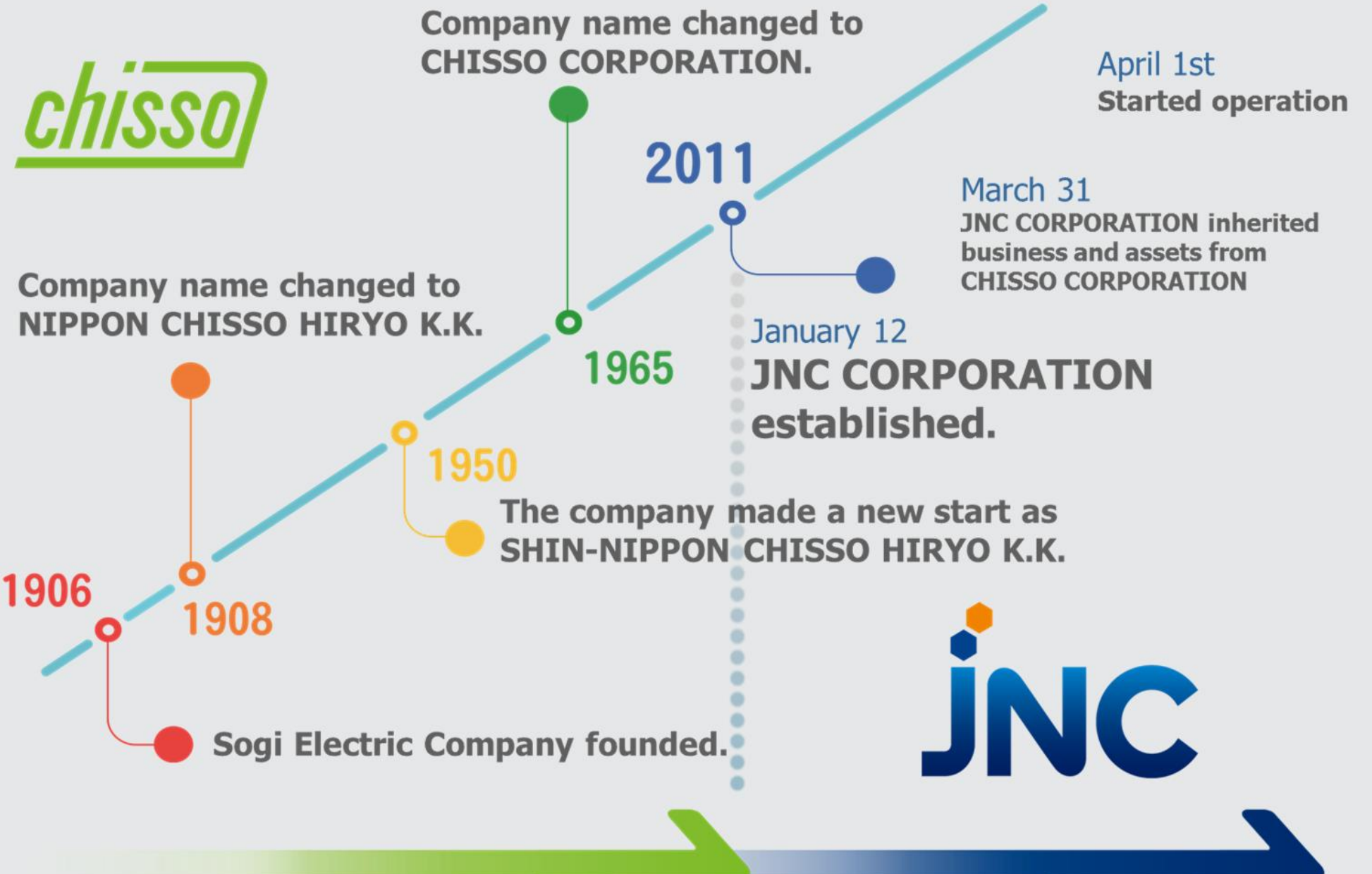


# Approaches of the development for life science products

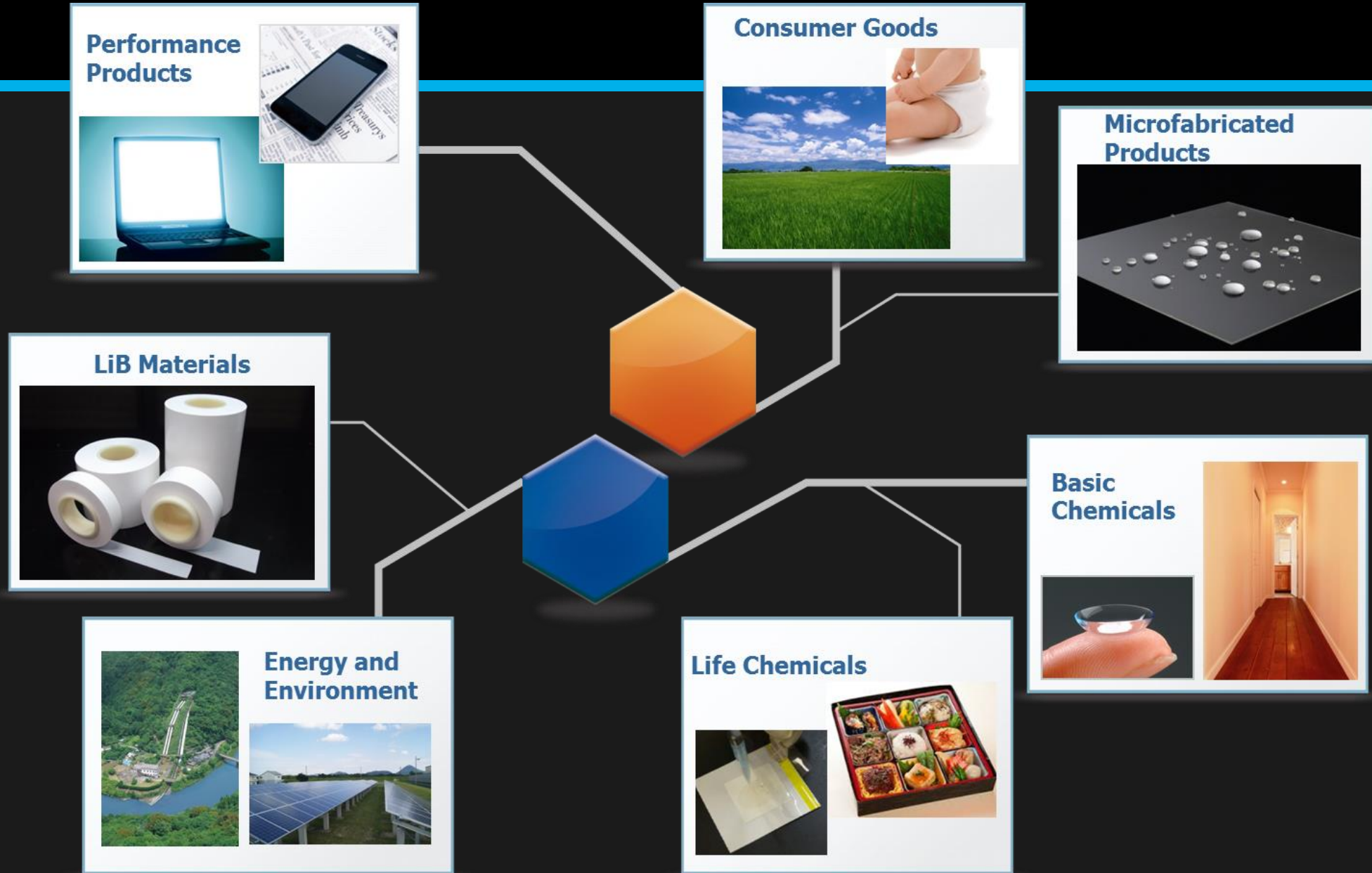


**JNC Corporation, Yokohama Research Center,  
Hajime Teramura**

# What is JNC Corporation?



# JNC Corporation's business segmentation



# R&D sections in Life Chemical Launch Office



## Cellufine™

Chromatography support  
(Spherical Cellulose Gel)



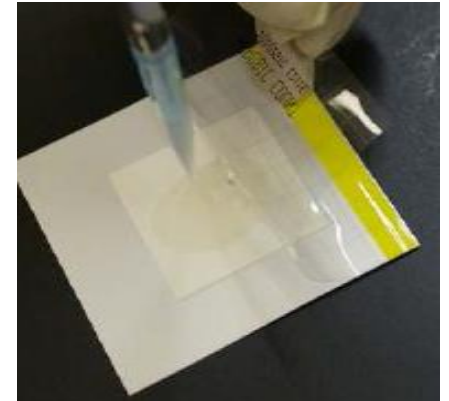
## ELISA Kits

Animal diagnostic kits



## Polylysine

Food preservative



## MC-Media Pad™

Dry culture media

# MC-Media Pad

The ready-to-use dry quantitative culture devices for food hygiene control.

