（株）食環境衛生研究所

略称/英文社名

（株）食環研/***Shokukanken Inc.***

Aug. 2023

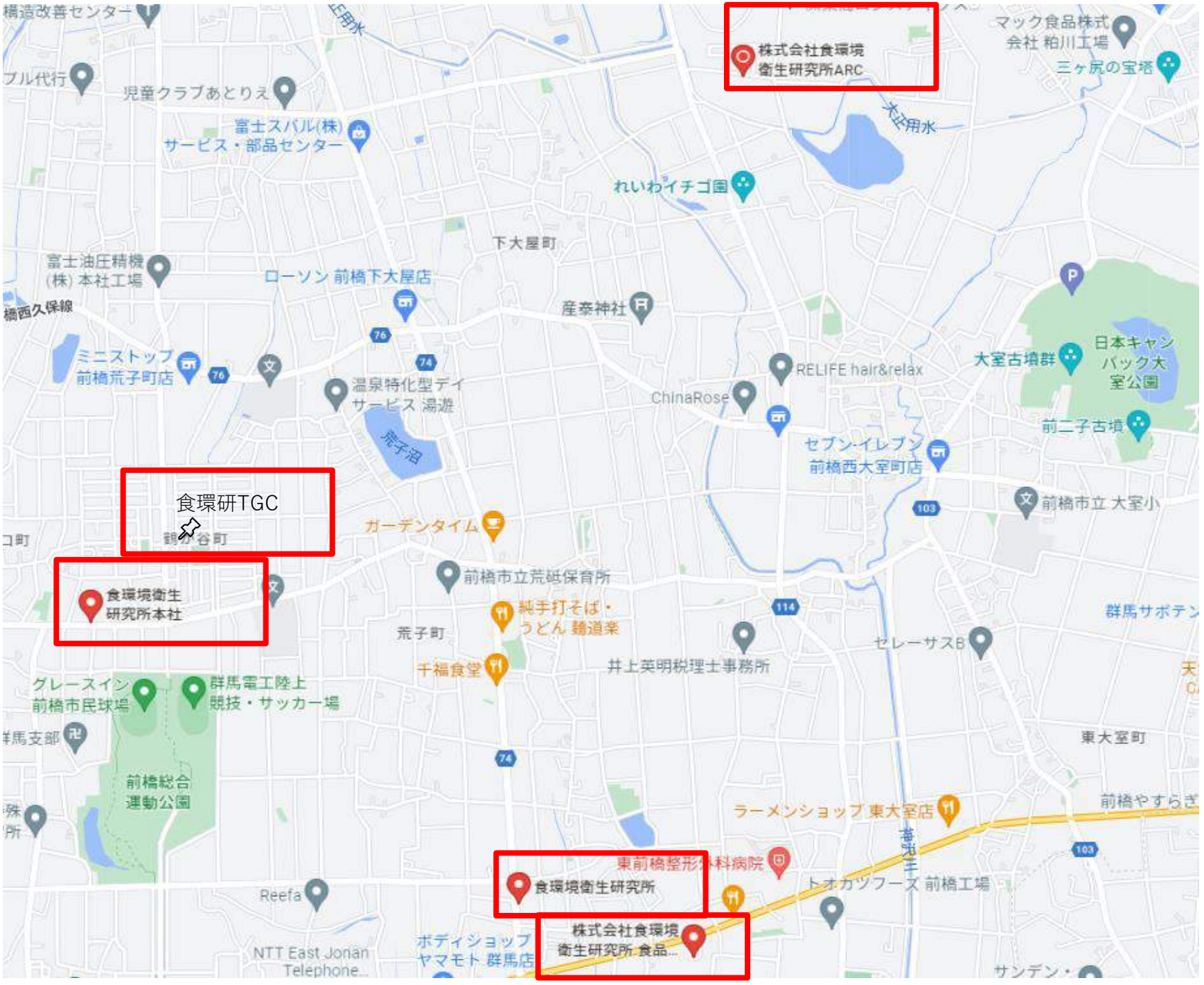
Profile

- President: Kazuhiro Kubo
- Capital: 10,000,000 yen
- Founding: July 21, 1998
- Number of employees: approx. 130
  (including 17 veterinarians)
- Locations:
  - Head office
  - Quality control center
  - Analysis center for food and drugs
  - Tokyo branch
  - Tohoku branch
  - West Japan branch
  - Animal research center
  - TGC Toxicity testing center

Management Philosophy

We contribute to the improvement of safety on the production and processing of foods, thereby realizing a social structure that can sustain human health and a favorable living environment.

