



nite

NBRC

Introduction to the history, management, and practice of NPMD/IPOD

**National Institute of Technology and Evaluation (NITE)
Biotechnology center (NBRC)
Patent Microorganism Depositary/
International Patent Organism Depositary**

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Today's Topics

1. Introduction of our organization
2. Decision to establish an IDA
3. Infrastructure and resource requests
4. Operational environment



1. Introduction of our organization

NITE's whole missions

Biological Resource Center

Developing biotechnology based on biological resources from microorganisms



Chemicals Management Center

Collecting and transmitting information required for total risk assessment and management of chemical substance



Global Center for Evaluation Technology

Emerging Technology Evaluation Field

Development of testing and evaluating methods for emerging technologies



Product Safety Technology Center

Collecting and transmitting information related to product safety and comfort in daily life

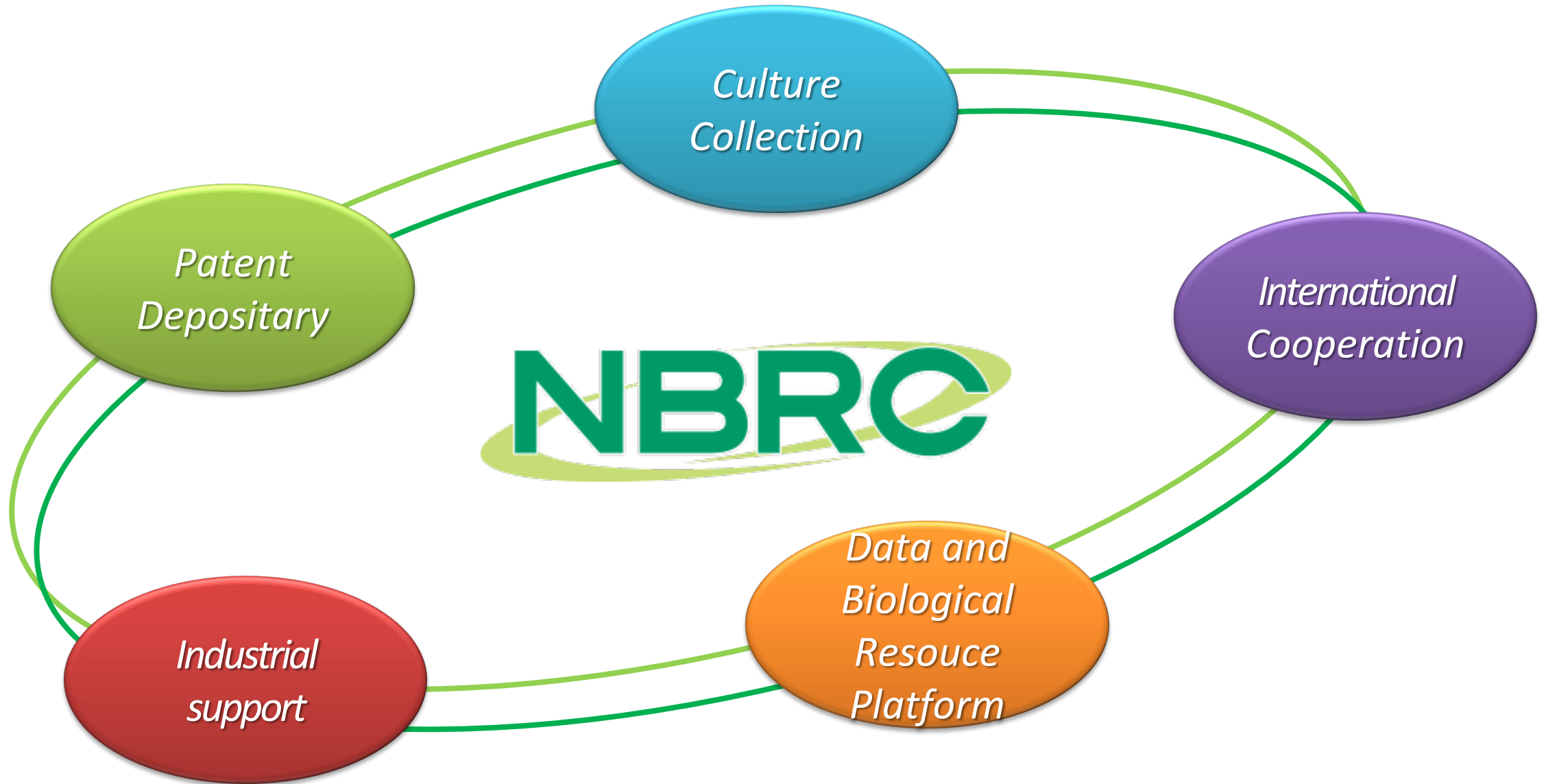


International Accreditation Japan

Constructing and administering reliable conformity systems that meet international standards



Activities of NBRC



NBRC's Collaboration with Vietnam

- NITE and the Institute of Microbiology and Biotechnology, Vietnam National University, Hanoi (VNUH-IMBT) have been cooperating since March 2004.
- On February 25, 2016, the MOU on the “Conservation and Sustainable Use of Microbial Resources” and the PA were renewed between NBRC and VNUH-IMBT.

The objective of the collaboration is to promote conservation and sustainable use of biological resources in Japan and Vietnam especially with a view to utilize them in the academic and industrial field.



2. Decision to establish an IDA

History of IDA in Japan (IPOD)

- 1966 • First Patent Organism Depository in Japan was established by Japan Patent Office at the Fermentation Research Institute, now the National Institute of Advanced Industrial Science and Technology (AIST)
- 1981 • designated as the international Depository Authority (IDA) under the International Budapest Treaty as International Patent Organism Depository (IPOD).

History of IDA in Japan (NPMD/IPOD)

