



**Title of Research:**16\_S01-02

Prediction method (Amino acid Derivative Reactivity Assay: ADRA) for skin sensitization using novel lysine and cysteine derivatives

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### **Summary of Research:**

In this study, we performed the validation study so that the alternative method for skin sensitization (ADRA) is adopted as OECD test guideline.

For the four participating laboratories, the two training sessions were held, and the two confirmation tests (Pre-training test and Training test) were performed because the lead laboratory confirmed that the assay technique was correctly transferred for the participating laboratories.

The Pre-training test was performed using 5 test chemicals to be easy to be categorized correctly. The predictive results for 5 chemicals at four participating laboratories were completely consistent with the results at lead laboratory, so it was thought that the first step of technical transfer was finished. The Training test was performed using 10 test chemicals that would be difficult to be categorized correctly. The Within-Laboratory Reproducibility at each laboratory were 100%, 90%, 100% and 100%, respectively, and so it was thought that technical transfer was completely finished because the goal was accomplished.

It was decided at VMT meeting that Phase-1 study (as Within-Laboratory Reproducibility) would be performed using three replicate sets of 10 chemicals and Phase-2 (as Between-Laboratory Reproducibility) study would be performed using one set of 30 chemicals in the ADRA validation study. The Within-Laboratory Reproducibility were 100% (10/10), 100%(10/10), 100%(7/7) and 90%(9/10) and these values were higher than expected in that the results of Phase-1 achieved the Within-Laboratory Reproducibility of more than 80% of target.

After Phase-1 validation study, VMT teleconference was held on January in 2019, and VMT member were evaluated the results of Phase-1 study. Because all the improvement items proposed by lead laboratory were approved by VMT members, and the Phase-2 study was started on February in 2019 as scheduled.



**Timeline:** March 1, 2016–

**Topics:**

1. Presented at ICCA–LRI & NIHS WORKSHOP–Awaji Island, Japan 「Validation study on Amino acid Derivative Reactivity Assay (ADRA) for prediction of skin sensitization」

**Publications:**

1. Presented at the 29<sup>th</sup> Annual Meeting of the Japanese Society of Alternatives to Animal Experiments (November 18, 2016) 「Reporting of Training and Transfer Outcome for Validation Study of Alternative Method (ADRA) for Skin Sensitization using Cys and Lys Derivatives」  
2. Planed to be presented at the 44<sup>th</sup> Annual Meeting of the Japanese Society of Toxicology (July 10–12, 2017) 「Multicenter Validation Study of Novel in chemico Skin Sensitization Assay (ADRA): 1<sup>st</sup> Report」