Head office:
561-21 Arakuchi-machi, Maebashi, Gunma


株式会社食環境
衛生研究所ARC
食環研TGC
食環境衛生
研究所本社
食環境衛生研究所
株式会社食環境
衛生研究所 食品...
マック食品株式
会社 粕川工場
三ヶ尻の宝塔
大正用水
れいわイチゴ園
下大屋町
富士スバル(株)
サービス・部品センター
児童クラブあとりえ
富士油圧精機
(株) 本社工場
ローソン 前橋下大屋店
産泰神社
ミニストップ
前橋荒子町店
温泉特化型デイ
サービス 湯遊
荒子沼
RELIFE hair&relax
ChinaRose
大室古墳群
日本キャン
バック大
室公園
前二子古墳
セブン-イレブン
前橋西大室町店
前橋市立 大室小
ガーデンタイム
前橋市立荒砥保育所
純手打そば・
うどん 麺道楽
荒子町
千福食堂
井上英明税理士事務所
セレーサスB
群馬サボテン
グレースイン
前橋市民球場
群馬電工陸上
競技・サッカー場
前橋総合
運動公園
東大室町
ラーメンショップ 東大室店
前橋やすらぎ
東前橋整形外科病院
トオカツフーズ 前橋工場
Reefa
ボディショップ
ヤマモト 群馬店
NTT East Jonan
Telephone...
サンデン・
橋西久保線
76
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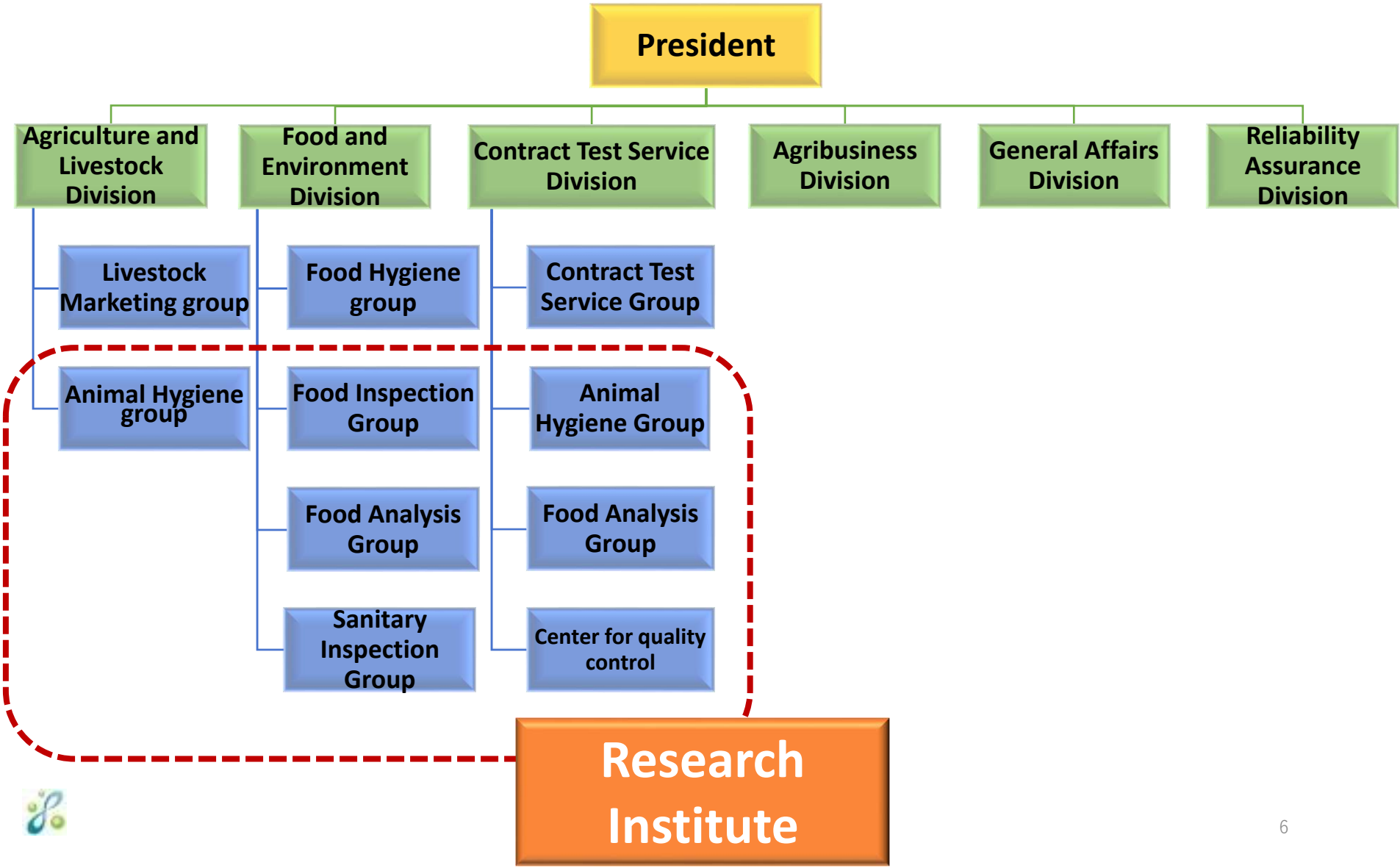
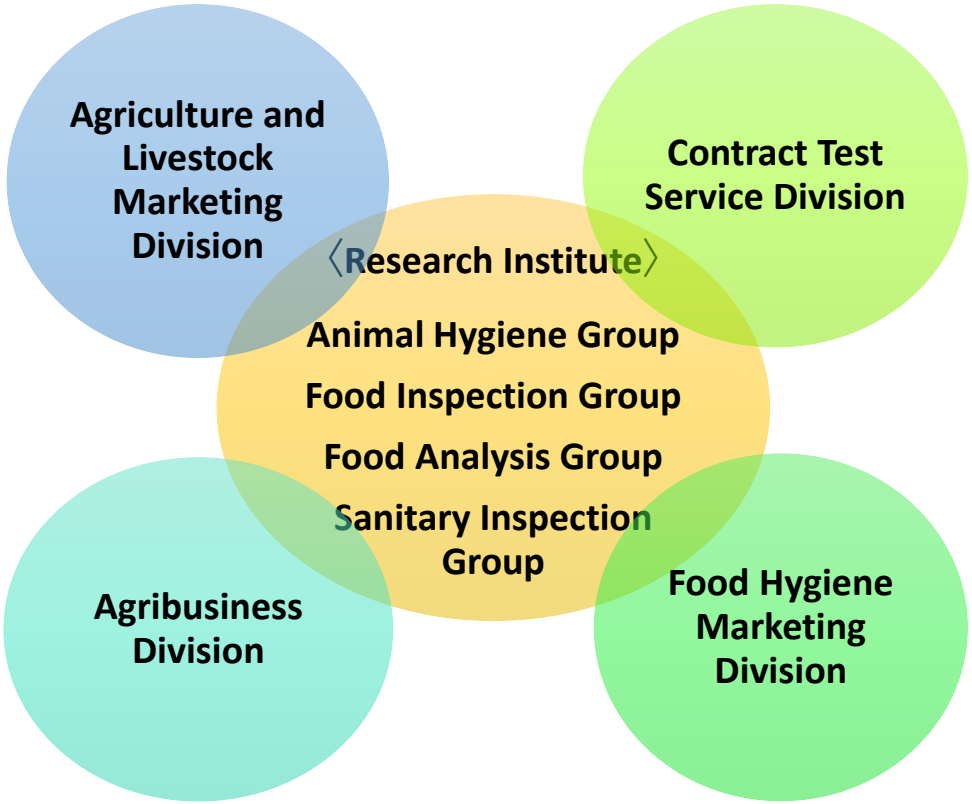
Organization

