



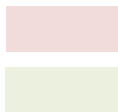
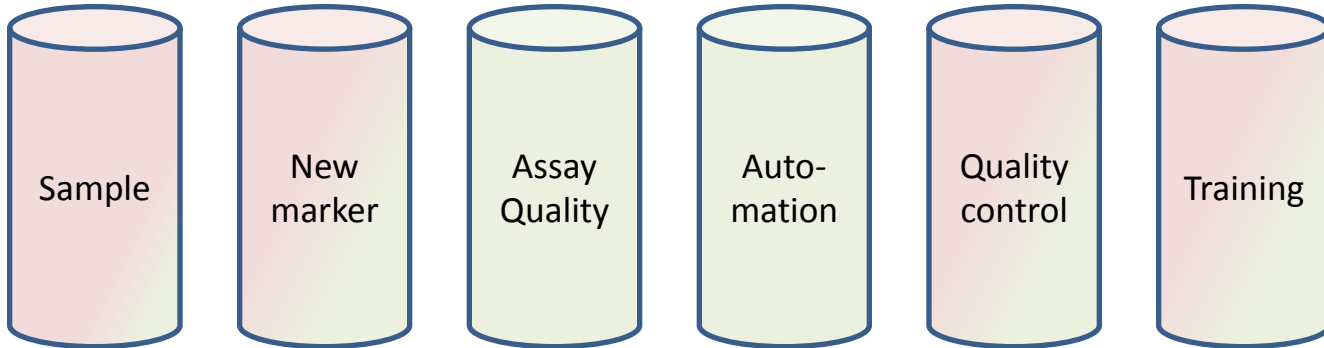
Contribution of EUROIMMUN to biomarker standardization - now and in the future

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GBSC 07/12/2014 Copenhagen



Scientific community & EUROIMMUN

Diagnostic accuracy



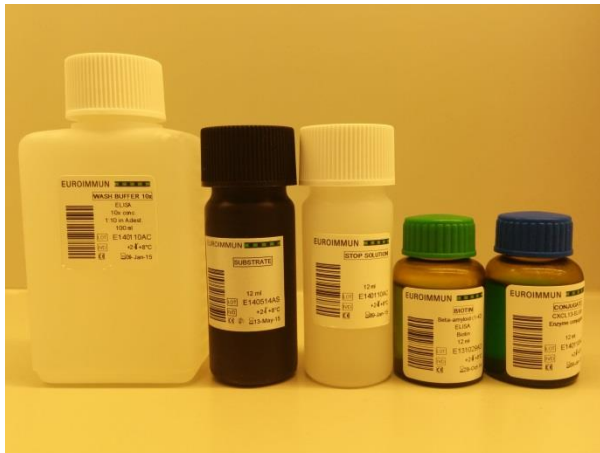
fields addressed by scientific community

fields EUROIMMUN is involved in/contributes to

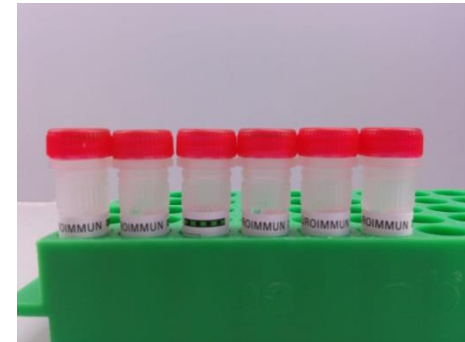


| | Beta-Amyloid (1-40) | Beta-Amyloid(1-42) | Total-tau |
|----------------------|----------------------|--------------------|----------------|
| Sample dilution | 1:21 | No predilution | No predilution |
| Sample volume | 15 µl diluted sample | 15 µl | 25 µl |
| Sample incubation | 3 h | 3 h | 3 h |
| conjugate incubation | 30 min | 30 min | 30 min |
| substrate incubation | 30 min | 30 min | 30 min |