Food safety

No well-maintained QC lab

No Specialist for QC operation

Conventional bacteriological method

Cumbersome operation

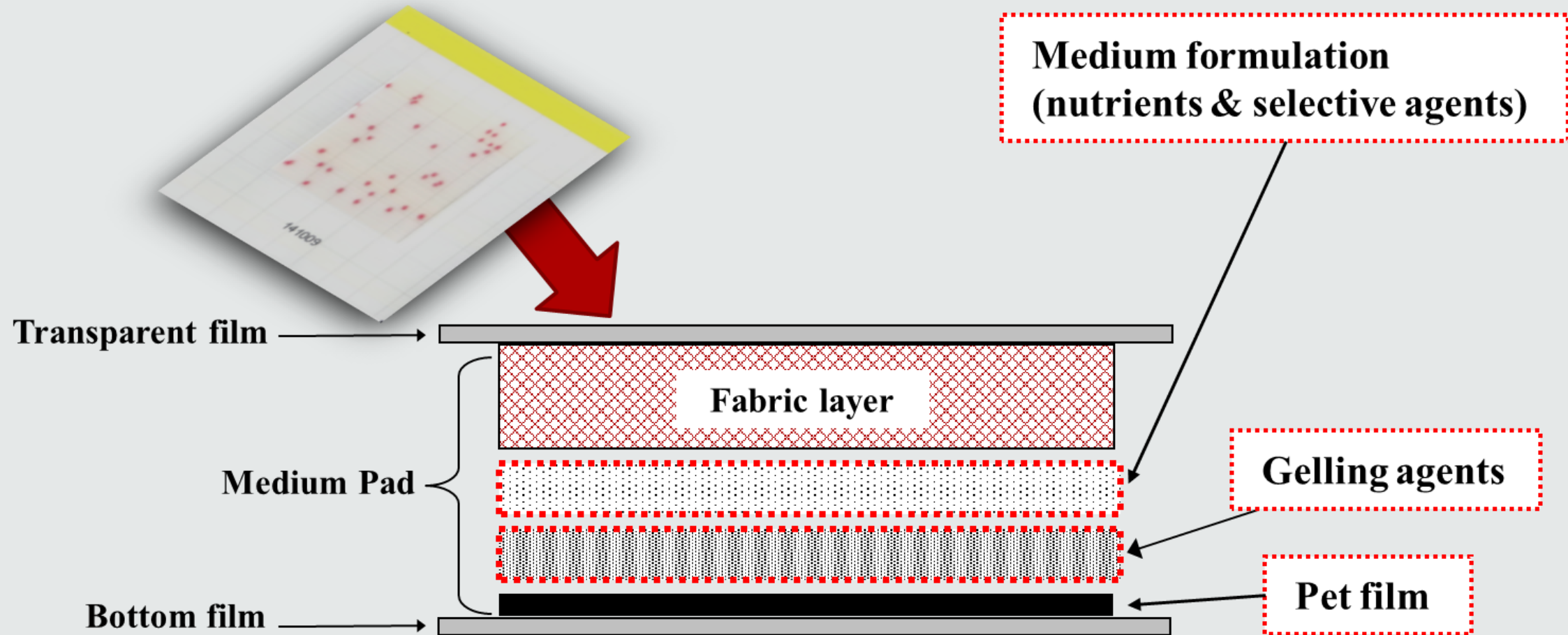
Need skills and experiences