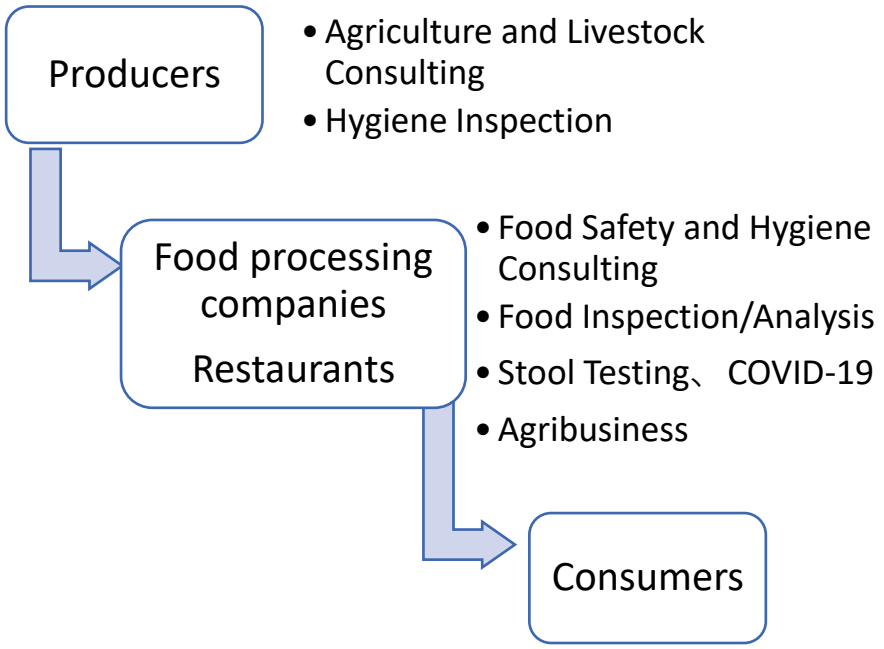


Organization

- Study/Examination Group
  - Agriculture/livestock exam, food/environment exam (micro-bacterial exam, genetic diagnosis, residue of pesticide, antibiotic analysis)
- Testing/Research Group
  - GLP, GCP and GPSP studies to get or maintain the approvals of veterinary medicine
- Livestock Marketing Group
  - Sales of feed additives and soil improvement agent
  - Consulting
- Food/Environmental Health Marketing Group
  - Hygiene control training of the restaurants based upon micro-bacterial exam
  - Consulting
- Agriculture Business Group
  - Management of entrusted farm land/vegetable farm based on the soil and pesticide residue exam

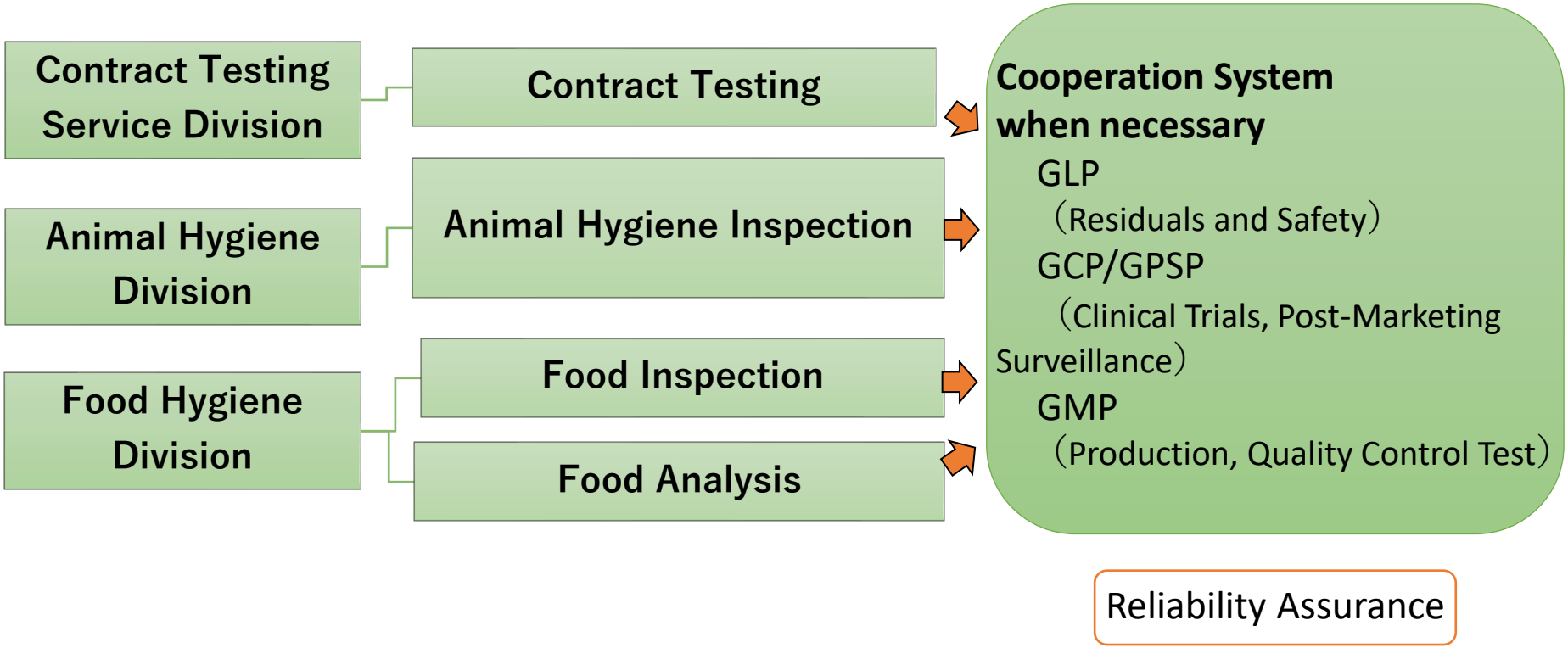
Area of Business





From food producers to consumers, we pursue a series of safety related to “FOOD"!

Testing System for Veterinary Drug Development



Reliability Assurance

Our Qualified Staff

- Pharmacists
- Veterinarians
- Clinical laboratory technicians
- Public health laboratory technicians
- Registered dietitian Nutritionists
- Nutritionists
- Experimental animal technicians
- Domestic animal artificial inseminationists
- Class I health supervisors
- Environment measurers (concentration)
- Class I working environment measurers
- Odor testers
- Class I water quality and pollution control managers
- Dioxins-related pollution control managers
- Asbestos work chiefs
- Asbestos diagnosticians
- Small business consultants

Study/Examination Group
総合研究所

食品分野
Food

- 検便検査　Examination of feces
- レジオネラ属検査　Detection of Legionella
- 一般栄養成分等分析　Examination of general nutrient component
- 香港栄養成分分析　Examination of nutrient component according to Hong Kong method
- 食品保存試験　Food preservation test
- 異物異臭検査　Examination for foreign particles and odor
- アレルギー物質検査　Detection of allergic substances
- ペットフード検査　Examination of pet foods
- 細菌・ウイルス検査　Bacterial and viral detection
- カビ毒分析　Analysis of fungal toxin
- 水質検査　Water examination
- 放射能検査　Examination for radioactivity
- 残留農薬分析　Analysis of residual pesticide
- 残留動物用医薬品分析　Analysis of residual veterinary drugs

畜産分野
Livestock

- 鶏 Chicken
  - 抗体検査 Antibody titration
  - 病性鑑定・細菌検査 Diagnosis (including bacterial detection)
  - 卵検査 (Egg examination)
- 豚 Swine
  - 抗体検査 Antibody titration
  - 病性鑑定・細菌検査 Diagnosis (including bacterial detection)
  - 豚品種識別検査 Examination of swine breed identification
- 牛 Bovine
  - 抗体検査 Antibody titration
  - 病性鑑定・細菌検査 Diagnosis (including bacterial detection)
- その他 Other
  - 畜産環境 Environment
  - 飼料分析 Analysis of feed
  - 肥料分析 Analysis of fertilizer
  - 肉質検査 Examination of carnosity

Animal Research Center
– Animal Hygiene group –

Animal Research Center

－ Animal Hygiene group －

Certifications & Accreditations

- Approved academic research organization compliant with the Act on Domestic Animal Infectious Disease Control (MAFF)
- Authorized to handle live pathogenic organisms of communicable diseases subject to regulatory control (MAFF)
- Verified to have control measures in place against dissemination of GMOs for Type 2 usage
- Licensed to receive imported hatching eggs (AQS)