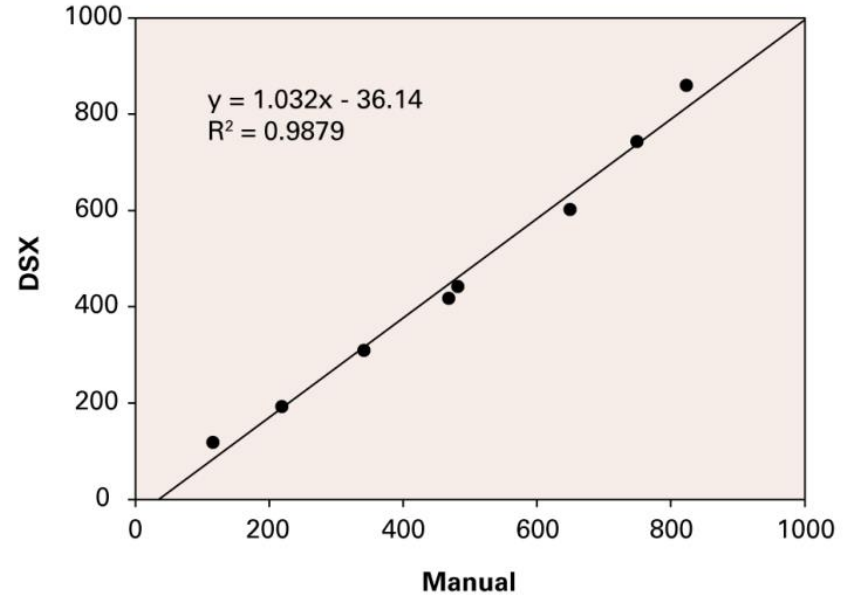
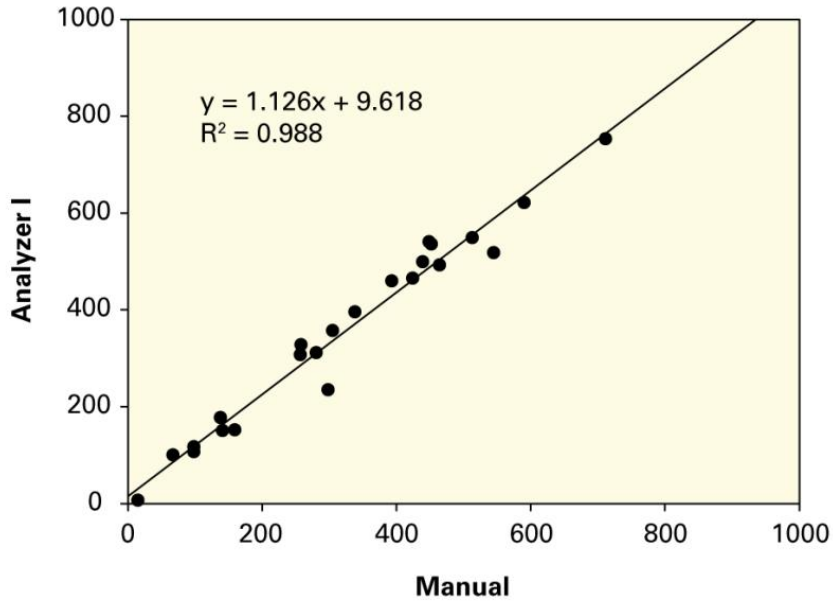
Results in one day



