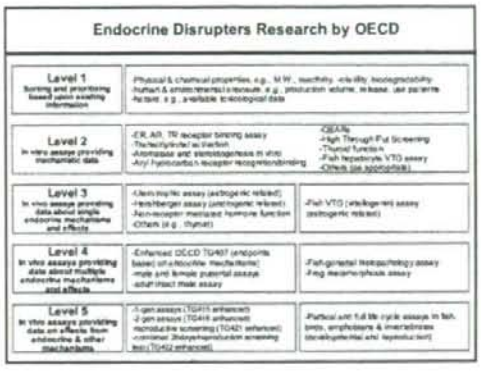
	ER-CALUX. T47 D (human breast cancer) cells with endogenous ERα + luciferase stably transfected	ag/antag	Validation in 2008, presentation of data in 1st quarter of 2009.	EC/ECVAM
	LUMI cell, BG1 cells with endogenous ERα + luciferase stably transfected (XDS Inc)	ag/antag	SPSF submitted. Peer Review report in 3rd quarter 2009.	US lead international collaboration study
	Performance-Based TG for ERα Concrete proposal to be discussed by VMG-NA7 and submitted to WNT22.			
	Retrospective validation of in vitro ER TA (T47D-KBluc) and AR TA (MDK-kb2) assays EPA's Office of Research and Development (ORD) developed the Estrogen Receptor Transcriptional Aactivation Assay (ER TA) using the T47D-KBluc cell line and the Androgen Receptor Transcriptional Activation Assay (AR TA) using the MDK-kb2 cell line. EPA is currently investigating whether it is possible to conduct a retrospective validation of these assays or the extent to which additional validation studies are necessary. EPA is compiling information on assay performance information from various laboratories.			
ERβ	HeLa, hERß/pcDNA3.1, ERE-AUG-Luc+	Transient, ag	Completed data collection for 250 compounds	CERI/MHLW
AR	CV-1 cells hAR/pcDNA3.1 receptor expressing plasmid and ARE-AUG-Luc+ reporter plasmid	Transient, ag/antag	Pre-validated and validated in Japan in 4 labs, with 5 chemicals. Should be considered for (preliminary) Peer review.	CERI/MHLW
	AR-Ecoscreen™ stable CHO clone	Stable, ag/antag	Validation report available in March 2008. SPSF submitted.	CERI/MHLW
	PALM. PC-3 (prostate adenocarcinoma) cells stably transfected with hAR and luciferase reporter gene	ag/antag	Validation in 2008.	EC/ECVAM
	CALUX. U2-OS (bone cell) cells stably transfected with hAR and luciferase reporter construct	ag/antag	Validation in 2008.	EC/ECVAM
	Chimpanzee recombinant AR binding assay. The US EPA developed a chimpanzee recombinant androgen receptor construct for production of recombinant AR protein using a baculoviral vector system. The US EPA developed a binding assay protocol for 96-well plate format to accompany the recombinant AR protein. The protocol was optimized at the US EPA and will be tested for protocol transferability using the recombinant chimp AR protein in one contract laboratory during winter/spring 2009			
TRβ	RXR co-transfected CHO cells are used	Transient, ag/antag	Under development, 150 chemicals tested so far.	MHLW

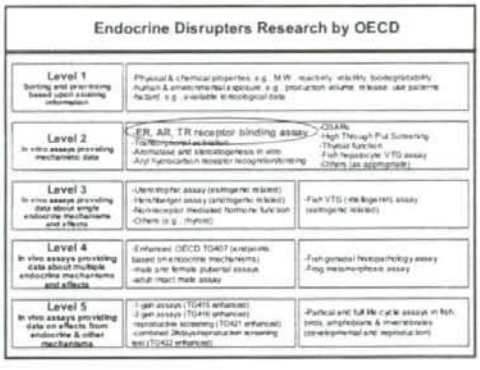
Aromatase & Steroidogenesis Assays				
	Microsomal aromatase assay, KGN cells		Validated, and the peer review report completed 12 January 2008.	
	H295R cell-based Steroidogenesis assay		Validation and peer review schedulled by 2nd quesrter 2009. SPSF submitted.	US lead international collaboration study