Animal Research Center

– Animal Hygiene group –

BSL-3 room

Animal Research Center

– Animal Hygiene group –

Serological testing

Bacterial testing

Viral testing

Microbial identification and antibiotic profiling

Parasite testing

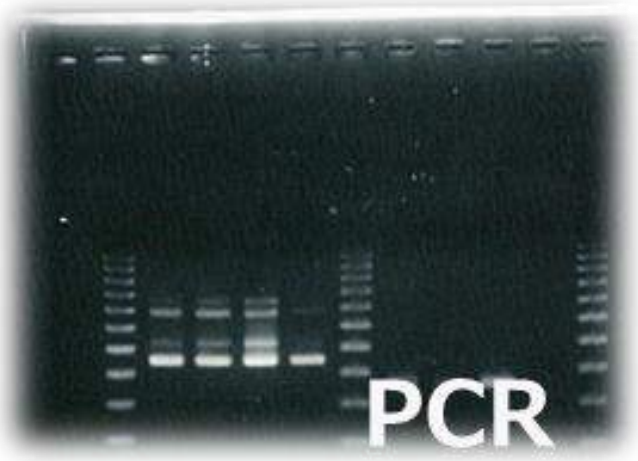
Pathological testing

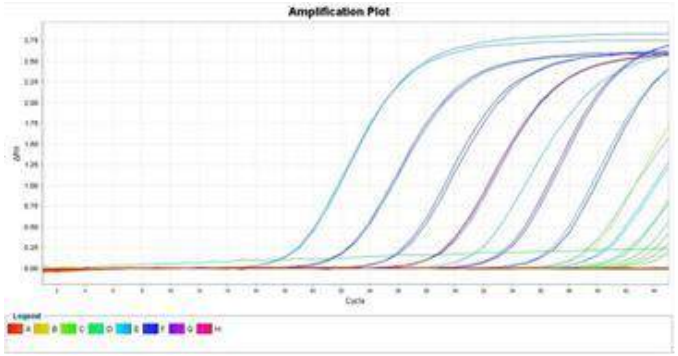
Animal Research Center

－ Animal Hygiene group －

解剖室

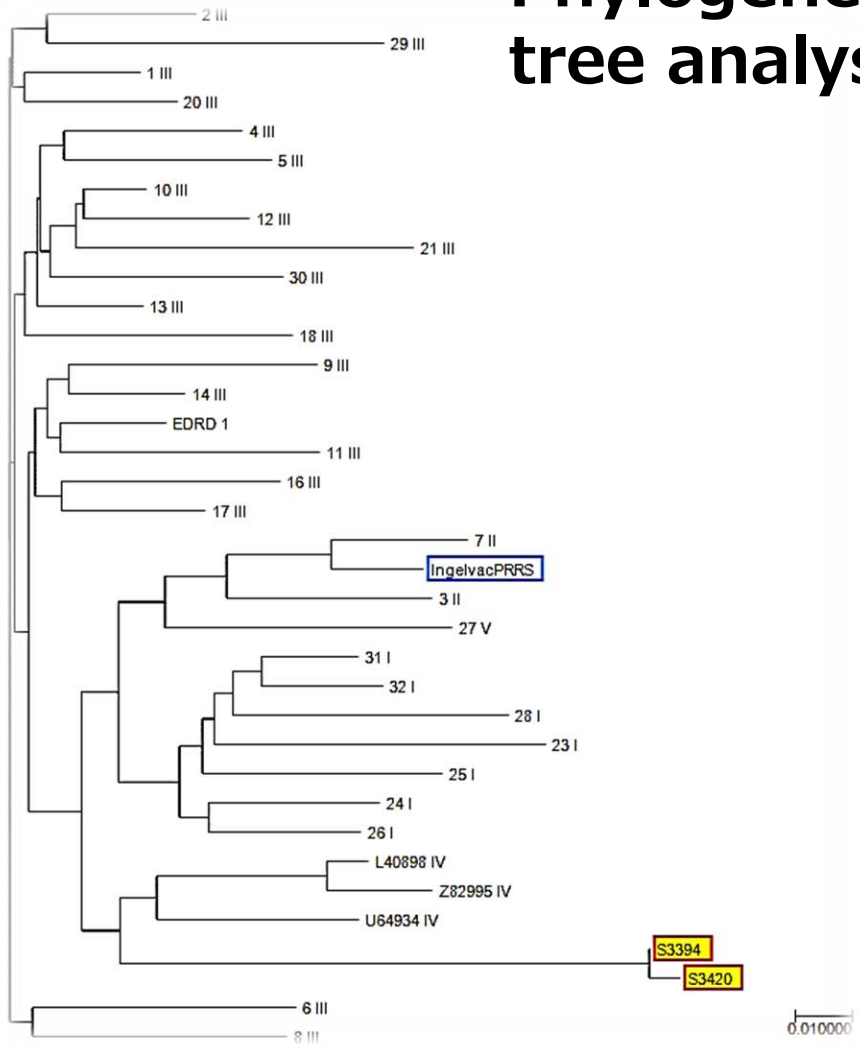
Antigen Detection by PCR





Realtime PCR

Phylogenetic tree analysis



Safety Evaluation Center

Analytical and Related Areas

Certifications & Accreditations

- ISO/IEC 17025
- Registered clinical laboratory
- Official measurement certification provider
- Examination organization of the voluntary food hygiene control certification program
- JGAP-approved agricultural chemical residue laboratory

Analytical Equipment

LC(Q)TOFMS

Amino Acid Analyzer

HPLC

Analytical Equipment

GC/MS

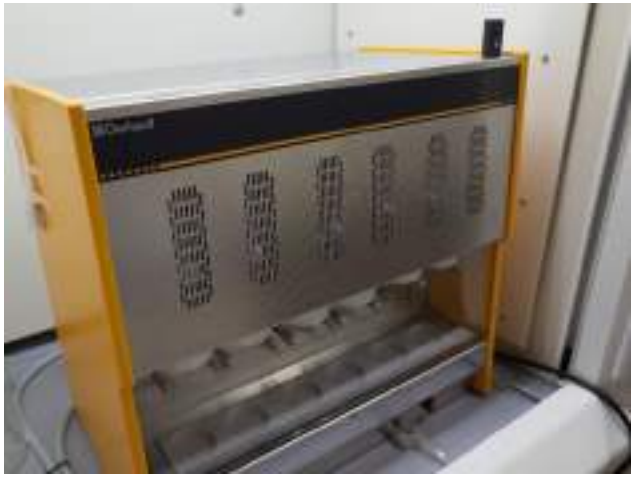
GC/MS/MS

LC/MS/MS

Analytical Equipment

ICP Luminescent Spectrophotometer (elemental analysis such as sodium)