- 2001 • Aside from the distribution of biological resources, patent depositary is also an important task for a biological resource center (BRC) to protect intellectual properties of individuals. This has been commonly practiced in overseas BRCs such as ATCC and DSMZ.

(OECD BRC guidelines: the role of the BRC is defined as a 'biorepository for the protection of intellectual property'.)



- 2004 • NITE Patent Microorganisms Depositary (NPMD) established at National Institute of Technology and Evaluation(NITE)
- designated as the depositary organization for Japan by the Japan Patent Office
 - Acquired status as an International Depositary Authority (IDA) under the Budapest Treaty
- 2013 • Succeeded to the International Patent Organism Depositary (IPOD) business of the National Institute of Advanced Industrial Science and Technology (AIST)

NITE operates two IDAs, NPMD and IPOD (the only one in Japan).

Merits of cooperation between NPMD/IPOD and NBRC

- NPMD can work to protect depositors' intellectual property through advanced technical assistance of the Biological Resource Center of NITE (NBRC).
- Microorganisms for which a patent deposit have expired, transfer them to NBRC if agreed by the depositors. They will then be preserved at NBRC and distributed to the public.

3. Infrastructure and resource requests

Equipment necessary for handling microorganism

Item	Purpose
Biological safety cabinet	Maintain aseptic environment and of potential biohazards
Incubator	Controlling temperature for incubation
Microscope (Uplight and/or Inverted) with camera	Viewing and assessing, and recording of microorganism
Refrigerator	Local storage of media and reagents
Freezer	For -20°C storage of unstable media and reagents
Low-temperature(<-80°C) freezer	Storing microorganism for patent purpose, unstable reagents
Liquid N ₂ tank	Storing cryosensitive microorganism
Sterilizing oven	Sterilization of glassware, metals, and heat-resistant plastics; can double as drying oven
Autoclave	Sterile of glass consumables, media
Centrifuge	Centrifuging cells to remove preservative or experimental additives. Collectionn of microorganism
pH meter	Mearuing pH in prepared media and reagent
Magnetic stirrer	Maintaining uniform suspension of media



Preservation of patent deposit strains

According to the characteristics, patent microorganisms are appropriately preserved for a long period of time.