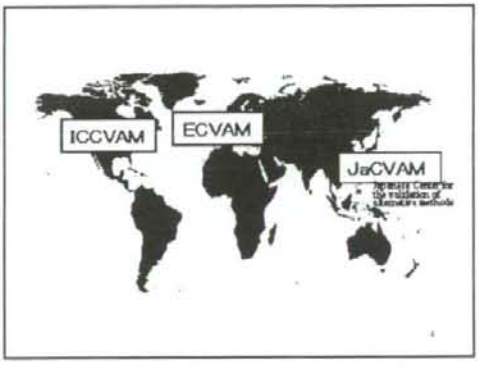
Update on Japanese activities

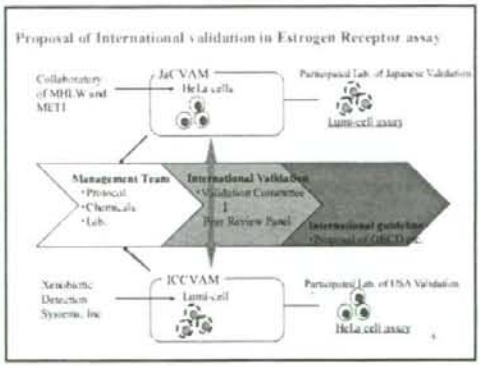
Introduction

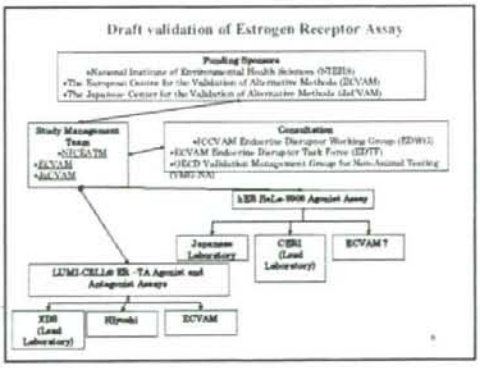
Hajime Kojima, Ph.D.,
Japanese Center for the Validation of Alternative Methods (JaCVAM)
National Institutes of Health Sciences (NIHS), WHLW, Japan











Brief Summary of Validation for Reporter Gene Assay using hER-HeLa-9903 Cell Line to Detect Estrogenic Activity

OECD

Transcriptional Activation (STTA) Assay and Technical Issues to be Addressed by the VMG-NA 5

The PRP identified some areas where the eight validation criteria where not completely met and additional information should be provided. These included:

1. Criteria for positive responses were unclear and needs to be further elaborated;
2. Guidance on the criteria for acceptable test performance was insufficient, and,
3. The STTA assay can at this point only be used for estrogen agonist testing and further studies would be needed if also estrogen antagonists could be tested.

Further work for multi-lab validation

- **Setting up the performance criteria**
- **Revision of SOPs**
- **Correcting data listed in ICCVAM report (especially negatives)**
- **Submission of SPSF to OECD**
- **Confirmation of reproducibility using changed plate format.**

LUMICELL® ER TA International Validation Study: Study Management Team and Participating Labs

Study Management Team:

- NICEATM
  - William S. Stokes, D.V.M., D.A.C.L.A.M. (NIEHS) Director, Project Officer
  - Raymond Tice, Ph.D. (NIEHS) Deputy Director
  - Frank Deal (ILS, Inc.) Project Coordinator
  - Patricia Cegar (ILS, Inc.) Asst. Project Coordinator
  - David Allen, Ph.D. (ILS, Inc.) Principal Investigator
- ECVAM
  - Thomas Hartung, Ph.D.
  - Miriam Jacobs, Ph.D.
  - Susanne Bremer, Ph.D.
- JaCVAM
  - Dr. Hajime Kojima
  - Dr. Atsushi Ono

Participating Laboratories:

- Xenobiotic Detection Systems, Inc. (Lead Laboratory), Durham, North Carolina, U.S.
- ECVAM internal laboratory, Ispra, Italy
- Hiyoshi Corporation, Omi Hachiman, Japan

Proposed Timeline for the LUMICELL® ER TA International Validation Study

TASK	ACTIVITIES	TIMELINE
Phase I	• Qualification/protocol refinement by testing reference standards and controls • Establish historical database for standards and controls by conducting independent experiments (16 each for the agonist and antagonist protocols) • Evaluate GLP compliance and QA/QC Procedures • Submission of draft report and review by SMT	Jul. 07 – Oct. 07
Phase IIa	• Four substances from ER mechanism list tested independently three times for agonism and antagonism (14 total experiments) (Phase IIa will be used for the evaluation of the new comprehensive plate layout using all 96 wells of the 96-well plate). • Evaluate GLP compliance and QA/QC Procedures • Submission of draft report and review by SMT	Oct. 07 – Nov. 07
Phase IIb	• Eight substances from ER mechanism list tested independently three times (24 total experiments) • Evaluate GLP compliance and QA/QC Procedures • Submission of draft report and review by SMT	Nov. 07 – Jan. 08
Phase III	• Remaining 41 substances from ER mechanism list tested once for agonism and antagonism (82 total experiments) • Evaluate GLP compliance and QA/QC Procedures • Submission of draft report and review by SMT	Jan. 08 – Mar. 08
Phase IV	• Testing of remaining 25 substances from ER list for agonism and antagonism (XDS only) (50 total experiments) • Evaluate GLP compliance and QA/QC Procedures • Submission of draft report and review by SMT	Apr. 08

