

PPMI α -synuclein interlaboratory study

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PARKINSON'S
PROGRESSION
MARKERS
INITIATIVE

Play a Part in Parkinson's Research



PPMI α -synuclein interlaboratory study

- Purpose: evaluate precision of 4 immunoassays, including within-run and between-run precision for each participating center
- Samples:
 - 12 aliquots each for 7 patient CSF samples
 - 12 aliquots each for 3 α -SYN standards (rPeptide synthetic α -SYN)
- Analyses: each center ran these samples together with a series of standards, prepared at each center, all in quadruplicate
- Statistics:
 - Statistical analyses will characterize for each center the precision within-run, between-run and total
- Lab ID: each laboratory was be assigned a letter, A, B, C or D, randomly assigned, to preserve anonymity. Only the individual laboratory will know their id letter.

PPMI interlaboratory study participants

| <u>Centers performing immunoassays & investigators</u> | | <u>Data analysis</u> | |
|--|---|----------------------|---|
| Covance/Univ of Ottawa | Peggy Taylor, ScD Michael Schlossmacher, MD | UPenn | Leslie M Shaw, PhD John Q Trojanowski, MD, PhD Michal Figurski, PhD |
| University of Washington | Jing Zhang, MD, PhD Jeff Armaly | | |
| Innogenetics | Eugeen Vanmechelin, PhD Hugo Vanderstichele, PhD | UIowa | Christopher Coffey, MD Ying Zhang, PhD |
| Elan | Jennifer Johnston, PhD Ruth Motter | | |
| | | | |

Patient CSF sample aliquots provided by Britt Mollenhauer; distributed by UPenn biomarker laboratory in sets of 3 aliquots per patient sample.

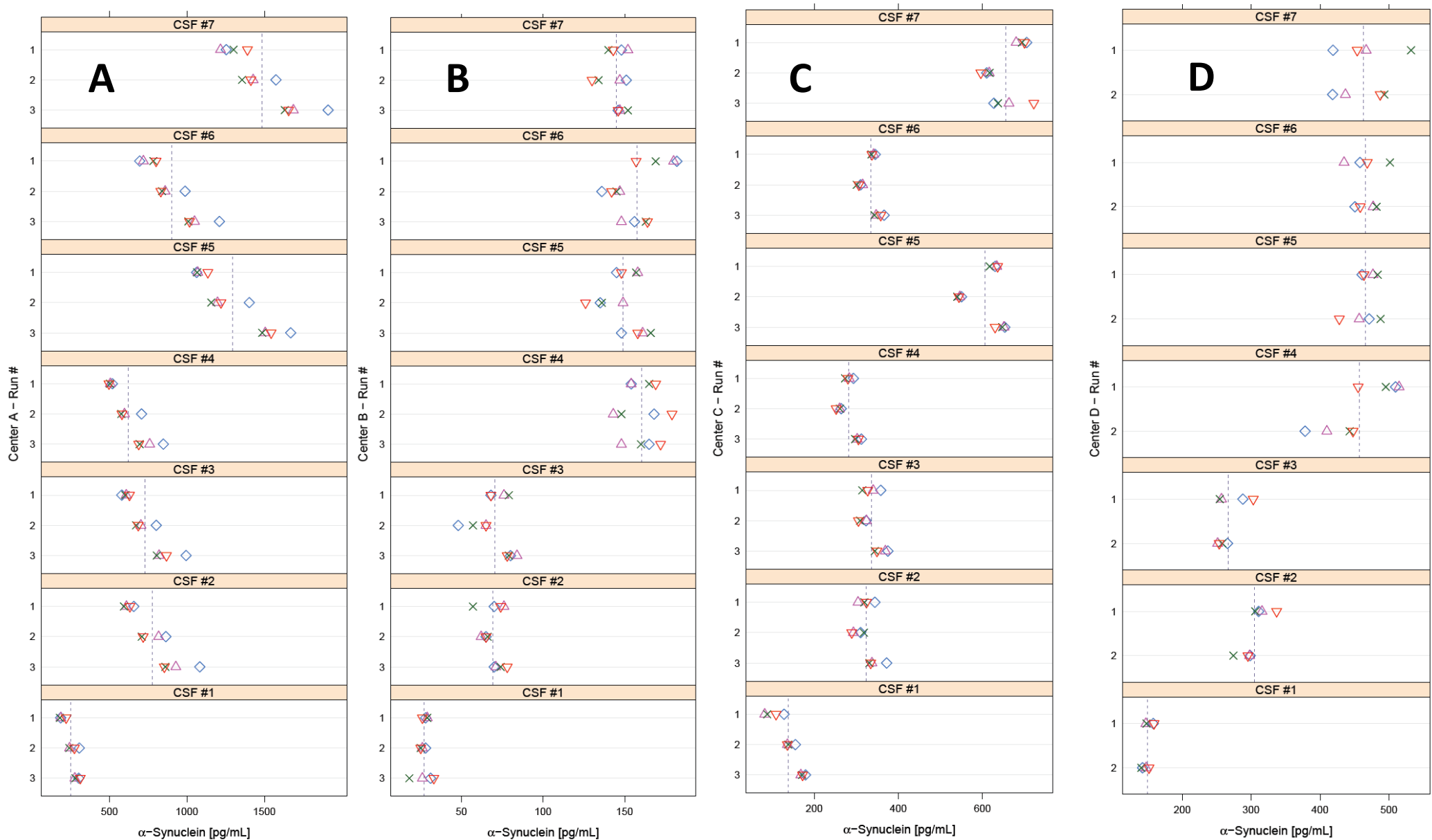
α -SYN QC sample aliquots provided by Eugeen Vanmechelin

