

**A NOVEL GENERATION OF ASSAYS
INTRODUCED BY A NOVEL
PARTNERSHIP**

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Alzheimer's disease - The biomarker needs

SAMPLES

- SOP (= consensus) for collection, storage, & long-term stability (*Sample-specific recipients?*)

BIOMARKER ASSAYS

Reference method compatible with performance in immunoassays
(*Harmonization between technologies*)

New markers for disease progression

Novel generation of assays with high **precision** AND **accuracy**, supported by clinical data (*Consensus on performance criteria*)

Regulatory: FDA approved assays for Dx and/or companion diagnostics

DATA-DRIVEN APPROACH

The ADx NeuroSciences – Euroimmun connection

The added value of the partnership

Founded

- Sep. 2011
- Employees: 9

Focus

- Identification of novel biomarkers
- Field: neurodegeneration
- Target: Dx & Companion Dx
- Technologies: single & multiplex assay formats
- Regulatory approvable (FDA) assays (platform independent)

Founded

- 25 years ago (Prof. Dr. W. Stöcker)
- Employees: > 1300 worldwide

Focus

- Science driven (affiliated institute for experimental immunological research)
- Field: autoimmun diseases, infections, allergology, **New: neurodegenerative diseases**
- Technologies
 - ELISA, IFA, Blot, Microarray
 - Automation systems (incl. lab software)
- Regulatory: affiliated accredited reference laboratory