Proposed Timeline for the LUMICELL® ER TA International Validation Study

TASK	ACTIVITIES	TIMELINE
Phase I	• Qualification/protocol refinement by testing reference standards and controls • Establish historical database for standards and controls by conducting independent experiments (16 each for the agonist and antagonist protocols) • Evaluate GLP compliance and QA/QC Procedures • Submission of draft report and review by SMT	Jul. 07 – Oct. 07
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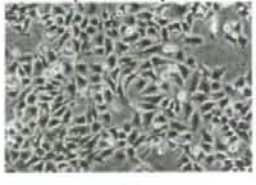
International validation study of ERα STTA antagonist assay using HeLa9930.

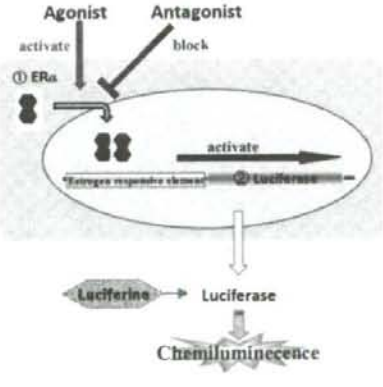
National Institute of Health Sciences(NIHS), MHLW, JP
CERI Chemicals Evaluation and Research Institute(CERI), METI, JP

6th VMG-NA
19-21, Nov. 2008
OECD Headquarters, Paris

ERα STTA assay using HeLa9903

hERα-HeLa-9903
(HeLa9903)





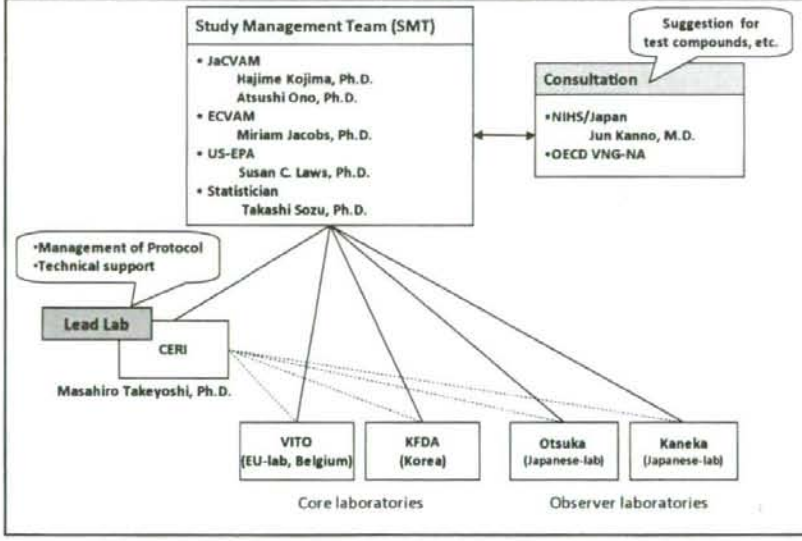
- Developed by Sumitomo Chemical Co.
- Host Cell: HeLa cell line (human cervical tumor cells)
- Inserted construct:
  - ① Human ERα expression vector (full-length)
  - ② Firefly luciferase reporter construct bearing five tandem repeats of a vitellogenin estrogen-responsive element (ERE) driven by a mouse metallothionein promoter TATA element
- Expression of other nuclear receptor
  No functional ERα, ERβ, AR, TRα and TRβ in host cell
- Available from JCRB (NIBIO)

ERα STTA assay using HeLa9903

Draft test guideline for "*the Stably Transfected Human Estrogen Receptor Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals*", was presented to the WNT20 in April 2008 for approval.

Comment by Peer Review Panel (PRP) included:
The STTA assay can at this point only be used for estrogen agonist testing and further studies would be needed if also **estrogen antagonists** could be tested.