Plate layout for analytical runs

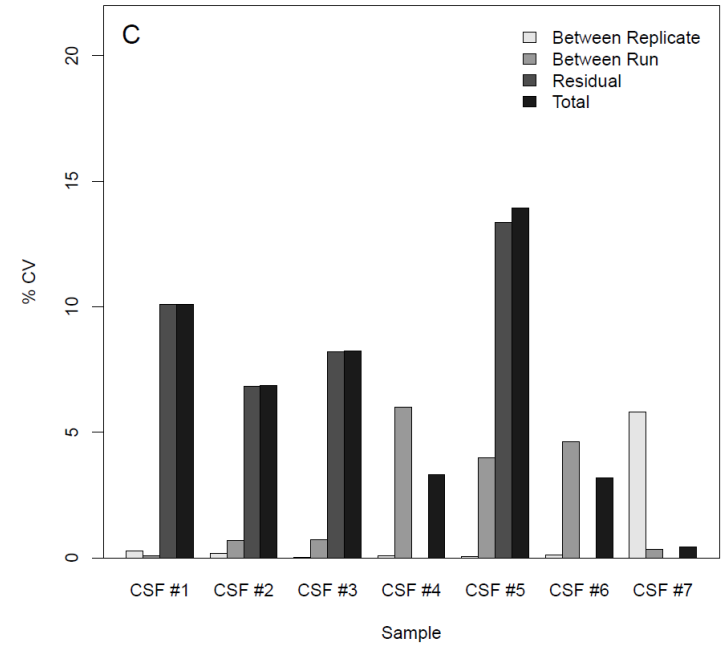
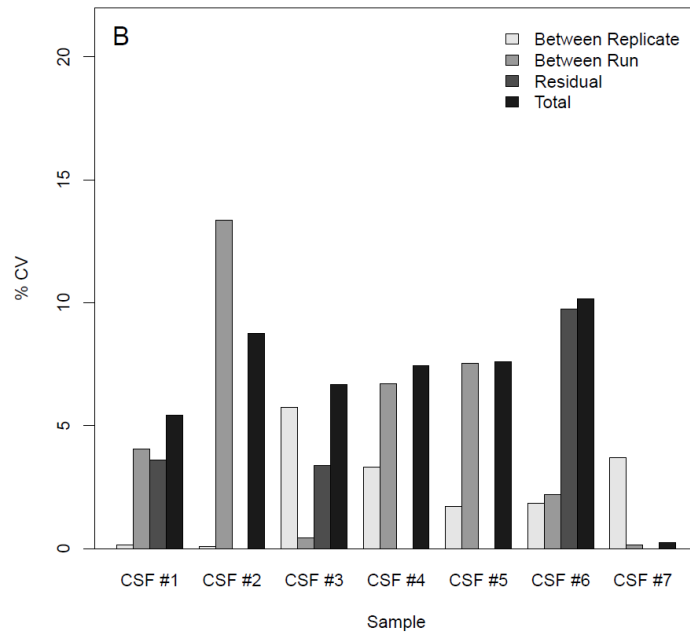
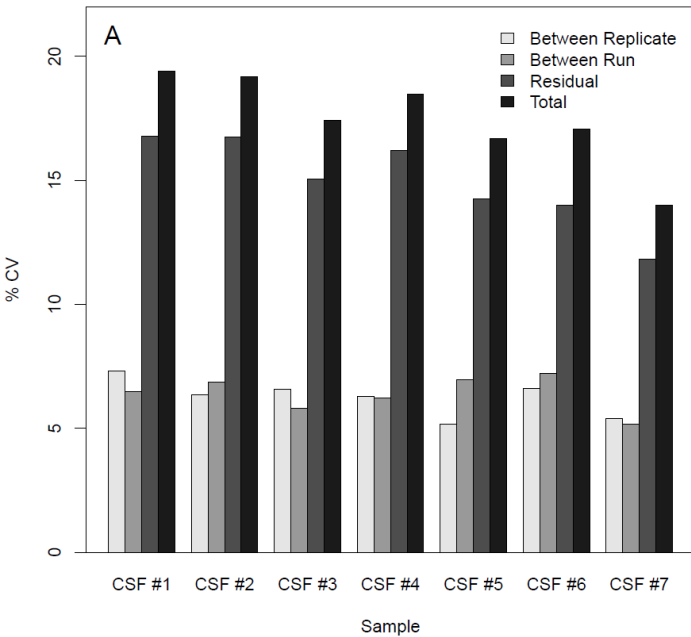
| plate 1 | α-syn* conc pg/m | rep1 | | rep2 | | rep3 | | rep4 | | MFI/OD | | | α-syn conc** pg/ml | | | | | |
|------------------------------|---------------------|---------|------------|---------|------------|---------|------------|---------|------------|--------|-------|-----|--------------------|-------|-----|--------------------|--|--|
| | | MFI /OD | conc pg/ml | MFI /OD | conc pg/ml | MFI /OD | conc pg/ml | MFI /OD | conc pg/ml | AVG | STDEV | %CV | AVER | STDEV | %CV | | | |
| standard 1 | | | | | | | | | | | | | | | | | | |
| standard 2 | | | | | | | | | | | | | | | | | | |
| standard 3 | | | | | | | | | | | | | | | | | | |
| standard 4 | | | | | | | | | | | | | | | | | | |
| standard 5 | | | | | | | | | | | | | | | | | | |
| standard 6 | | | | | | | | | | | | | | | | | | |
| standard 7 | | | | | | | | | | | | | | | | | | |
| standard 8 | | | | | | | | | | | | | | | | | | |
| Blank | | | | | | | | | | | | | | | | | | |
| Control 1 | 333pg/ml | | | | | | | | | | | | | | | | | |
| Control 2 | 111pg/ml | | | | | | | | | | | | | | | | | |
| Control 3 | 12 pg/ml | | | | | | | | | | | | | | | | | |
| CSF #1 | | | | | | | | | | | | | | | | | | |
| CSF #2 | | | | | | | | | | | | | | | | | | |
| CSF #3 | | | | | | | | | | | | | | | | | | |
| CSF #4 | | | | | | | | | | | | | | | | | | |
| CSF #5 | | | | | | | | | | | | | | | | | | |
| CSF #6 | | | | | | | | | | | | | | | | | | |
| CSF #7 | | | | | | | | | | | | | | | | | | |
| * conc standards theoretical | | | | | | | | | | | | | | | | ** conc calculated | | |

Each patient CSF sample and control sample was run in quadruplicate, in 3 different runs.