4°C stock room for freeze-drying and Liquid-drying samples



Liquid nitrogen tanks (15 units in vapour phase, 1 unit in liquid phase) for frozen samples



-80°C deep-freezer for frozen samples (7 units)



Plant growth chamber for active cultures (28 units)



Risk management for infrastructure

Risks during long term storage

1. Natural disasters

- earthquakes, typhoons, floods, tornadoes and so on

2. Accidents:

- fire, power failure, explosion, equipment failure



1. Install of private power generation equipment in the building

2. Daily inspections and 24-hour surveillance by specialist staff



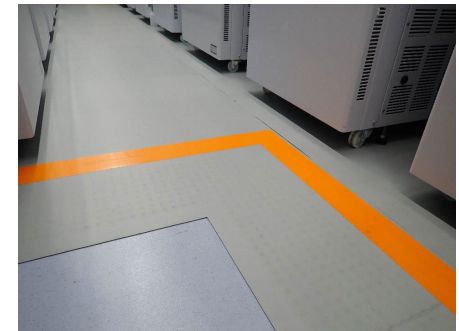
Risk management for equipment at NPMD/IPOD

According to the Budapest treaty, NPMD/IPOD is keeping strict security for patent microorganisms.

1. Temperature monitoring system in each storage unit



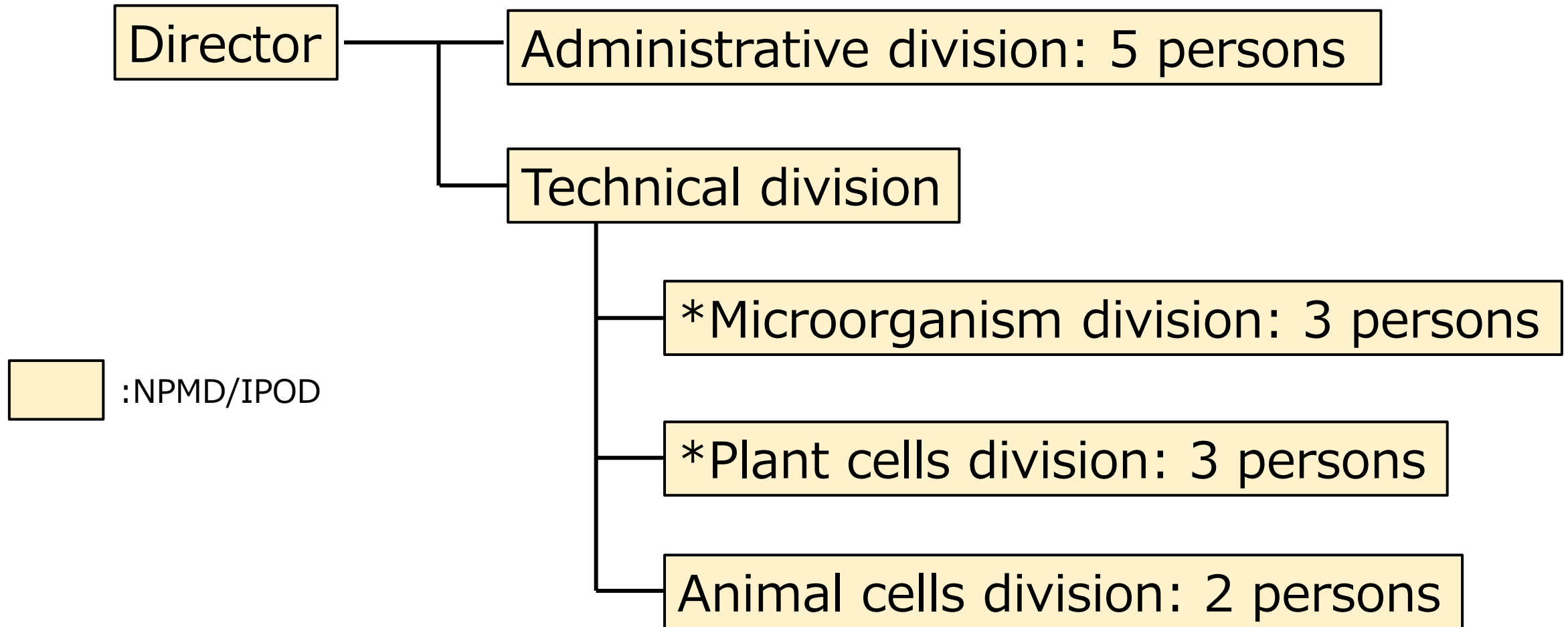
2. Installation of quake-absorbing floors for incubator of Active culture (plant cell culture)