Validation Organization



Study Design and Schedule

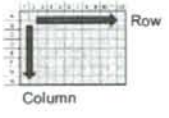
Tasks	Purpose	Note	Schedule
Start chemical distribution from JaCVAM.			**2008.5 ~**
Start cell culturing at each lab and prepare cell stocks.			**2008.6 ~**
Task-1	**Confirm the edge effects (establish the plate layout)**	**no edge effects→ use 96-well edge effects are expected →not use edge wells**	Data should be submitted until the end of 2008.6.[#1] **All data was submitted at 2008.10.**
	Confirm if the test system is properly setup and the participating lab can provide the basic assay performance.	**Test un-coded 3-4 chemicals in "Agonist" Assay.**	
Task-2	**Confirm lab performance for "Antagonist" (ATG) assay (including range finding test, cytotoxicity (cytotox.) test)**	**Test un-coded 4 chemicals in "Antagonist" Assay.**	Data should be submitted until the Mid. of 2008.9. [#1] ***Now ongoing!***
Task-3	**Test coded chemicals**	**•Test "anti-estrogenic" activities of coded 12 chemicals.**	Data should be submitted until the end of 2008.12. [#1]

[#1] Original schedule

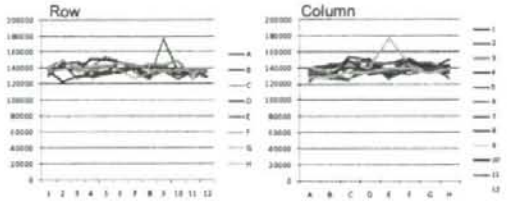
5

[Task-1] Edge effects

1. Expose 1 nM of E2 to all wells in a 96-well plate
2. Check if the value of coefficient of variation (CV) value among all wells of luminescence intensity is less than 10%.



Edge effects result of Lab #1



Edge effects result of all participant laboratory

	#1	#2	#3	#4	#5
AVG	138496.3	7.604556	5977.635	391838.9	127916
SD	7789.0	0.5	519.1	24460.2	10035.7
CV(%)	5.6	6.9	8.7	6.2	7.8

6

[Task-1] Procedure of ER agonist assay

[Assay Procedure]

Culture cells with 10% FBS-EMEM

Seeding cells at 1x10⁴/100 μL/wells in a 96-well plate

Incubate for 2-3 hours in CO_2 incubator at 37°C

Expose chemicals, vehicle control and positive controls to cells

●: Vehicle Control (VC)
●: 1 nM of E2

Incubate for 20-24 hours in CO2 incubator at 37°C

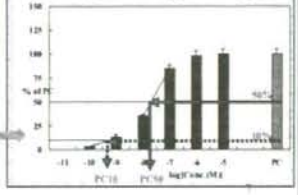
Measure luciferase activity

[Test Chemicals]

[Data Analysis]

Endpoints

- **PC10**
- **PC50**
- **EC50 (Hill's Equation)**



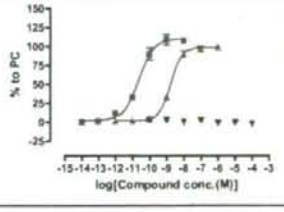
Task-1
[Quality Control and Performance Standard]

Quality Controls

Fold-induction of Positive Control (1 nM of E2) [=(AVG of PC)/(AVG of VC)]	>=4
10% fold-induction of 1 nM E2	> 1 ± 2SD of fold-induction of VC
CV of the raw data triplicates (i.e. luminescence intensity) of the data points that are used for the calculation of PC10	within 20%

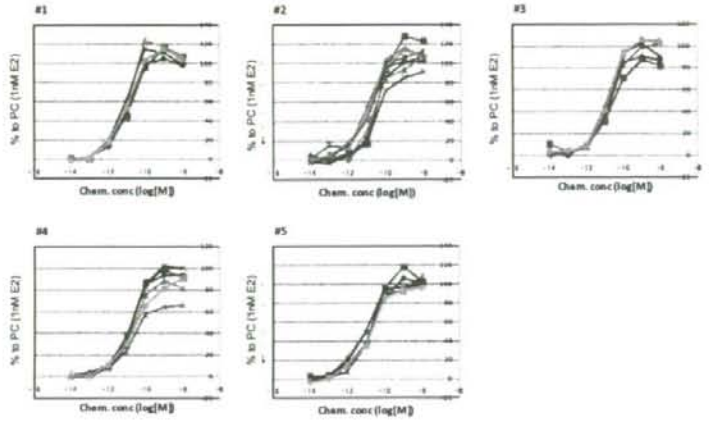
Performance Standard

	log [PC50 (M)]	log [PC10 (M)]	log [EC50 (M)]	Hill Slope
17beta-Estradiol	-11.4 ~ -10.1	<-11	-11.3 ~ -10.1	0.7 ~ 1.5
17alpha-Estradiol	-9.6 ~ -8.1	-10.7 ~ -9.3	-9.6 ~ -8.4	0.9 ~ 2.0
Corticosterone	-	-	-	-