Prototype Development Validation Registration Market integration

ADx

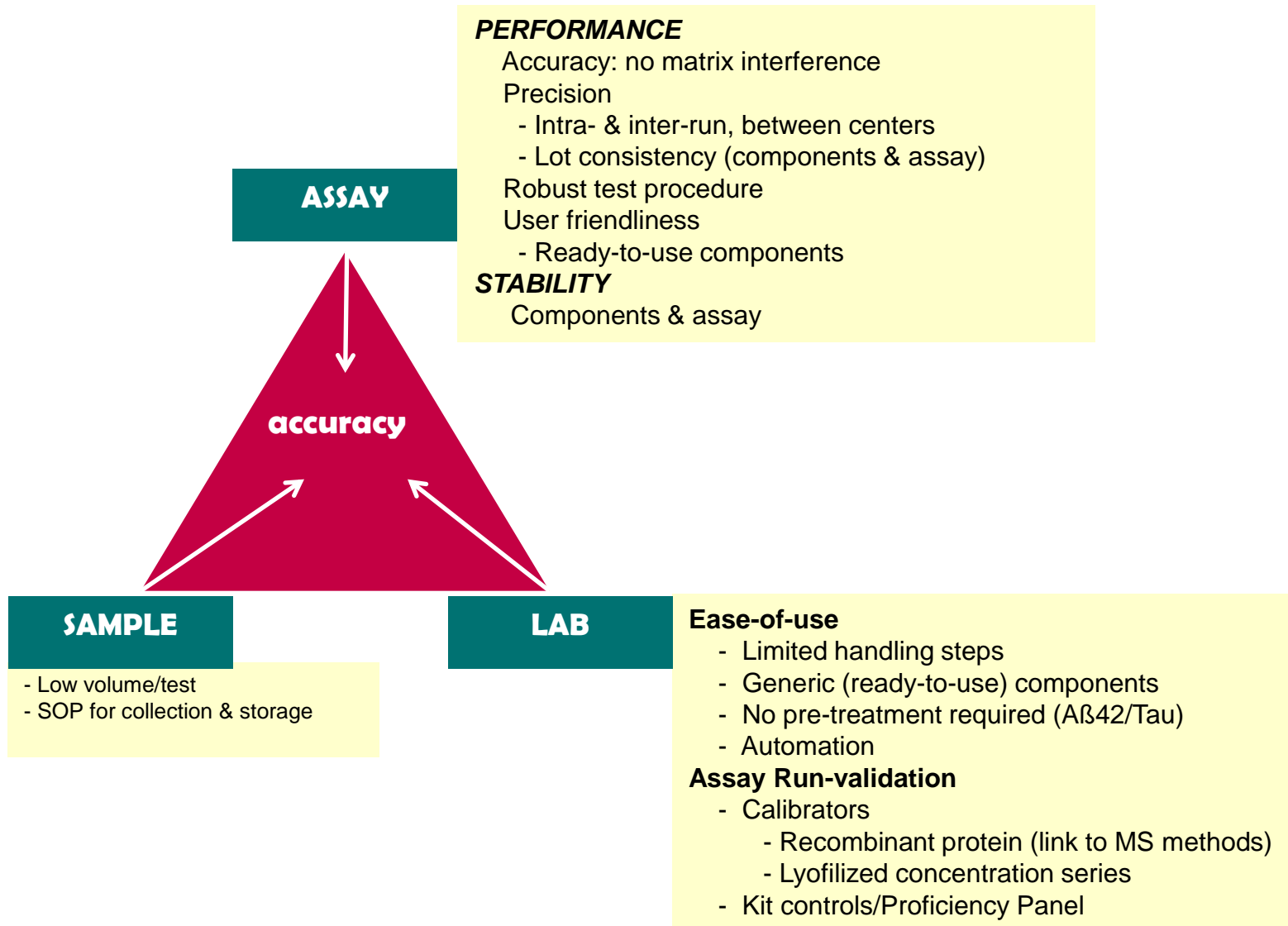


EUROIMMUN



The novel assays - our development approach

Goal: precise and accurate measurements



Our Performance data

THE PLATFORM

ELISA



The future
- Multiplex
- Point-of-need

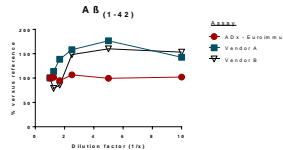
THE ASSAYS

- β-Amyloid(1-42)
- β-Amyloid(1-40)
- Total Tau
- (P-TAU)

THE PERFORMANCE

ACCURACY

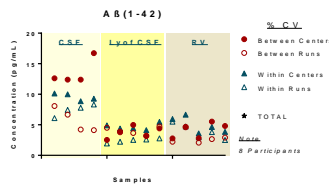
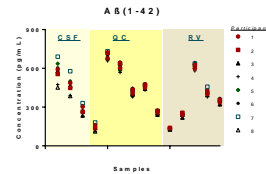
(= no matrix interference)



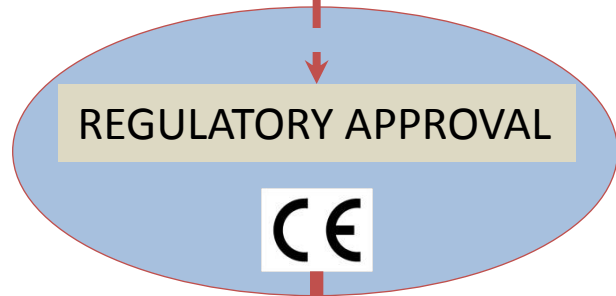
PRECISION

BIAS

% CV



AUTOMATION



FDA

Dx
Tx

Novel assays - Multicenter evaluation

PARTICIPANTS (9)

US

- Philadelphia **Shaw Les**
- St Louis **Fagan Anne**

Europe

- Belgium **Engelborghs S**
ADx NeuroSciences (= reference)
- France **Buée L/S Schraen**
- Germany **Otto M**
Euroimmun (= reference)
- Sweden **Blennow K/Zetterberg H**
- The Netherlands **Teunissen C/Scheltens P**

TEST PROCEDURE

- **TRIAL RUN**, followed by approval
- **TEST RUNS (3)**
 - Samples
 - CSF (N = 4); three aliquots/run
 - QC (n=5); one aliquot/run
 - RV (n=5); three aliquots/run
 - Calibrators
 - Lyophilized
 - Ready-to-use

SAMPLE TYPES (#)

CSF (4)

- Pooled CSF from commercial supplier
- Ready-to-use aliquots

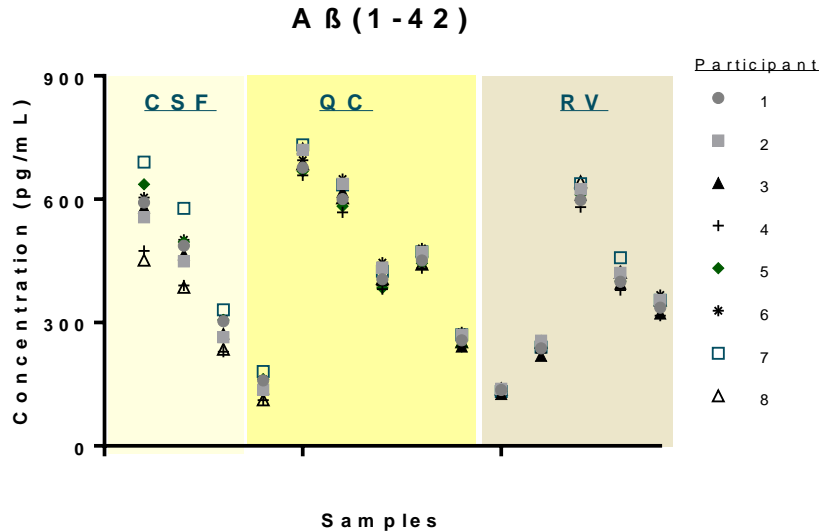
LYOPILIZED CSF (= QC) (5)