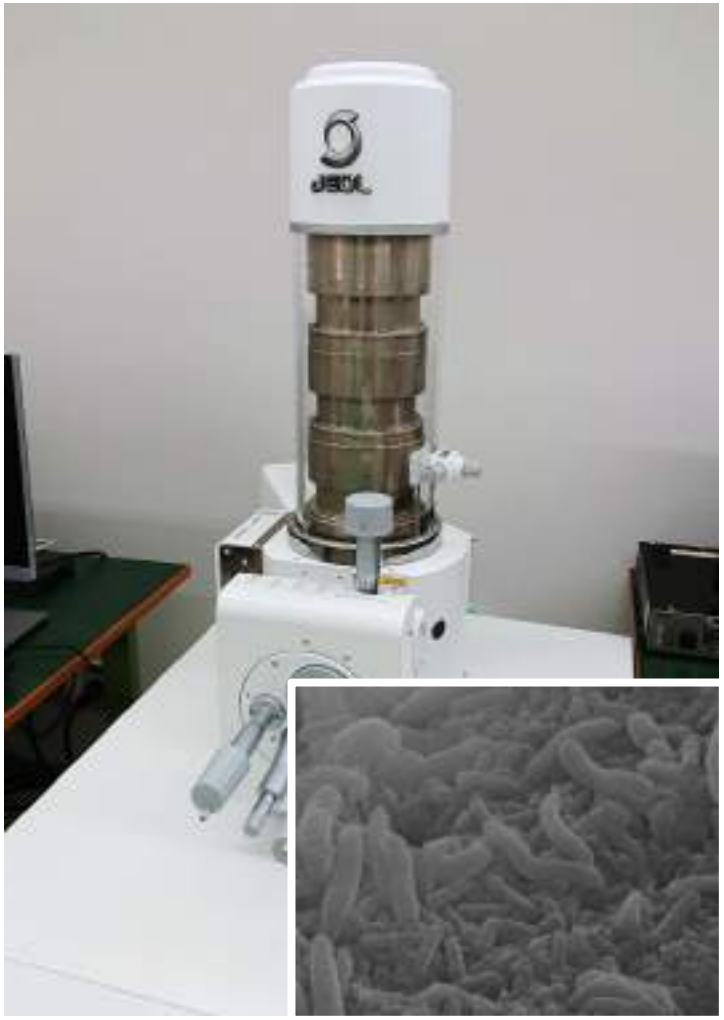
Kjeldahl distillation Device (for protein)



Fully automated Soxhlet Device (for lipids)

Analytical Equipment

Germanium-based Semiconductor Detector
(for radiation test)



Scanning Electron Microscope（SEM）

Testing/Research Group

受託試験部

- **General tests 一般受託試験**
  - Evaluation of anti-microbial activity
  - Identification of micro organisms
  - Challenge test using pathogens

  etc.

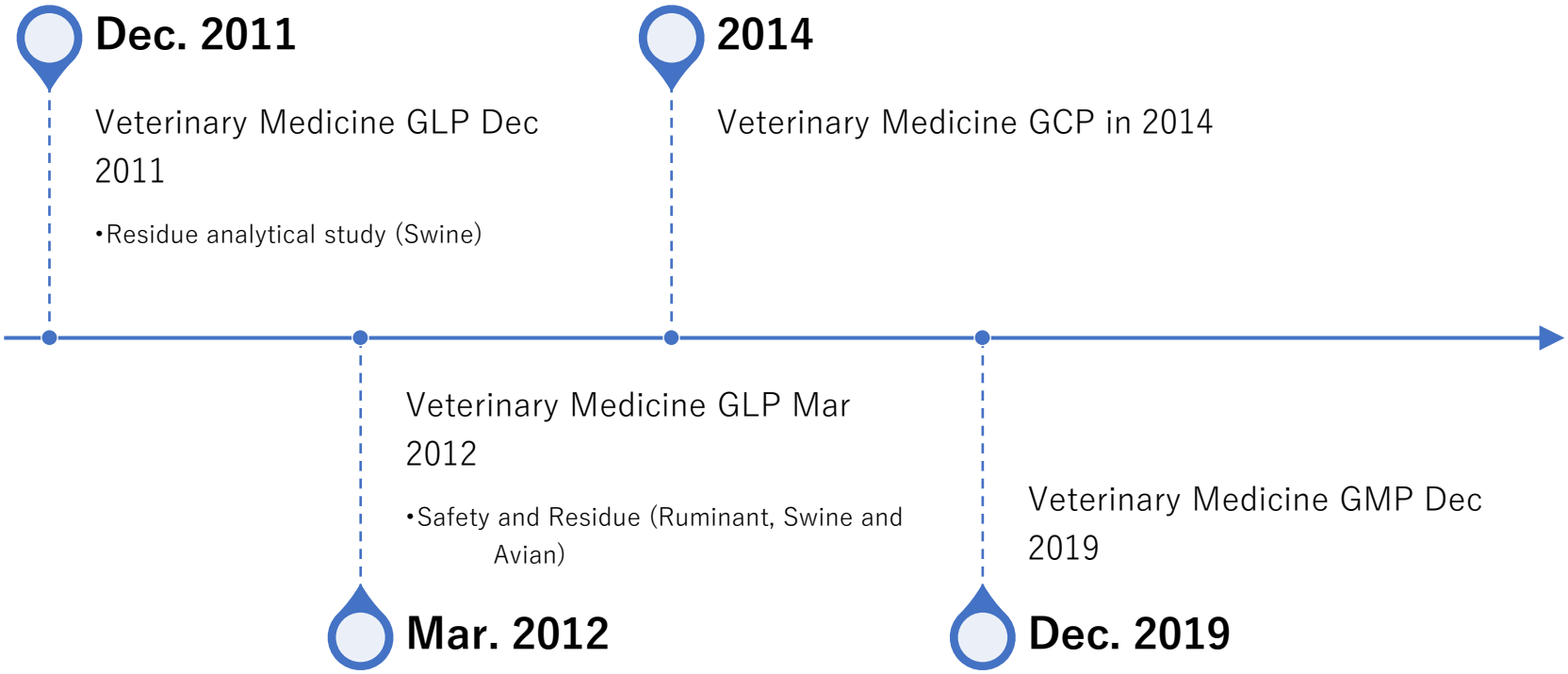
- **Studies according to GCP or GLP**
  動物用医薬品試験（GCP・GLP）

Whats we are

- Veterinary Pharmaceutical Consultation
- Clinical trials for animal drugs
- Quality control studies
- Specification testing
- Safety studies

As one of the few veterinary contract research organizations (CRO) in Japan, we are conducting a diverse range of preclinical and clinical researches every day. We also offer consulting services for clinical trials, regulatory requirements, and application and registration for all types of animal health products from pharmaceuticals, quasi-drugs, and medical devices to feed additives.