3. Entrance restrictions to the building of NPMD/IPOD



Human resource of NPMD/IPOD



Total: 13 persons

* One technical manager manages two departments.

4. Operational environment

Two kinds of Patent Deposit in Japan

	Deposit under BT	Deposit enforcement of regulation of patent law
Patent application	Contracting party under BT (including Japan)	Only Japan
Regulation	Budapest treaty Enforcement of regulations of the patent law Article 27 2,3	Enforcement of regulations of the patent law Article 27 2,3
Storage period	30 years	Annual renewal (can continue for desired number of years on application)
Change of deposit	Impossible	Possible
Withdrawal during the deposit periods	Impossible	Possible

Schedule of Fees

Category	VND
(a) Storage	
(i) refrigerated or frozen	
- original deposit (for 30 years)	19,075,138.5 ^{*1}
- new deposit	7,069,553.7 ^{*1}
- extension of storage duration (per year)	1,518,778.8 ^{*1}
(ii) subculturing of active culture	
- original deposit (for 30 years)	287,031,112.5 ^{*1}
- new deposit	7,069,553.7 ^{*1}
- extension of storage period (per year)	10,450,644.6 ^{*1}
(b) Issuance of an attestation under Rule 8.2	460,236(tax exempt) ^{*2}
(c) Issuance of a viability statement	
(i) when a viability test is carried out	5,803,904.7 ^{*1}
(ii) based on the last viability test	460,236(tax exempt) ^{*2}
(d) Furnishing of a sample (shipping fee excluded)	
- the destination is Japan	7,159,957.2 ^{*1}
- the destination is outside of Japan	6,509,052(tax exempt) ^{*2}
(e) Issuance of a communication under Rule 7.6	460,236(tax exempt) ^{*2}