- Reconstitution before testing
- Good stability
- Additives to reduce absorption problems

RUN-VALIDATION (5)

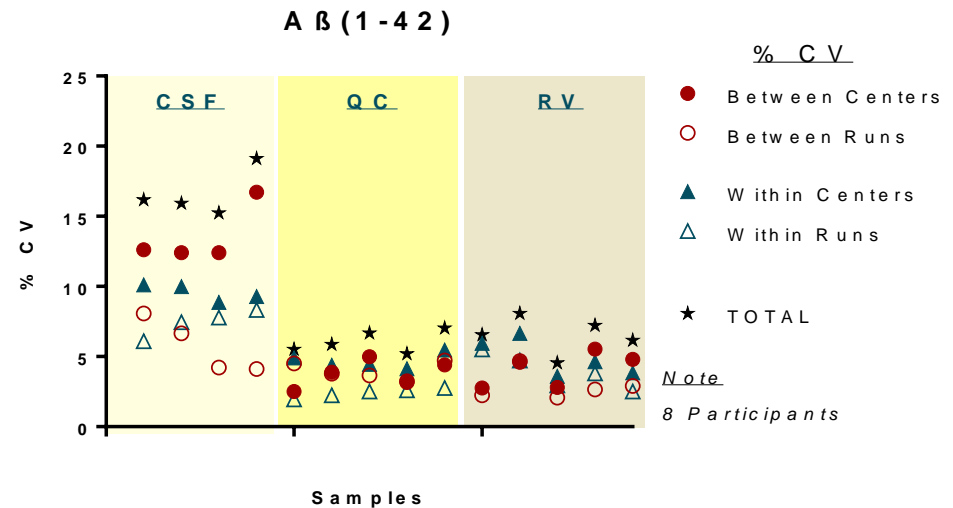
- Recombinant protein in buffer

The facts: BIAS and Precision



Limited BIAS in analyte concentration generated in the labs of the participants, even using a manual test procedure.

Good between-center and between-run Precision, especially for a new type of CSF sample preparation (= QC).