GLP/GCP/GMP License



Our Capabilities

- Consultation and support for animal drug application and registration
- Processes related to feed additive approval and listing
- Full evaluation of international product registration forms and dossiers
- Quality assurance auditing
- Gap analysis
- GCP studies (cattle, pigs, chickens, dogs, and cats)

GLP studies (cattle, pigs, chickens, dogs, cats, and fish)

1) Animal drug safety studies
2) Animal drug residue studies
3) Biological safety studies

Quality control studies for veterinary pharmaceuticals

1) Specification setting studies for drug substances
2) Stability studies
3) Safety studies
4) Potency/strength testing
5) Other quality-related studies

Post-marketing studies for veterinary pharmaceuticals

1） GPSP-related procedures (preparation of re-evaluation application documents and related support)
2) GPSP studies (efficacy and safety)

GMP services for veterinary pharmaceuticals (packaging, labeling, and classified storage)

Certifications & Accreditations
Veterinary Pharmaceuticals and Related Areas

・Animal drug GLP certification (MAFF)
・Feed additive GLP certification (MAFF)
・Animal drug GCP certification (MAFF)
・Approved academic research organization compliant with the Act on Domestic Animal Infectious Disease Control (MAFF)
・Authorized to handle live pathogenic organisms of communicable diseases subject to regulatory control (MAFF)
・Registered animal drug manufacturer and GMP facility (packaging, labeling, and classified storage)
・Verified to have control measures in place against dissemination of GMOs for Type 2 usage
・Accredited laboratory animal care facility compliant with animal welfare standards
・Licensed to receive imported hatching eggs (AQS)
・ISO/IEC 17025:2005

Activities Examination/Studies around animal health

- GLP/GCP/GMP studies for veterinary drugs
  - Tissue residue: 20/year
  - Target animal safety:5/year
  - Field trials: 10 – 20/year

- Others
  - Bacteria isolation and identification
  - Diagnosis of infectious disease
  - Antibody titration:
  - Quality control
    - Test for release
    - Stability
    - Basic study for setting up of specification and QC methods

Animal Facilities

@ head office

Animal facilities (2)

- **Animal facilities (3)**

Animal Health Support Center (AHSC)

Pigs

Cows

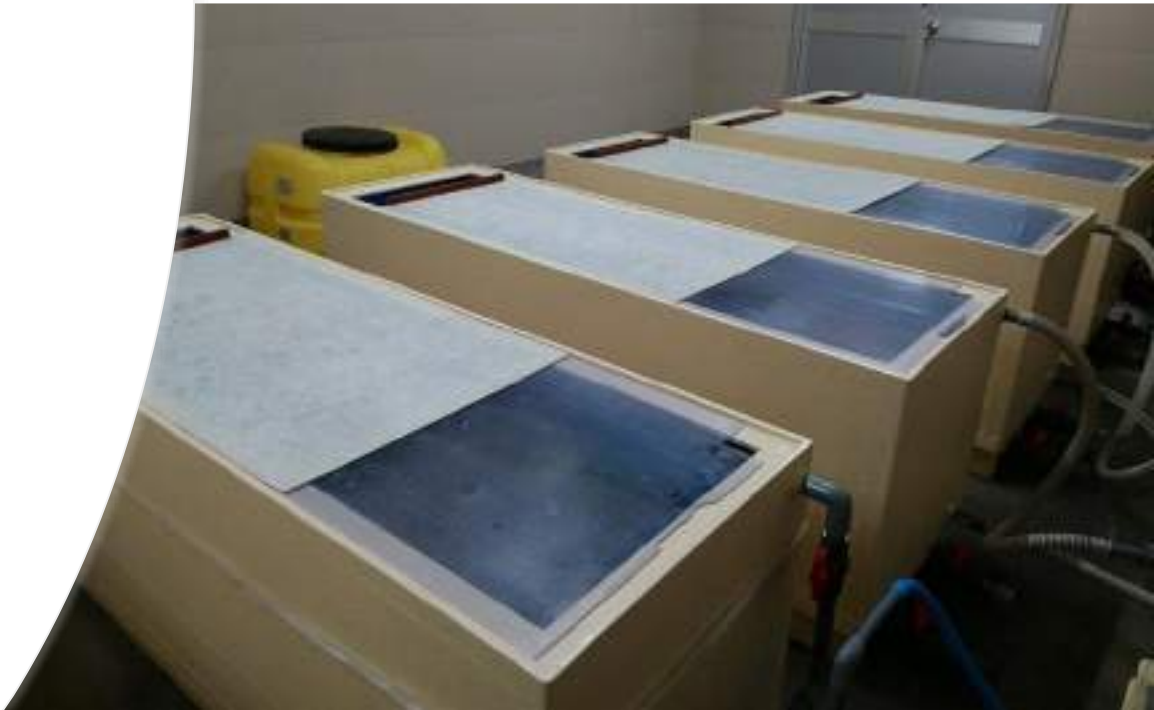
- **Animal Health Support Center (AHSC)**

Chickens

- **Animal Health Support Center (AHSC)**

Animal Health Support Center (AHSC)

- **Fish**



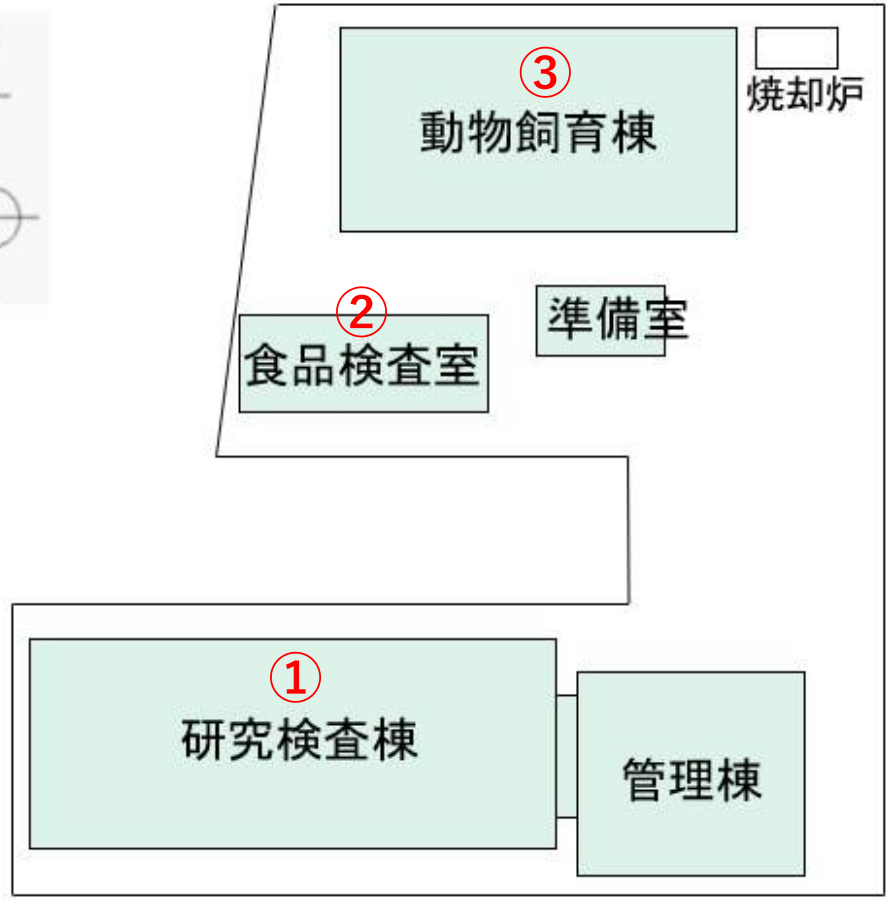
Consulting

Activities in Swine and Avian Fields

- Management consultant
  - Swine Farm: 200 (All prefecture except Okinawa)
  - Poultry Farm: 12 (Kanto and Tohoku area)