1 JPY = 146.37 VND
(2023/11/03)

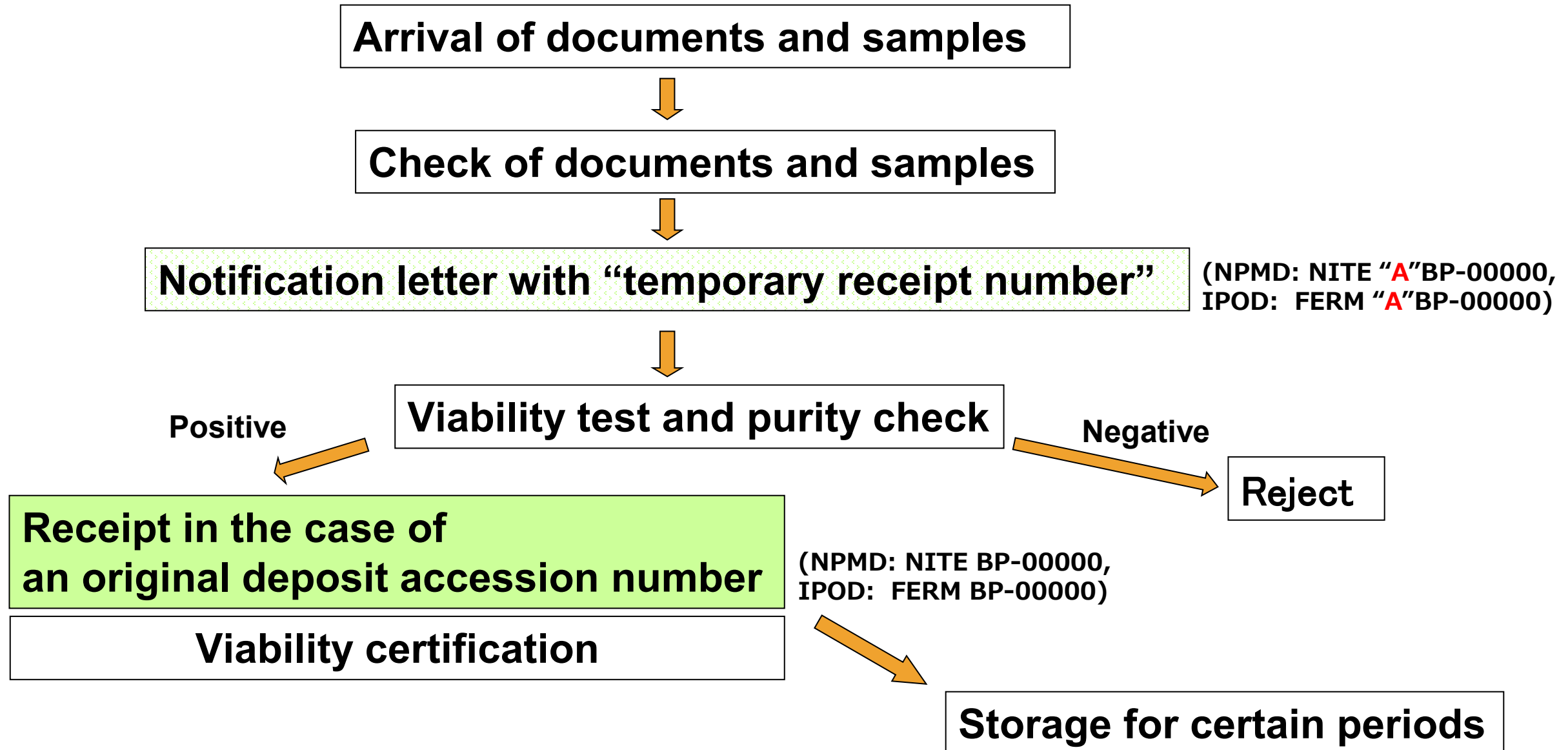
^{*1} An additional charge of 4,730 JPY will be charged for orders paid from outside Japan.

^{*2} An additional charge of 4,300 JPY will be charged for orders paid from outside Japan.