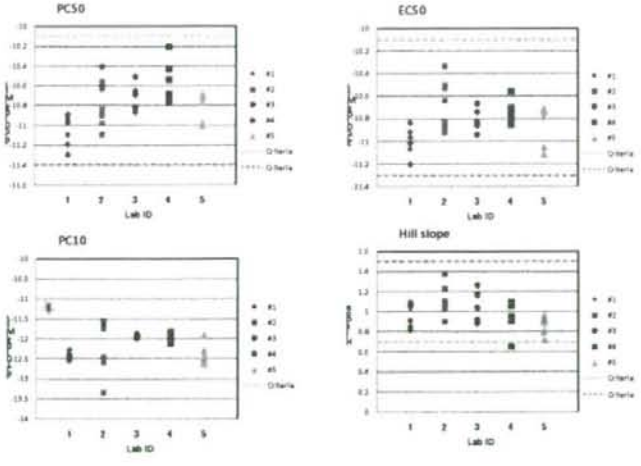


*QC and performance criteria is shown in the guideline for agonist assay.

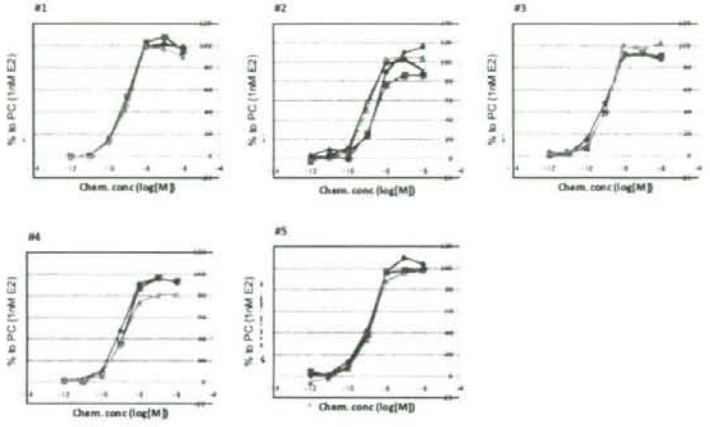
[Task-1] 17β-estradiol dose response



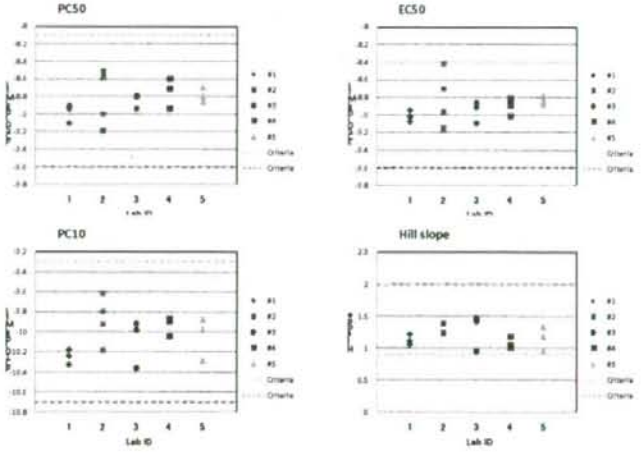
[Task-1] 17β-estradiol Performance standard



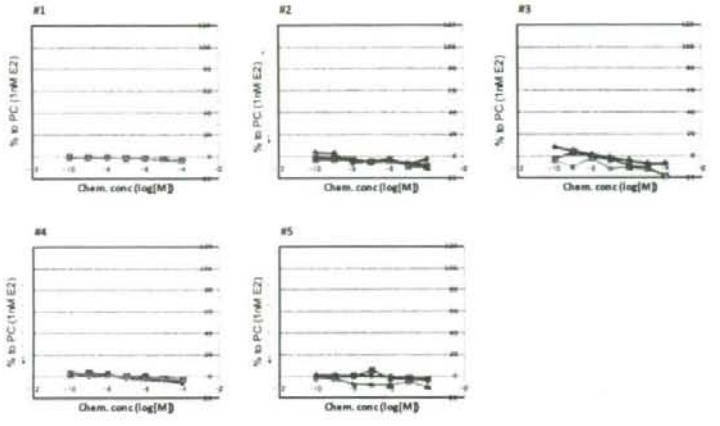
[Task-1] 17α-estradiol dose response



[Task-1] 17α-estradiol Performance standard



[Task-1] Corticosterone dose response



[Task-2] Procedure of ER antagonist assay

[Assay Procedure]