Ready-to-use **generic** reagents
Buffers limits absorption to recipients



Lyophilized calibrator
Stability at RT

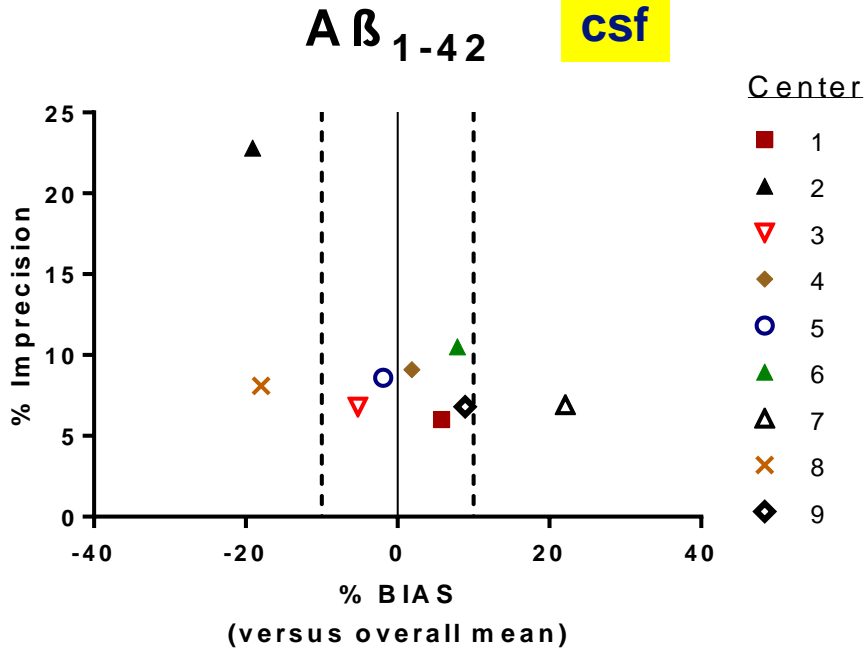


Bias
Intra-assay variability

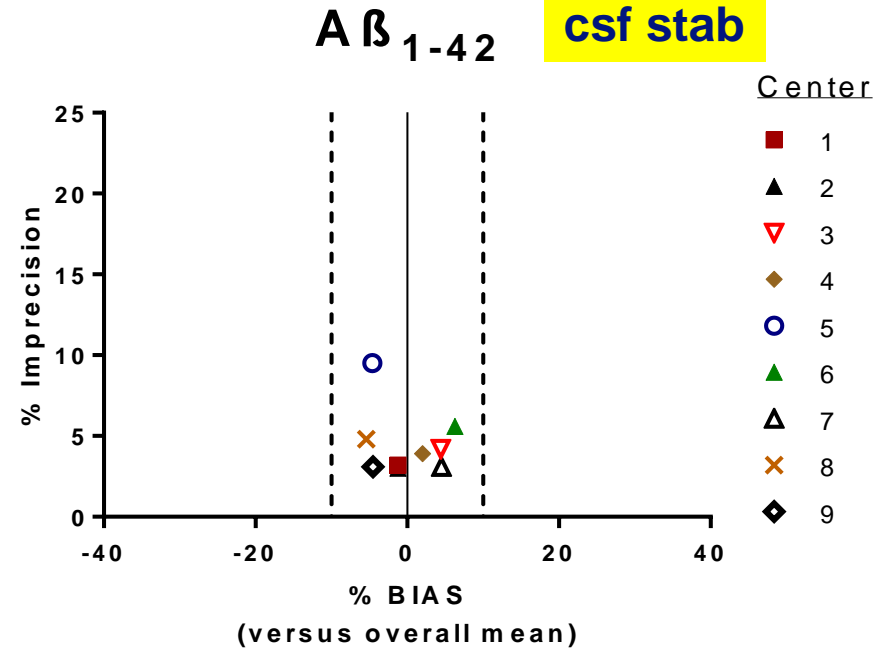




| Location | | Principal Investigator |
|------------|-----------------|------------------------|
| US | Philadelphia | L. Shaw |
| | St. Louis | A. Fagan |
| Europe | Belgium | S. Engelborghs |
| | France | S. Schraen |
| | Germany | M. Otto |
| | Sweden | K. Blennow |
| | The Netherlands | C. Teunissen |
| References | ADx | |
| | EUROIMMUN | |