Kind, Amount, and Storage Forms of Samples

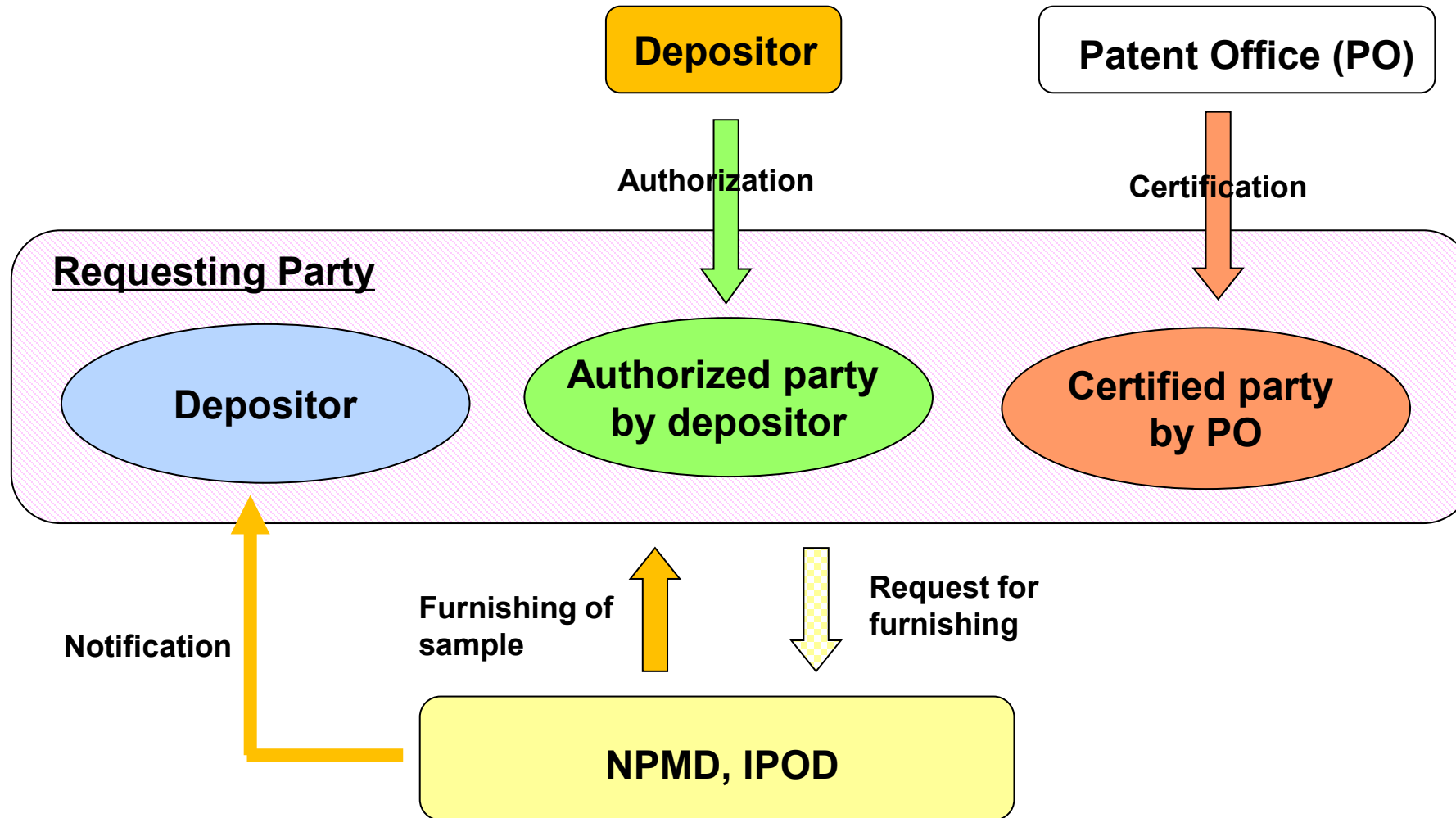
Kinds	Forms	Amount
Bacteria, Actinomycetes, Archaea, Yeasts, Fungi, Bacteriophages	L-dried, lyophilized, frozen, or active culture	10 ampoules or tubes
Plasmids	dried or frozen	10 tubes
Animal Cell Culture	frozen	12 tubes
Embryos	frozen	12 tubes (12 embryos constitute one tube)
Plant Cell Culture	frozen or active culture	10 tubes in frozen, 5 strains in active culture
Protozoa	frozen or active culture	10 tubes in frozen, 5 strains in active culture
Algae	frozen or active culture	10 tubes in frozen, 5 strains in active culture
seed	dried	100 package (2500 seeds) (25 seeds in one package)