Need EASY, SIMPLE, and ACCURATE method

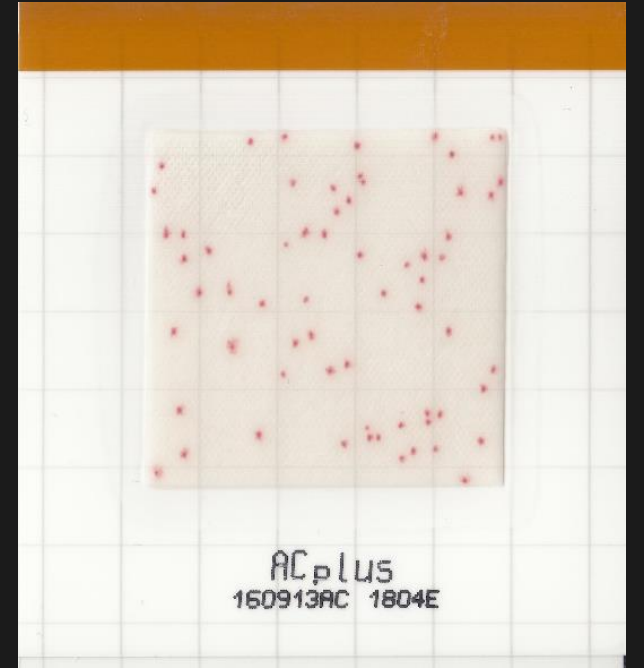
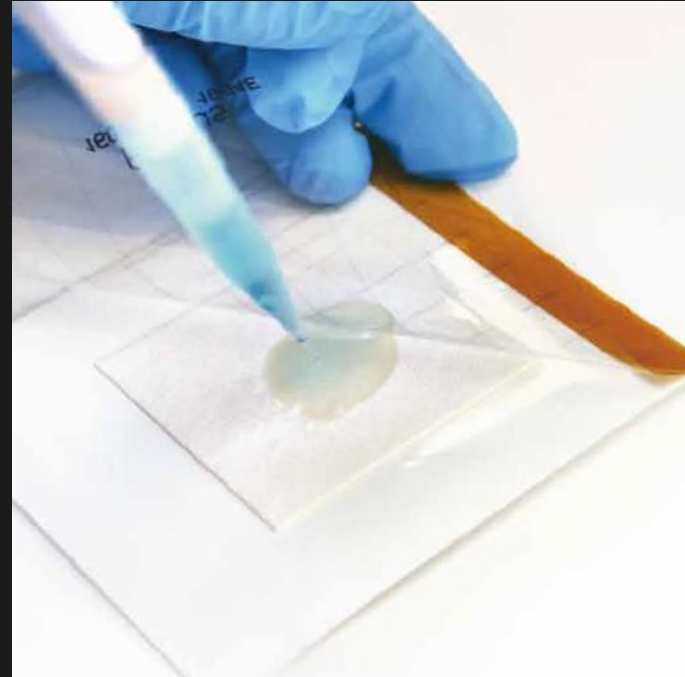


# Structure

There are core technologies in 1mm of thickness of MC-Media Pad.....