Acceptable precision and BIAS



% BIAS can be improved by stabilized CSF

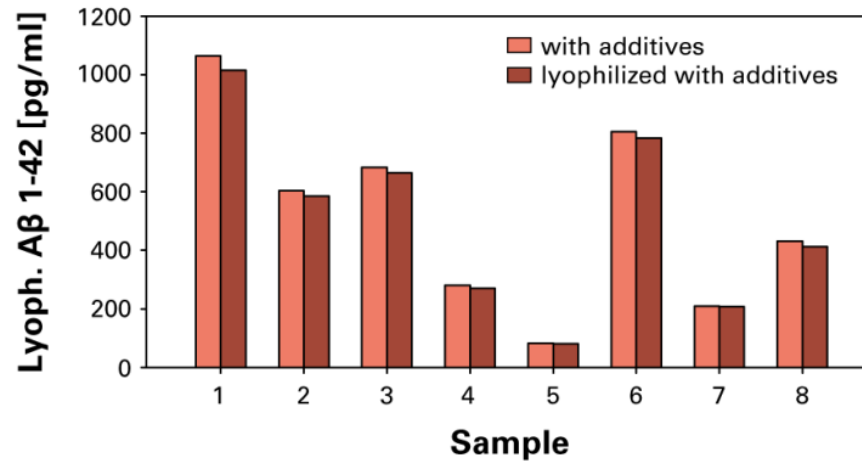
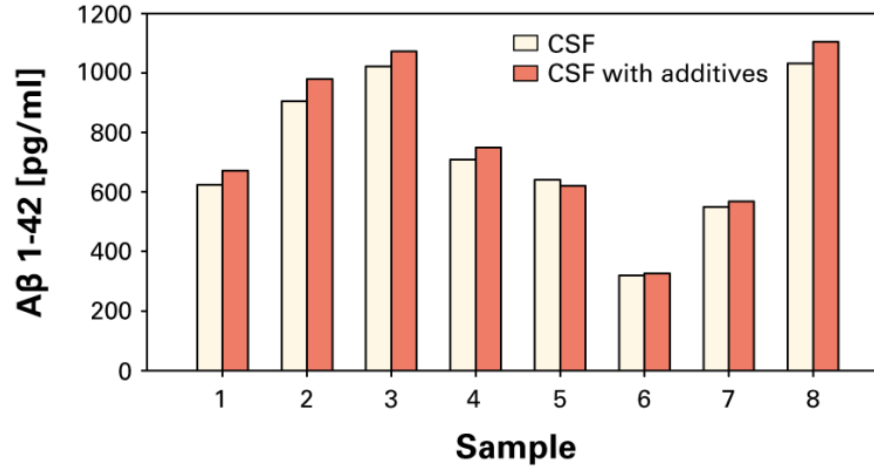