- Presentations and Publications (2011 to 2023)
  - 30 presentations:
    - Japanese Society of Veterinary Science
  - 2 publications:
    - Journal of the Japan Veterinary Medical Association
  - Serialize articles:
    - The pig magazine and Pig Journal

Other Facilities



本社見取り図

④ 品質管理センター

⑤ AHSC

Other Facilities(2)

Main customers in Animal Health

- Zoetis Japan
- Elanco Japan
- Virbac Japan
- Boehringer Ingelheim Vetmedica Japan
- MSD Animal Health
- Kyoritsu Seiyaku
- Ceva Japan
- Ab agri
- HIPRA JAPAN

- Scientific Feed Laboratory Co. Ltd.
- Nisseiken Co. Ltd.
- KM bio(Meiji Seika Pharma Co. Ltd.)
- ISHIHARA SANGYO KAISHA
- MITSUI & CO., LTD.

Chicken: Antibody titration

Disease	Abbreviation	Method
Mycoplasma gallisepticum infection	MG	RSA
		RSA
		HI
Mycoplasma synoviae infection	MS	RSA
		RSA
Newcastle disease	ND	HI
Infectious coryza serogroup A	IC-A	HI
Infectious coryza serogroup C	IC-C	HI
Egg drop syndrome-1976	EDS-76	HI
Infectious bronchitis	IB	ELISA
		AGP
Infectious laryngotracheitis	ILT	ELISA
Infectious brusal disease	IBD	ELISA
		AGP
Salmonella pullorum infection	SP	RSA
		AGP
Salmonella enteritidis infection	SE	ELISA
Avian encephalomyelitis	AE	ELISA
Avian influenza	AI	AGP
Turkey rhinotracheitis	TRT	NT
Leucocytozoonosis	Leuco	AGP

RSA: Rapid slide agglutination

HI: Hemagglutination Inhibition

ELISA: Enzyme-linked immunosorbent assay

AGP: Agarose gel precipitation

NT: Neutralization test

Chicken: Pathological Appraisal and Antigen Detection

Examination		Unit	Method	Remark
Salmonella characteristic		1 sample	According to Journal of The Japanese Society on Poultry Diseases, vol. 37 (1)	
Salmonella serotype detection		1 sample	According to Kauffmann–White scheme	After isolation of *Salmonella spp.*
Salmonella serotype detection (partial)		1 sample	According to Kauffmann–White scheme	*S. enterica serovar Enteritidis, S. enterica serovar Typhimurium, S. enterica serovar Infantis, S. enterica serovar Hadar*
Egg test–1		10 eggs (pooled)	According to Journal of The Japanese Society on Poultry Diseases, vol. 37 (1)	Egg content: *Salmonella* Egg shell: General bacteria population, coliform group, *Salmonella* Egg white and egg yolk: O–157
Egg test–2		10 eggs (pooled)	According to Journal of The Japanese Society on Poultry Diseases, vol. 37 (1)	Egg content: *Salmonella* Egg shell: General bacteria population, coliform group, *Salmonella*
		10 eggs		Haugh unit, color chart of egg yolk, egg weight
Parasites		1 sample	OPG count	Coccidosis etc.
Count of bacterial number		1 bacteria per sample		*E. coli, Staphylococcus aureus, Clostridium* etc.
Bacteria detection in organs		1 tissue	Stamp	*E. coli, Staphylococcus aureus, Clostridium, Salmonella* etc.
Bacteria count with intestinal contents or fece		1 bacteria per sample		*E. coli, Clostridium, Salmonella* etc.
Infectious coryza isolation		1 swab sample	Nasal swab	
Drug sensitivity test	Aerobic	1 bacteria	Disc	10 discs, at least
	Microaerophilic	2 bacteria	Disc	10 discs, at least
	Anaerobic	3 bacteria	Disc	10 discs, at least
Mycoplasma isolation		1 sample		Cost for 1 kind of pathogens (MG、MS, mainly)
Virus isolation		1 sample		Cost for 1 kind of pathogens (IB、ILT、POX、ND、TRT, mainly)
Detection by PCR		1 sample		Cost for 1 kind of pathogens (IB、ILT、ND、TRT、MG、MS、CAV, mainly)
Necropsy		5 chickens at most	Macro observation	Cost for disposal after necropsy

Swine: Antibody titration

Disease	Abbreviation	Method	Remark
Japanese encephalitis	JE	HI	
Swine parvovirus infection	PPV	HI	
Getah virus infection	Getah	HI	
Leptospirosis	Lepto	GA	*L. canicola, L. icterohaemorrhagiae, L. hardjo, L. pomona, L. grippo-typhosa, L. bratislava*
Toxoplasmosis	Toxo	Latex	
Influenza (H1N1)	IF(H1N1)	HI	
Influenza (H3N2)	IF(H3N2)	HI	
Transmissible gastroenteritis	TGE	NT	
Porcine pluropneumonia	App1	CF	
	App2	CF	
	App5	CF	
Bordetella bronchiseptica infection	Bord	AG	
Aujeszky disease	AD	NT	
		Latex	
		g1-ELISA	Detection of antibody against field strain (g1+)
Glasser's disease	Hps	CF	
Swine erysipelas	SE	WP	
Arcanobacterium pyogenes infection	AP	AGP	
Porcine reproductive and respiratory syndrome	PRRS	ELISA	
Porcine epidemic diarrhea virus	PED	NT	
Swine enzootic pneumonia	SEP	CF	
		ELISA	
Pasteurella multocida infection	Pm(DNT)	ELISA	Antibody detection against darmonecrotic toxin
Lawsonia intracellularis infection	PPE	IFA	
		ELISA	
Circovirus type 2 infection	PCV2	ELISA	
Streptococcus suis type 2 infection	S.suis2	ELISA	
Salmonella infection	Sal	ELISA	