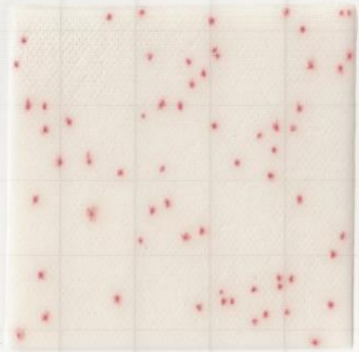


# How to use



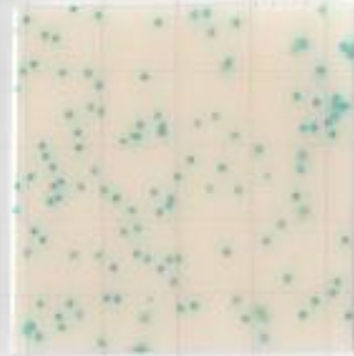
# Product lineup

No skills necessary No experiences



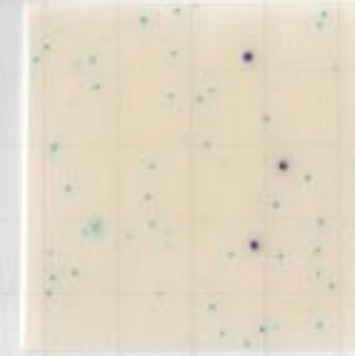
ACplus:  
Rapid aerobic count

3-7



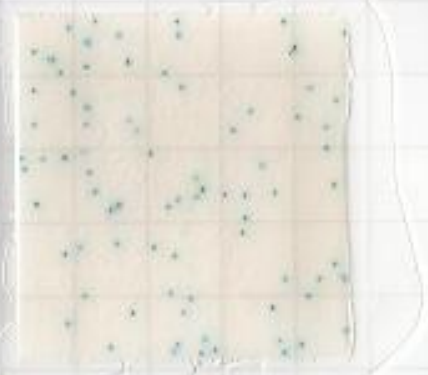
CC:  
Coliform count

18-3

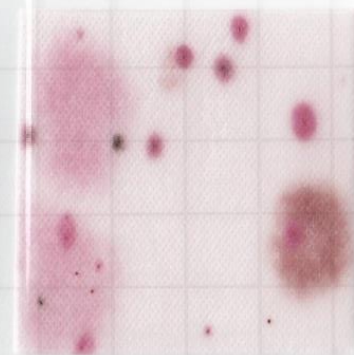


EC:  
*E. coli* & coliform count

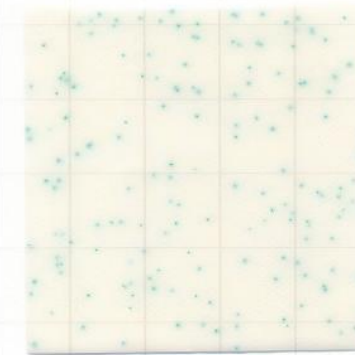
2



SA:  
*S. aureus* count



YM:  
Yeast & mold count



SAL:  
*Salmonella* spp.



# Effectiveness

Product	Reference
ACplus	Hajime Teramura, Mihoko Iwasaki, Masashi Ushiyama, and Hirokazu Ogihara: Evaluation of a novel dry sheet culture method for rapid enumeration of total aerobic count in foods. <i>J. Food Prot.</i> Vol. 78(10), 1885-1890. 2015.
CC & EC	Hajime Teramura, Kojiro Sota, Mihoko Iwasaki, and Hirokazu Ogihara: Comparison of the quantitative dry culture methods with both conventional media and most probable number method for the enumeration of coliforms and <i>Escherichia coli</i> /coliforms in food. <i>Lett. Appl. Microbiol.</i> Vol. 65(1), 57-65. 2017.
SA	Hajime Teramura, Mihoko Iwasaki, and Hirokazu Ogihara: Evaluation of the quantitative dry culture method (Sanita-kun™ SA) for the enumeration of <i>Staphylococcus aureus</i> in artificially contaminated food samples. <i>Biocontrol Sci.</i> Vol. 20(4), 297-301. 2015.
YM	Hajime Teramura, Masashi Ushiyama, and Hirokazu Ogihara: Evaluation of a novel dry sheet culture method (Sanita-kun) for rapid enumeration of yeasts and molds in foods. <i>J. Microbiol. Methods.</i> Vol. 109, 16-19. 2015.

# Authorization

## Official methods

Authorized method by each country

## Commercially available test kits

Customer use voluntary

## Concept of ISO 16140 (international Organization for Standardization)

Validated kit can be approved as alternative method for reference methods.

Test kit need validation according to ISO 16140.

※ISO 16140: Microbiology of food and animal feeding stuffs. Protocol for the validation of alternative methods.

Needs approval for international standard methods.

# Certification bodies

Standard of EU

**ISO**

**Certification body**

MicroVal (Netherlands)

AFNOR (France)

NordVal (Denmark)

Standard of JP

**ISO**

Approved method by certification body  
can be used as alternative methods.  
(MicroVal, AOAC-OMA, AFNOR, NordVal)

Standard of US

**FDA-BAM, USDA, etc.**

**Certification body**

AOAC International

AOAC-OMA: for method  
(*Official methods of analysis*)  
AOAC-PTM: for product  
(*Performance tested methods*)

ISO and AOAC have been harmonized.