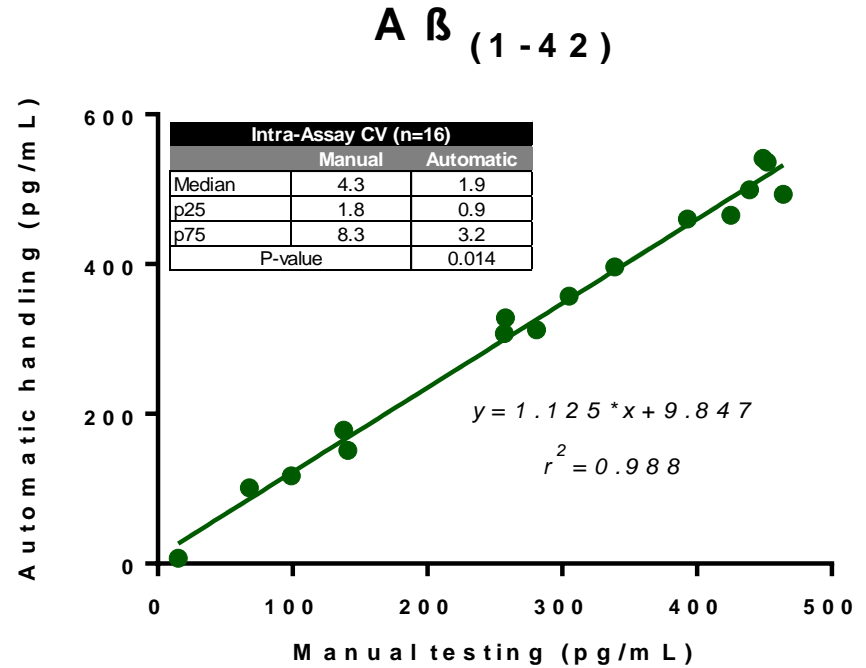


The facts: automation qualified

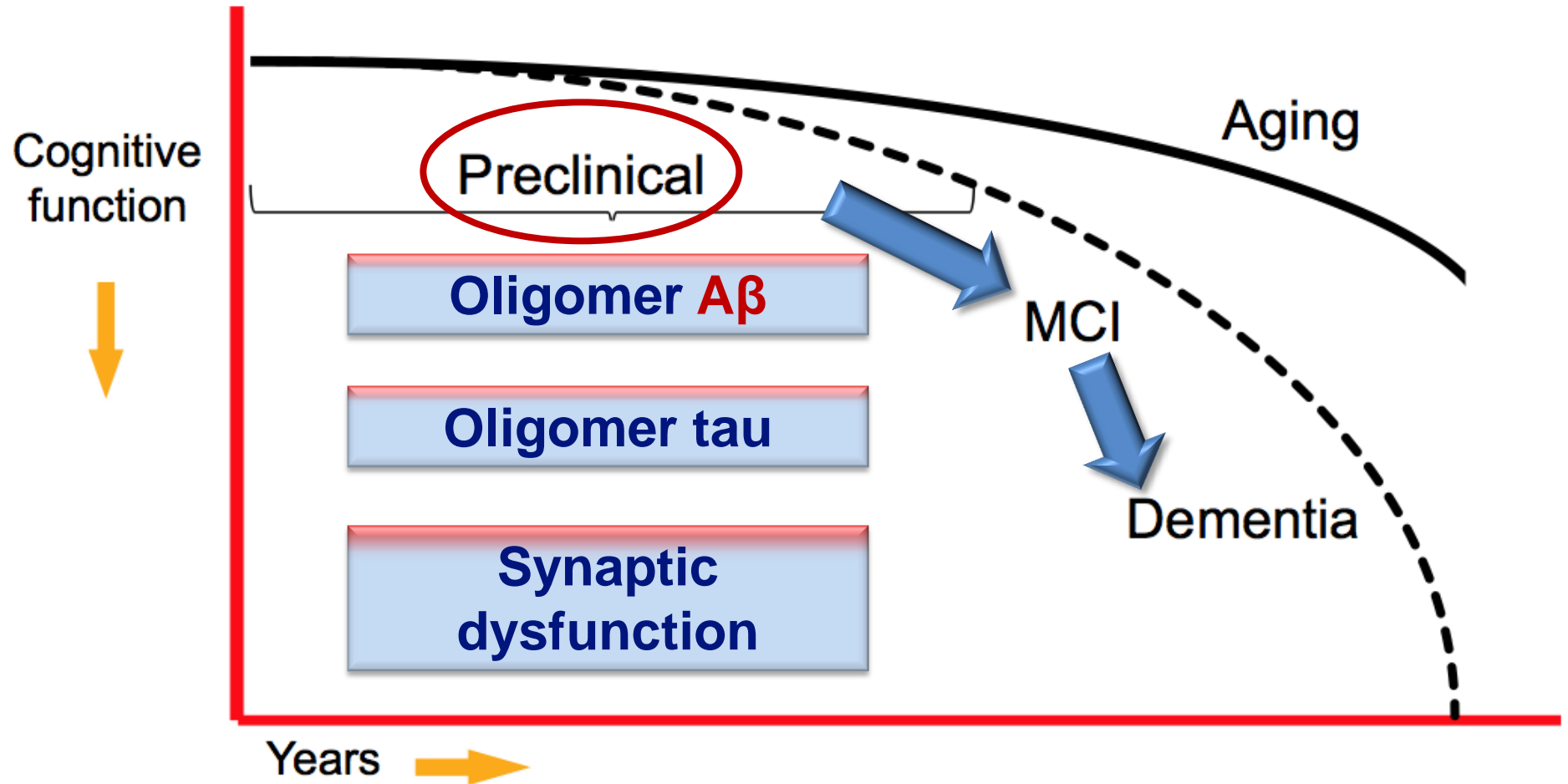
Analytical performance



EUROIMMUN Analyzer-I



Future projects



ADx – Euroimmun

Strong partners – now and in the future

Contact info

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