A Multi-Center Ring Trial of Allergen Exposure Assessment using Fluorescent Multiplex Array Technology

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INTRODUCTION

Standardization of allergen exposure measurements is important to ensure reproducibility of results obtained by different laboratories.

We have conducted a Multi-Center Ring Trial with 9 participating centers in the US and Europe to evaluate intra- and inter-laboratory reproducibility of a Multiplex ARray for Indoor Allergens (MARIA™). MARIA ™ enables the simultaneous quantitative detection of eight common indoor allergens of dust mite, cat, dog, mouse, rat and cockroach in a single test. MARIA™ uses xMAP® technology and is ideally suited to large epidemiologic studies and routine environmental assessment of allergen exposure.

METHODS

Study Design

- 151 dust extracts
- Measured by 9 participating laboratories
- For 8 indoor allergens using MARIA
- On 3 separate occasions

❖ All participants were trained by the coordinating center

❖ Statistical evaluations were performed by Rho Inc., NC

Comparison of over 32 000 allergen measurements

Participating Centers:

U.S.:

Dr. E King	Indoor Biotechnologies Inc., VA (Coordinating center)
Dr. D Zeldin	NIEHS, Research Triangle Park, NC
Dr. D Schmechel	NIOSH, Morgantown, WV
Dr. T Platts-Mills	University of Virginia, VA
Dr. R Hamilton	Johns Hopkins University, Baltimore, MD
Dr. P Thorne	University of Iowa, IA
Dr. D Milton	University of Massachusetts, MA

Europe:

Dr. R van Ree	Academic Medical Center, Amsterdam, The Netherlands
Dr. B Brunekreef	IRAS Div Occ & Envl Health, Utrecht, The Netherlands

RESULTS

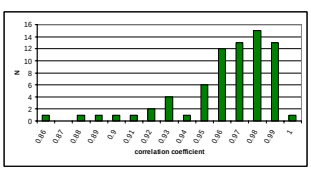
Range of Allergen Concentrations: Allergen Concentrations in the 151 dust extracts covered a wide range for all measured allergens, between below detection limit (<LOD) and >130ug/g (Mus m 1: <35ug/g).

INTRA-LABORATORY REPRODUCIBILITY

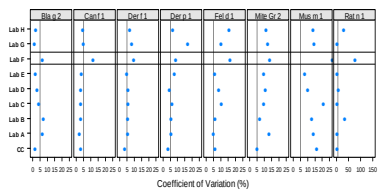
Results between 3 separate measurements of 151 samples within each study site were evaluated using Intra-class Correlations and Coefficients of Variation (CV%).

- **Results within each study site correlated very closely.**
- **53% of median CV% within laboratories were within the 5% CV margin and 75% fell within 10% CV.**
- **The actual level of intra-laboratory reproducibility, however, differed slightly between study sites.**

Frequency distribution of intra-class correlations (N = 72)



Median of CV% between 3 runs for each sample and allergen



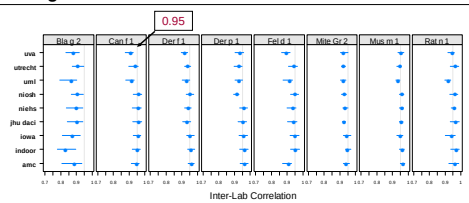
INTER-LABORATORY REPRODUCIBILITY

Results between study sites were evaluated using Intra-class Correlations, Comparison of Overall Means and Coefficients of Variation (CV%).

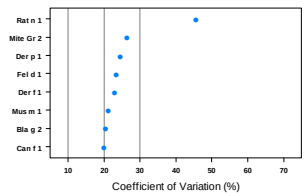
- **Results between labs were highly correlated for all allergens (~0.95).**
- **Overall means of results were comparable between labs.**
- **Inter-lab CV% ranged between 19% and 27%.**

* Higher variability for Rat n 1 is not significant due to the low number of positive samples.

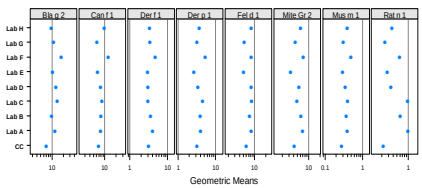
Median and range of 8 correlations between each lab and all other labs



Median of CV% between study sites by allergen



Comparison of overall means



CONCLUSIONS

❖ MARIA results are reproducible both within and between laboratories.

❖ The actual level of reproducibility is dependent on the operator.

❖ Precise data interpretation instructions are important.

❖ MARIA will improve standardization of allergen exposure assessment.

❖ Continued proficiency testing programs will verify inter-laboratory reproducibility.

REFERENCES

Earle CD, King EM, Tsay A, Pittman K, Saric B, Vailes L, Godbout R, Oliver KG, Chapman MD. High-throughput Fluorescent Multiplex Array for Indoor Allergen Exposure Assessment. J Allergy Clin Immunol 2007; 119:428-433.

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