# Approval of MC-Media Pad



## CERTIFICATE OF COMPLIANCE LLOYD'S REGISTER QUALITY ASSURANCE

hereby declares that the certification assessment has demonstrated that

### MC-Media Pad™ ACplus

Manufactured and supplied by: JNC Corporation 2-2-1 Otemachi Chiyoda-ku Tokyo Japan, 100-8105	Production site: JNC Corporation Yokohama Research Center 5-1, Ookawa Kanazawa-ku Yokohama Japan, 236-8605
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has been validated and revealed to be at least equivalent to the reference method as demonstrated by the validation study report. The summary of the validation report is available on the MicroVal website: [www.microval.org](http://www.microval.org)

Reference method: ISO 4833-1:2013 Microbiology of the food chain — Horizontal method for the enumeration of microorganisms Part 1: Colony count at 30 degrees C by the pour plate technique

Scope: A broad range of foods

The validation and certification has been performed in accordance with EN ISO 16140-2: 2016 and the MicroVal Rules and Certification Scheme version 8.

This certificate is valid only in association with the certificate schedule bearing the same number on which the distributor applicable to this approval is listed.

Certificate no.: 2015LR52

First approval date: 29 January 2018  
Expiry date: 28 January 2022

ISSUED BY: Lloyd's Register Nederland B.V.  
Rotterdam, The Netherlands

Certificate no.: 2015LR52

29-01-2018

Page 1 of 2

K.P. v.d. Mandelieaan 41a, 3062 MB Rotterdam, The Netherlands. KvK nr.: 24247948  
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.



## CERTIFICATION

### AOAC® Performance Tested<sup>SM</sup>

Certificate No.

**091702**

The AOAC Research Institute hereby certifies that the performance of the test kit known as:

### MC-Media Pad ACplus

manufactured by  
**JNC Corporation**  
**2-1, Otemachi 2-chome**  
**Chiyoda-ku Tokyo 100-8105**  
**Japan**

This method has been evaluated in the AOAC® Performance Tested Methods<sup>SM</sup> Program, and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Performance Tested<sup>SM</sup> certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (September 05, 2017 – December 31, 2017). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

*Deborah McKenzie*

Deborah McKenzie, Senior Director  
Signature for AOAC Research Institute

September 05, 2017  
Date

2275 Research Blvd., Ste. 300, Rockville, Maryland, USA Telephone: +1-301-924-7077 Fax: +1-301-924-7089  
Internet e-mail: [aoacri@aoac.org](mailto:aoacri@aoac.org) \* World Wide Web Site: <http://www.aoac.org>

# Current status of approval

Product	Approval	Reference method	Title
ACplus	MicroVal AOAC-PTM for a variety of foods	ISO 4833-1:2013, AOAC OMA 966.23, USDA FSIS MLG 3.02, Standard Methods for the Examination of Dairy Products Chapter 6	Hajime Teramura, and Gail Betts: MC-Media Pad ACplus for the enumeration of total aerobic count in a variety of foods. <i>J. AOAC Int.</i> Vol. 101(3), 769-782. 2018.
CC	MicroVal AOAC-PTM for a variety of foods	ISO 4832:2006	Hajime Teramura, Aya Ogura, Linda Everis, Gail Betts: MC-Media Pad CC for Enumeration of Total Coliforms in a Variety of Foods. <i>J. AOAC Int.</i> in press.
EC	MicroVal AOAC-PTM for a variety of foods	ISO 4832:2006 (coliform), ISO 16649-2: 2001 ( <i>E. coli</i> )	Hajime Teramura, Aya Ogura, Linda Everis, Gail Betts: MC-Media Pad EC for Enumeration of Escherichia coli and Coliforms in a Variety of Foods. <i>J. AOAC Int.</i> in press.
SA	MicroVal AOAC-PTM for a variety of foods	ISO 6888-1:1999 (= FDA-BAM Chapter 12)	Hajime Teramura, and Gail Betts: MC-Media Pad SA (Sanita-kun SA) for the enumeration of <i>Staphylococcus aureus</i> in a variety of foods. <i>J.</i> <i>AOAC Int.</i> Vol. 101(2), 456-467. 2018.
YM	MicroVal AOAC-OMA AOAC-PTM for all foods which have aw >0.95	ISO21527-1:2008, FDA-BAM Chapter 18	Oscar Caballero, Susan Alles, Quynh-Nhi Le, Mark Mozola, and Jennifer Rice: Validation of the NeoFilm for Yeast and Mold Method for Enumeration of Yeasts and Molds in Select Foods. <i>J. AOAC Int.</i> Vol. 98 (3), 798- 805. 2015.

Thank you for Kind attention!