HI: Hemagglutination Inhibition
NT: Neutralization test
Latex: Latex agglutination
ELISA: Enzyme-linked immunosorbent assay
AG: Agglutination
CF: Compliment fixation
AGP: Agarose gel precipitation
GA: Growth agglutination
IFA: Immuno-fluorescent assay

Swine: Pathological Appraisal and Antigen Detection

Examination (Sampling organ)		Unit	Method	Remark
Atrophic rhinitis	Bacteria isolation	1 sample	Detection with nasal swab	*Bordetella bronchiseptica*
Organ of respiration	Bacteria isolation	1 sample	Swab or stamp	Hps App Pm
Blood and organs	Bacteria isolation	1 sample	Stamp	*Streptococcus spp., Erysipelothrix rhusiopathiae, Arcanobacterium pyogenes*
Intestinal content or feces	E. coli	1 sample	Smear culture	Vero toxin: Stx2e, ST, LT Fimbrial antigens: K88, K99, 987P, F18 Intimin
	Clostridium	1 sample	Smear culture	
	Salmonella spp.	1 sample	Smear culture	
	Salmonella identification	1 sample	According to Kauffmann-White scheme	
Skin	Bacteria isolation	1 sample	Sampling of skin	*Staphylococcus hyicus*
Bacteria isolation, others		1 bacteria per sample	Stamp	
Drug sensitivity test	Aerobic	1 bacteria	Disc	10 discs, at least
	Microaerophilic	1 bacteria	Disc	10 discs, at least
	Anaerobic	1 bacteria	Disc	10 discs, at least
MIC test		1 bacteria per sample	Method established by Japanese Society of Antimicrobials for Animals	
Parasites	Intestinal content or feces	1 sample	OPG, microscopic observation	Whipworm, nematode, Eimeria, Balantidium, trichomonad etc.
	Intestinal mucosa	1 sample	Microscopic observation after Giemsa staining	Isospora
Rotavirus		1 sample	Latex agglutination test	
Mange		1 sample	Microscopic observation after alkali treatment	
Brachyspira hyodysenteriae		1 sample	Microscopic observation	
Influenza A or B		1 sample	Detection by diagnosis kit	
Isolation of swine acid-fast microorganism		1 sample	Culture and PCR	
Mycoplasma	Bacteria isolation	1 bacteria per sample	Culture	
	Detection by PCR	1 bacteria per sample	PCR	*M. hyopneumoniae M. hyorhinis*
Virus isolation		1 virus per sample		IF、TGE、AD、PED
Detection by PCR		1 antigen per samp		PRRS、PCV2、TGE、PED、JE、PPV、AD、PPE、IF、Lepto、Pm (DNT)、*M. hyopneumonia*e、*M. hyorhini*s、MAC
PCV2—subtyping by PCR		1 sample	PCR using 3 pairs of primers	Group 1 or 2
PCV2-quantitive PCR test		1 sample	Q-PCR	
PRRS-quantitative PCR test		1 sample	Q-PCR	
E. coli Toxic factor detection		1 sample	PCR	Stx2e, ST, LT
E. coli adherent factor detection		1 sample	PCR	K88, K99, 987P, F18, Intimin
Necropsy		1 pig	Macro observation	Cost for disposal after necropsy

Bovine: Antibody Titration

Disease	Abbreviation	Method	Remark
Parainfluenza type 3	PI3	NT	
Adenovirus type 7	AD7	HI	
Bovine leukemia	BL	AGP	
Bovine RS virus disease	RS	NT	
Bovine rhinotracheitis	IBR	NT	
Bovine viral diarrhea-mucosal disease	BVD/MD	NT	
Leptospirosis	Lepto	GA	*L. canicola, L. icterohaemorrhagiae, L. hardjo, L. pomona, L. grippo-typhosa, L. autumnalis, L. australis*

HI: Hemagglutination Inhibition
NT: Neutralization test
ELISA: Enzyme-linked immunosorbent assay
GA: Growth agglutination
AGP: Agarose gel precipitation

Bovine: Pathological Appraisal and Antigen Detection

Examination (Sampling organ)		Unit	Method	Remark
Nasal swab or organs	Bacteria isolation	1 sample	Swab, stamp	*Histophilus somni* *Mannheimia haemolytica* *Pasteurella multocida*
keratoconjunctival epitherium	Bacteria isolation	1 sample	Swab	*Moraxella bovis*
Intestinal content or feces	E.coli	1 sample	Smear culture	Vero toxin, fimbrial antigens (K99)
	Clost	1 sample	Smear culture	
	Salmonella isolation	1 sample	Smear culture	
	Salmonella identifica	1 sample	According to Kauffmann-White	
	Rotavirus detection	1 sample	Latex	
Mastitis	① Bacteria (rapid identification)	1 sample	Smear culture	Rapid test targeted Staphylococcus, Streptococcus, E. coli and coliform group
	② Bacteria tests	1 sample	According to a method established by National Agricultural Insurance Association	
	Basic treatment			
	Staphylococcus			*S. aureus*, CNS
	Streptococcus			Streptococcus agalactiae, Non-agalactiae Streptococcus
	Coliform group			E. coli, coliform group
	Pseudomonas aeruginosa, Pasteurella			Identification of oxidase-positive Gram (-) rods
	Arcanobacterium			Gram(+) rods (non-sporeforming, hemolytic, catalase-negative)
	Corynebacterium			Gram (+) rods (non-sporeforming, non-hemolytic, catalase-positive)
	Clostridium			Gram (+) rods (sporeforming, anaerobic)
	Bacillus			Gram (+) rods (sporeforming, aerobic)
	Somatic cell count	1 sample	Direct macroscopic SSC	Rapid test for mastitis
	Bacteria count	1 sample		
Abortion	Brucella isolation	1 sample	Smear culture	*Brucella abortus*
	Campylobacter isolation	1 sample	Smear culture	*Campylobacter fetus*
Necrobacillosis	Bacteria isolation	1 sample	Smear culture	*Fusobacterium necrophorum*
Drug sensitivity test	Aerobic	1 bacteria	Disc	10 discs, at least
	Microaerophilic	1 bacteria	Disc	10 discs, at least
	Anaerobic	1 bacteria	Disc	10 discs, at least
	Bacteria causing mastitis	1 bacteria	Disc	10 discs, at least, selecting specific for mastitis treatment
Parasites	Coccidium egg	1 sample	OPG count	
	Nematode egg, Coccidium egg	1 sample	Wisconsin method modified	
	Lungworm egg	1 sample	Emigration method	
	Nematode egg identi	1 sample	Identification after culture	
	Trematode egg	1 sample	Beads method	
Mycoplasma detection		1 sample per bacteria		*M. bovirhinis* *M. bovis* *M. disper* *M. bovigenitalium* *U. diversum*
PCR検査		1 sample per bacteria		BVDV、BAV、RSV、PI3、IBR
Necropsy		1 animal	Macro observation	Excluding cost for disposal after necropsy