Culture cells with 10% FBS-EMEM

Seeding cells at 1x10⁴/100 μL/wells in a 96-well plate
(prepare 2 plates for ATG and cytotox. assay each)

Incubate for 2-3 hours in CO_2 incubator at 37°C

Expose chemicals, vehicle control and positive controls to cells
(plate format for ATG and Cytotox. assays are same)

[ATG assay] [Cytotx. assay]

●: Vehicle Control (VC)
●: 1 nM of E2
○: 25 pM of E2
●:10 μM of OHT
○: Cytotox. Control

Incubate for 20-24 hours in CO2 incubator at 37°C

Measure luciferase activity | Measure cell viability

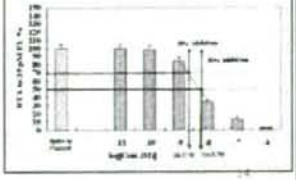
[Test Chemicals]

	1	2	3	4	5	6	7	8	9	10	11	12
A	4-Hydroxy tamoxifen			Tamoxifen			RU-486			Negative		
B												
C												
D												
E												
F												
G	Spike-in Control (25 pM of E2)			10uM of OHT			Cytotox. Ctrl.					
H	Vehicle Control (DMSO 0.1%)			Positive Control (1nM of E2)								

[Data Analysis]

Endpoints

- **linIC30**
- **linIC50**
- **IC50 (Hill's Equation)**



Task-2
[Quality Control and Performance Standard]

Quality Controls

Fold-induction of Spike-in Control (25 pM of E2)	> 6
RTA of 1 nM E2	> 100%
RTA of 1 μM OHT	< 16.9%
RTA of 100 μM Digitonin (cytotox. control).	< 0%

RTA: Relative transcriptional Activation to 25 pM E2

Performance Standard

	log [lin.IC30]	log [lin.IC50]	log [IC30]
4-Hydroxytamoxifen	-9.86 ~ -8.76	-9.79 ~ -8.28	-9.15 ~ -8.94
Tamoxifen	-7.88 ~ -6.99	-7.48 ~ -6.50	-7.17 ~ -6.77
RU-486	-6.20 ~ -5.32	-5.70 ~ -5.09	- 6.22 ~ -5.32
Negative	-	-	-

•Re-define the performance criteria, if necessary, from Task2 results.

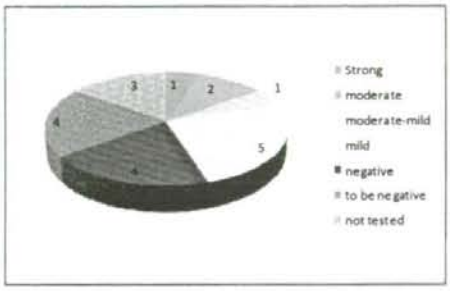
[Task-3] Study design

All lab will participate task-1 and task-2.
Core and Observer lab will test each 12 chemicals (5 chemicals are overlap).
Lead lab (CERI) test all 20 chemicals.

CERI	Core	Observer	
X	X	X	
X	X	X	
X	X	X	Test at 5 labs 5chemicals
X	X	X	
X	X	X	
X	X		
X	X		
X	X		
X	X		
X	X		
X	X		
X	X		
X		X	
X		X	
X		X	Test at 3 labs 14chemicals
X		X	
X		X	
X		X	
X		X	
X		X	
X			Test at 1 lab 1 chemical

Chemical Selection for Task-3

- Chemicals for Task 3 are selected based on ICCVAM and ECVAM (ReproTect) lists.
- Cytotoxic chemicals (antagonist negatives and positives) are included to strength the sensitivity of the assay.
- "Additional" chemicals are selected from the ER binding (and uterotrophic) assay(s).
- Proposed distribution of Positives and Negatives is as below,



Current status

		2008 4	5	6	7	8	9	10	11	12	2009 1	2	3
• Protocol Finalization		⇨											
• Chemical Selection for Task3			⇨										
• Chemical Distribution from JaCVAM			⇨										
• Distribution of Cell Line			⇨										
Task-1	Edge effects & agonist assay			⇨									
	Data Check							⇨					
Task-2	antagonist & cytotox. assays						⇨						
	Data Analysis								⇨				
Task-3	Antagonist assay (coded chemicals)									⇨			
	Antagonist assay (additional chemicals)									⇨			
	Data Analysis											⇨	
• Preparation of Report												⇨	

Dates indicated are the deadline of data submission.