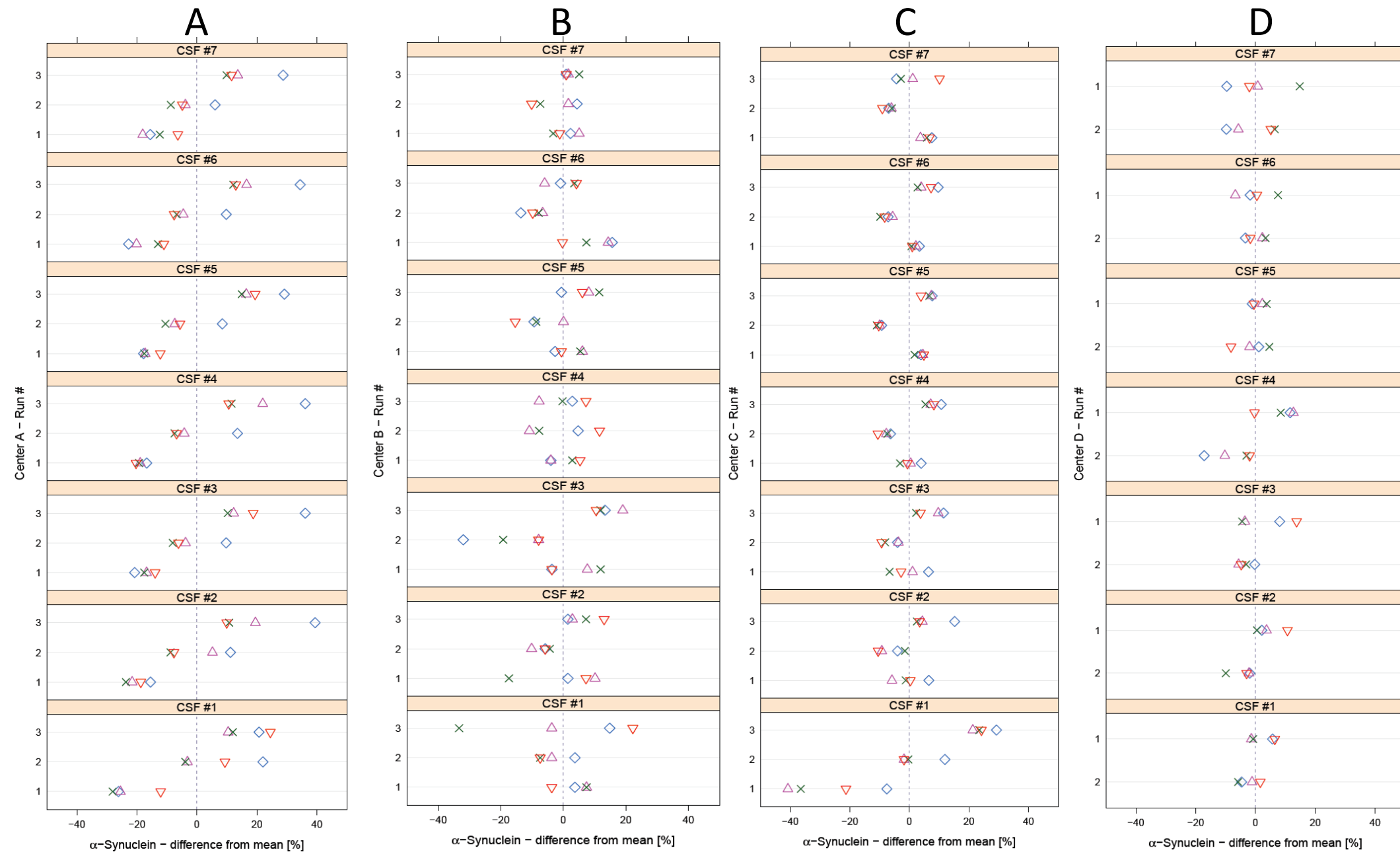
Data points for each run for each of 4 participating laboratories for 7 patient CSF samples