Depository Procedure



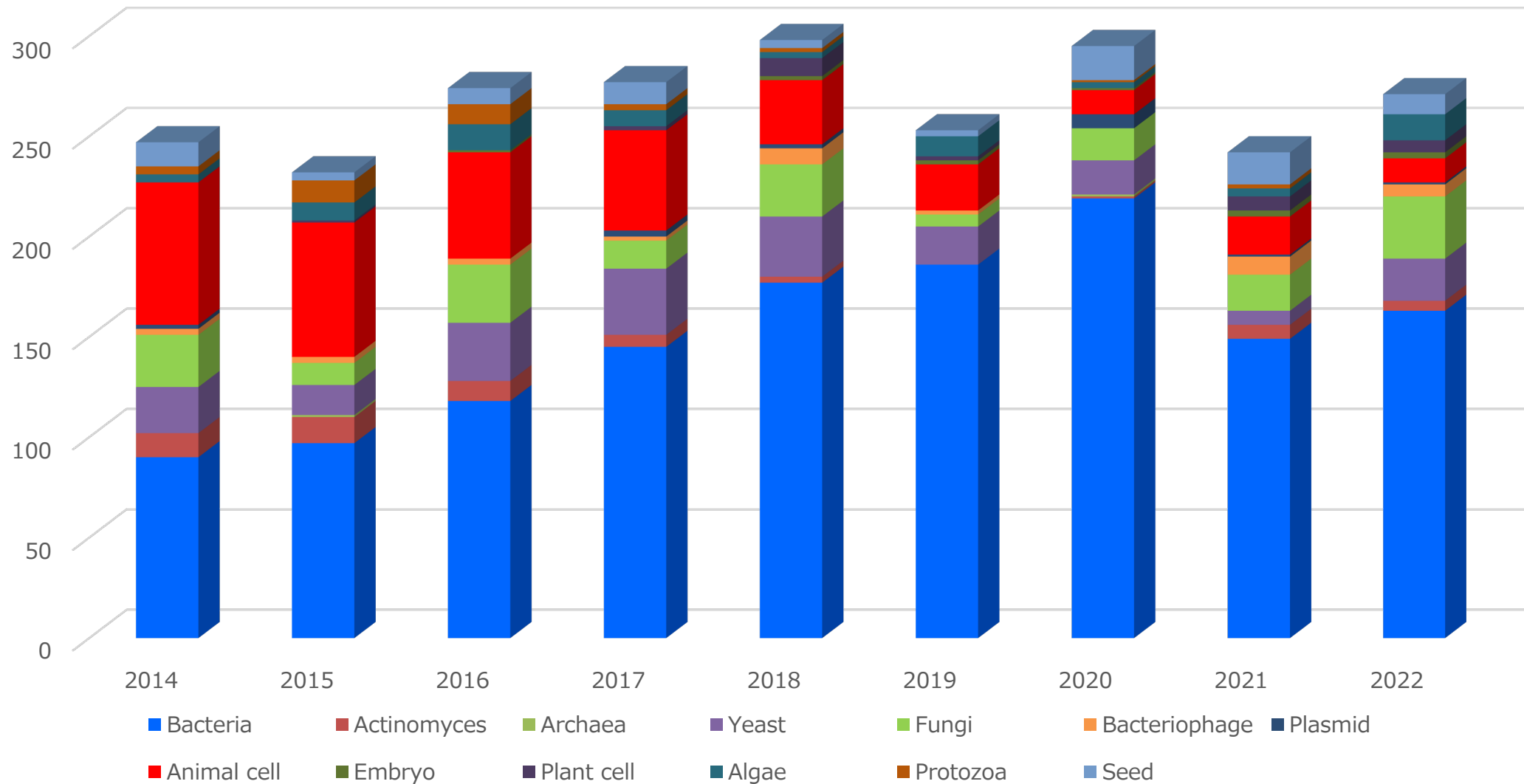
Furnishing Procedure for patent microorganism

Patent microorganisms are distributed to those who want to confirm and test the inventions.