OECD TEST GUIDELINES PROGRAMME

Standard Project Submission Form

If you require further information please contact the OECD Secretariat
Return completed forms to:
env.tgcontact@oecd.org

PROJECT TITLE

Non-Radioisotope version of the Local Lymph Node Assay (LLNA)

SUBMITTED BY (Country / European Commission / Secretariat)

Japan (Dr. Yamamoto, Japan National Coordinator for the OECD Test Guidelines Program)

DATE OF SUBMISSION TO THE SECRETARIAT

January **, 2009

DETAILS OF LEAD COUNTRY/CONSORTIUM

Country /Organisation:	Japan
Agency/ministry/Other:	Lead Institute: Japanese Centre for the Validation of Alternative Methods (JaCVAM), National Institute of Health Sciences (NIHS) Supporting Ministry: Ministry of Health, Labour and Welfare (MHLW), Japan
Mail Address:	National Institute of Health Sciences, 1-18-1 Kamiyoga, Setagaya-ku, Tokyo 158-5801, Japan
Phone/fax:	Phone: +81-3-3700-9874 (Kojima); Fax: +81-3-3700-9874
Email:	h-kojima@nihs.go.jp (Hajime Kojima, Director, JaCVAM, NIHS)

PROJECT OUTCOMES

☐ New Test Guideline	☐ Guidance document
☒ Revised Test Guideline	☐ Detailed Review Paper
☐ Deletion of an existing Test Guideline	☐ Other, please specify below

PROPOSED WORK PLAN and RESOURCE NEEDS:

1. Draft workplan for development of the proposal, including any need to establish Ad Hoc Expert Group and mode of meetings (face-to-face, teleconference; electronic discussion group). Indicate key milestones, including first and subsequent drafts of documents and timing of meetings.

The Japanese Centre for the Validation of Alternative Methods (JaCVAM) and the Japanese Society for Alternatives to Animal Experiments (JSAAE) performed validation studies on the non-radioisotope (RI) version of the Local Lymph Node Assay (LLNA) in order to revise the LLNA that was defined by OECD Test Guideline No.429 from 2005 to 2007. These revised assays are named LLNA-DA and LLNA-BrdU ELISA. The LLNA-DA and the LLNA-BrdU ELISA are based on adenosine triphosphate (ATP) content and the incorporation of 5-bromo-2'-deoxyuridine (BrdU) instead of ^{3}H-thymidine uptake. These validation studies provided strong evidence that LLNA-DA and LLNA-BrdU ELISA are reliable methods. To that end, JaCVAM and ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods) have each evaluated these methods by a peer review system, and JaCVAM has already recommended regulatory acceptance of LLNA-DA in Japan. We propose to publish additional information on these methods in Test Guideline No.429.

2. Will additional information, including generation or collection of data, be required? If yes, please describe the anticipated process and timelines.

Unfortunately, these Japanese validation studies were performed before the ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods) or ECVAM (European Centre for the Validation of Alternative Methods) performance standards were published. Therefore, the results of these validation studies do not fully satisfy these performance standards.

We are submitting the report on the LLNA-DA validation study (see attachments No. 1). Furthermore, We will submit a report on the LLNA-BrdU ELISA validation study and additional information, including the reference chemicals on the ICCVAM and ECVAM performance standards by the leading laboratory, by the 21st Meeting of National Coordinators of the Test Guidelines Programme in March, 2009, in Paris, France.

We have heard that the ICCVAM peer review will also be completed next April. Therefore, we will be able to submit each independent peer review report on these methods to the OECD secretary by this summer.

3. Indicate the estimated overall resource need (time/money) for member country / consortium and Secretariat

We will submit the reports on the validation studies and the ICCVAM and JaCVAM independent peer reviews on these methods to the OECD secretary by this summer.

4. Is this proposal intended to replace an existing Test Guideline or lead to the deletion of an existing Test Guideline?

No. These are additional test methods for an existing Test Guideline.

ESSENTIAL INFORMATION

In this section, please provide the information required by the Working Group of National Coordinators of the Test Guidelines Programme to assess the suitability of the project for the workplan of the Test Guidelines Programme

1. What is the existing or expected regulatory need/data requirement that will be met by the proposed outcome of the project? Please provide details below or as an attachment.

The revised test methods will be used to meet regulatory measures that are necessary to evaluate the skin sensitization of chemicals.

or as attachment No.__

2. How will the work contribute to further international harmonisation of hazard and risk assessment? Please provide details below or as an attachment.

