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

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.

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.

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


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