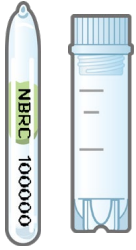


Withdrawal of samples from LN₂ tank

Changing trend in the number of deposited microorganisms



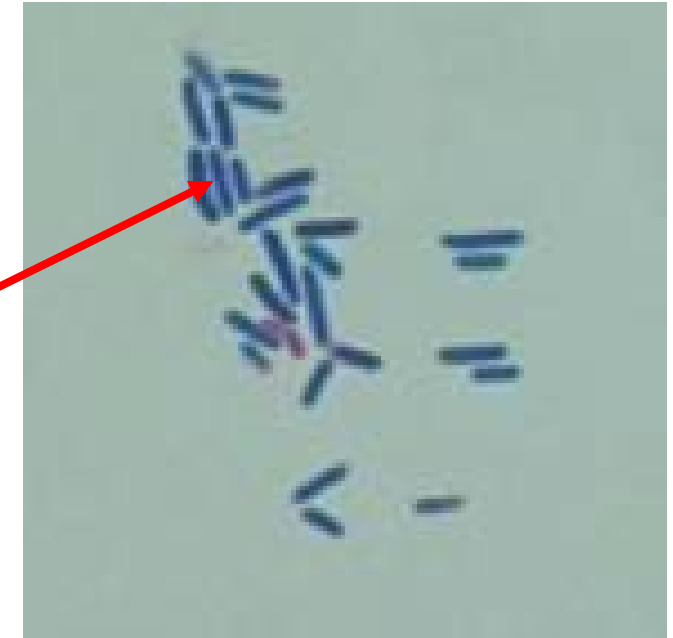
Viability Tests of microorganisms



◆ Measurement of colony forming units



◆ Morphological observation of colony by stereomicroscope



◆ Morphological observation of microorganism by microscope

Contamination Tests of microorganisms



◆ Detection of contamination by different culture methods

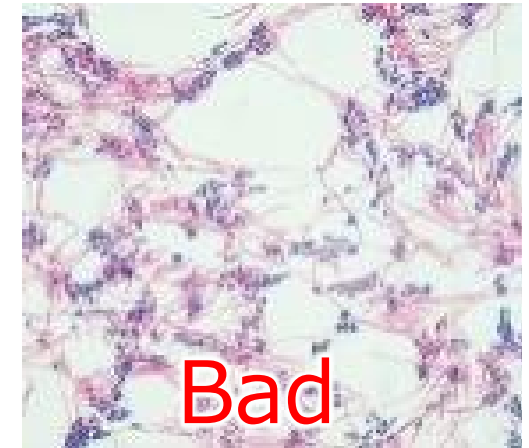
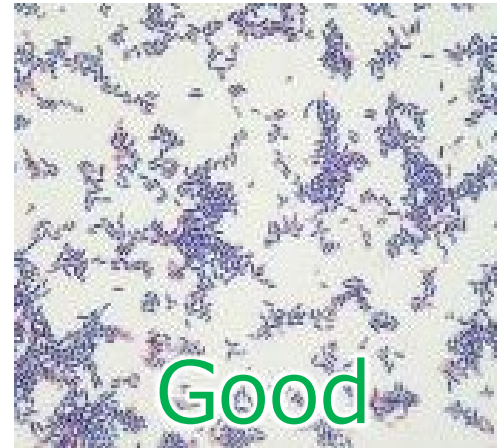


Anaerobic condition



Aerobic condition

◆ Gram staining of lactic acid bacteria



Blue:

Gram-positive bacteria (lactic acid bacteria)

Red:

Gram-negative bacteria (contamination)

Number of days required for viability test of each microorganism

Kinds	Number of days for test
Archaea, Bacteria	3 days
Bacteriophage, Yeasts	5 days
Actinomycetes, Fungi	7 days
Plasmids	1 days
Animal Cell Culture	21~28 days
Embryos	7 days
Algae, Plant Cell Culture, Protozoa	14~28 days
seed	21~28 days

Thank you for your listening!!



NITE Biological Resource Center
(NBRC)



Patent depository centers
(NPMD and NITE-IPOD)