External quality control programs

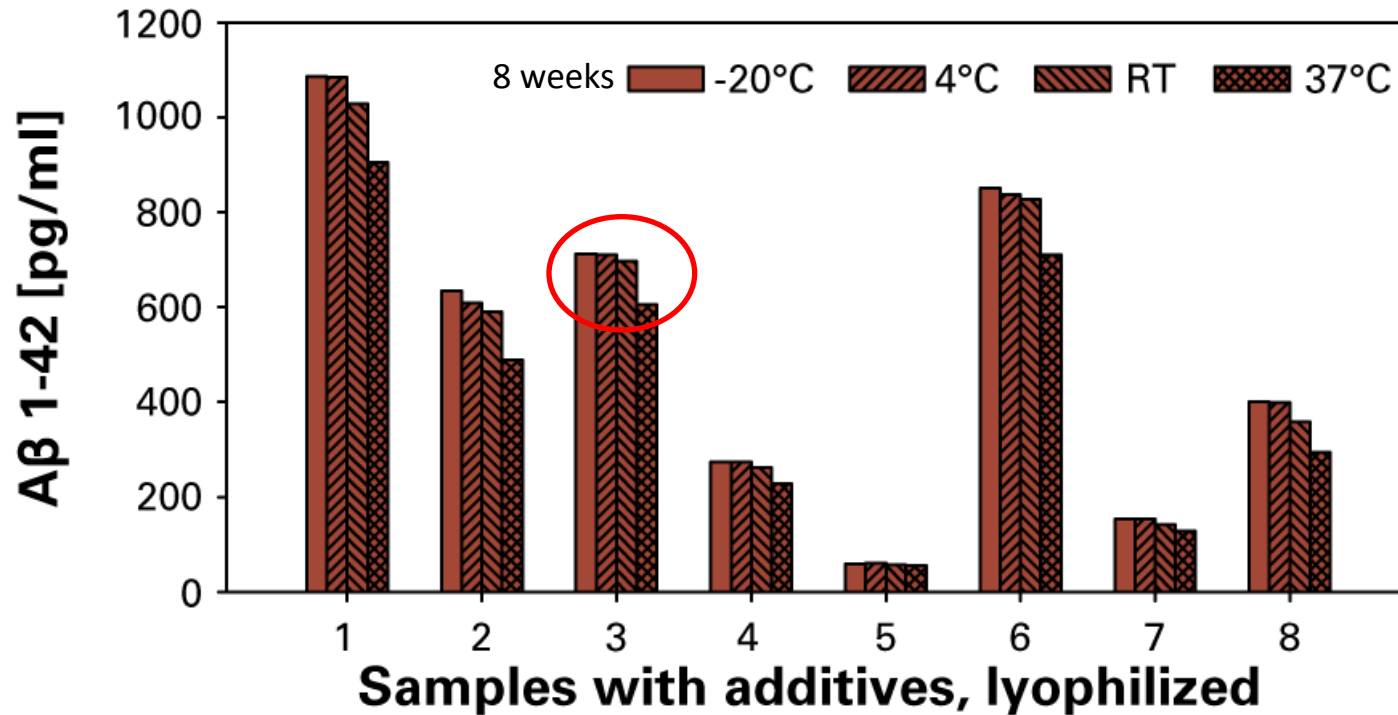
- AAQC
- INSTAND

Internal quality control

- Kit controls - Run validation
- Quality Control Panel
 - Validation
 - Training
 - Long-term QC



Impact on concentration by inclusion of additives and lyophilization is minor.



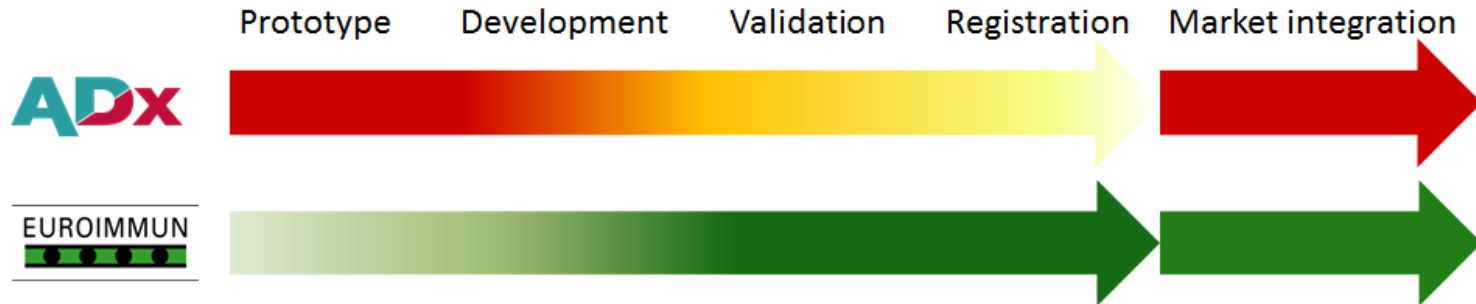
The method to prepare the CSF samples will result in long(er) term stability.



| Analyte | Regulatory status | Sample | Round Robin |
|----------------|-------------------|---------------|-------------|
| A β 1-42 | CE | CSF | X |
| | Prototype | Plasma | |
| A β 1-40 | CE | CSF | X |
| | Prototype | Plasma | |
| Total Tau | CE | CSF | X |
| A β 1-38 | Development phase | CSF | |
| | Prototype | Plasma | |
| ApoE(4) | Prototype | CSF plasma | |
| pNFH, BACE1 | | | |

Total offering solution

- Technology: ELISA
- Test procedure: manual testing & automation
- CSF-like proficiency panel
- If possible, integration in QC programs/Consortia



Strong partners – more to come...