These test methods allow the hazards of skin-sensitizing substances to be identified in accordance with the LLNA classification.

or as attachment No.__

3. How will the proposed project address issues and /or endpoints which are of major human health or environmental concerns? Please provide details below or as an attachment.

These test methods will provide a measure of the ability to screen skin-sensitizing substances.

or as attachment No.__

4. Will the project have general support from OECD member countries or is the outcome relevant for just one or a few member countries / stakeholders? Provide details of the countries and the rationale for this view below.

☒ Many countries ☐ A few countries ☐ Only for the submitting country

OECD Test Guideline No.429 has already been used in many countries to assess chemical

safety. We hope these test methods have also been investigated for a revised Test Guideline.

5. If the Test Guideline is not intended for general use, indicate if the Test Guideline would be intended for:

☐ Specific (limited) applications such as pesticide usage, or

☐ for specific classes of chemicals (e.g. surfactants) rather than for chemicals in general.

6. If the expected outcome of this proposal is a Test Guideline or a Guidance Document, provide information on the intended use, applicability and limitations of the test method.

These methods are rather simple and do not require sophisticated equipment. Specialized facilities for a RI are not necessary.

7. Provide supporting information on the validation status (i.e. relevance and reliability) of the method. Principles for validation of test methods for OECD Test Guidelines are described in Guidance Document 34.

Provide justification and rationale for the test, including data.

If there are no or limited data available to support the reliability and relevance of the proposed test, indicate if validation work is included in the project.

If there is no need for validation provide a detailed justification.

JaCVAM and JSAAE managed these validation studies, and the validation studies were conducted in accordance with OECD Guidance Document 34.

ADDITIONAL INFORMATION

In this section please provide further information to allow the Working Group of National Coordinators of the Test Guidelines Programme to assess the suitability of the project for the workplan of the Test Guidelines Programme

1. If the expected outcome of the project proposal is a Test Guideline and is based on existing, regional or international documents such as guidelines, protocols or guidance material, please provide that information here or as an attachment.

The report of the LLNA-DA validation study proposed by the validation management team is provided as attachment No. 1.

We will submit a report on the LLNA-BrdU ELISA validation study and additional information, including the reference chemicals on the ICCVAM and ECVAM performance standards by the leading laboratory, by the 21st Meeting of National Coordinators of the Test Guidelines Programme in March, 2009, in Paris, France.

or as attachment No. 1

2. If Animal Welfare considerations are addressed in the project proposal, provide details below or as an attachment. Explain if the project is aimed at refining, reducing and/or replacing the use of animals.

If the project is not specifically developed for animal welfare purposes, indicate if the animal welfare considerations have been a component of the project proposal.

Indicate if animal welfare considerations are irrelevant to the project, for example for physico-chemical properties.

According to OECD Test Guideline No. 429, these methods use improved animal protocols that do not require the use of a RI.

or as attachment No.__

3. Provide information on expected or possible resource savings in member countries as a result of this project.

The costs of conducting these test methods following GLP are cheaper than the original method because it is not necessary to have specialized facilities and equipment for a RI.

4. If the expected outcome of the proposed project is a Guidance Document or Detailed Review Paper, will it be directly linked to the development of a particular Test Guideline or a series of Test Guidelines?

☐ Yes, it is the initial step in the development of a new or revision of existing Guidelines.

☒ Yes, additional guidance is needed for the most appropriate selection of the Guidelines on the subject.

☐ No, the guidance is on issues related to testing or the development of Test Guidelines in general.

There are _1_ attachments added to this form.

ASSESSMENT OF PROJECT PROPOSAL

(To be completed by all member countries /stakeholders except the submitter)

Country / Organisation:	

Representative: (Preferably NC):	

Taking into account the project information, requested above, does this project meet the needs of the member countries for addition to the workplan of the Test Guidelines Programme

☐ Yes ☐ No ☐ Further information needed

If the response is "No" or "Further information needed", please provide justification:

Remarks as appropriate, including further information needs, if any:

OECD TEST GUIDELINES PROGRAMME

Standard Project Submission Form

If you require further information please contact the OECD Secretariat
Return completed forms to:
env.tgcontact@oecd.org

PROJECT TITLE

***In vitro* human epidermal model to assess skin irritation: LabCyte EPI-MODEL24**

SUBMITTED BY (Country / European Commission / Secretariat)

Japan(Dr. , Japan National Coordinator for the OECD Test Guidelines Program)

DATE OF SUBMISSION TO THE SECRETARIAT

January, **,2009