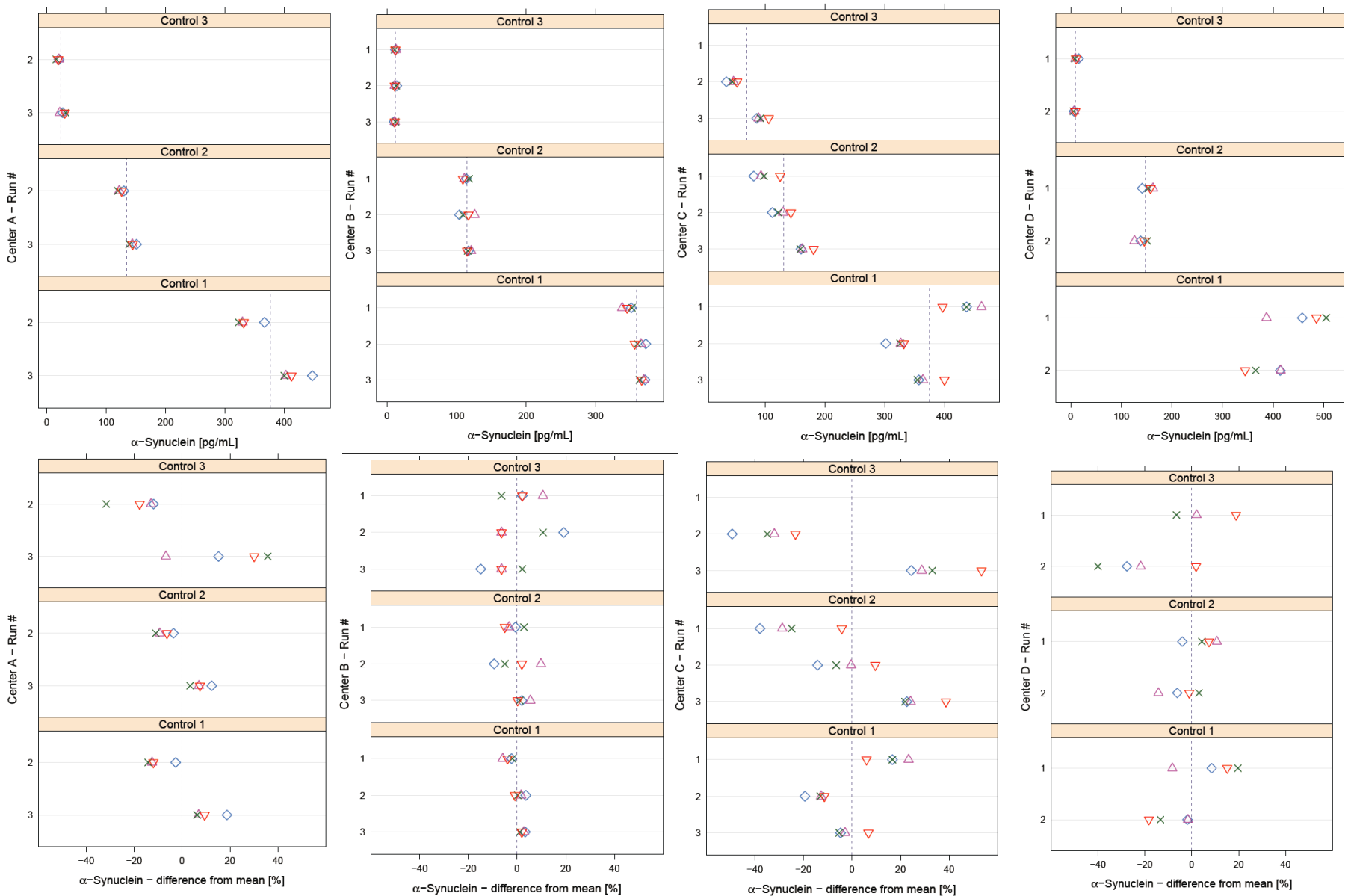
Mixed-model precision analyses for Labs A, B & C



Percent difference from the mean value for 7 CSFs within each center



Precision performance for 3 α -SYN quality control samples



Summary

- Databank with 848 analytical results has been prepared at UPenn and, independently, at Ulowa
- Analyses of data is underway with plans for review of the data by teleconference within the next month
- The results of the study whose primary purpose is to assess the precision performance of 4 immunoassays using patient CSF samples and α -SYN quality control samples will be summarized and a report generated for upload on the PPMI web site