

Ortho Clinical Diagnostics

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

AUTOMATED AB42 AND TAU ASSAYS ON THE ECIQ UPDATE

DEVELOPED IN PARTNERSHIP WITH
BRISTOL-MYERS SQUIBB AND
J&J ORTHO CLINICAL DIAGNOSTICS



BECAUSE NO TWO
PATIENTS ARE ALIKE



Salvatore J. Salamone
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Vancouver

DIAGNOSTIC PLATFORM

VITROS[®] ECIQ

IMMUNODIAGNOSTIC SYSTEM

Advantages:

- Short analysis time (amenable to quick turn-around – e.g. 1 hr)
- Minimal requirements for lab tech time
- Robust and precise assays
- FDA-cleared platform

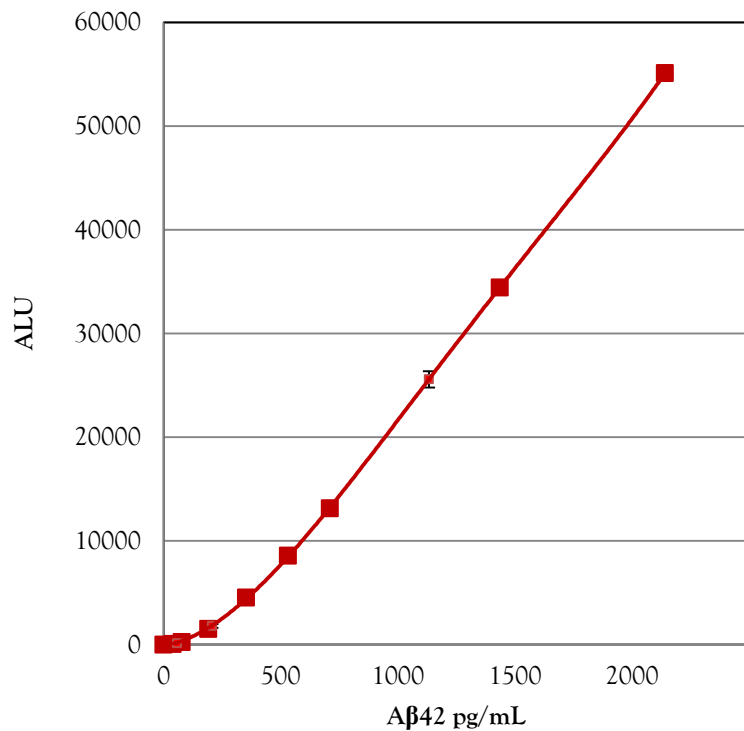


- 30 reagent channels
- 90 samples/hour
- Sample types: Serum, Plasma, Urine, Amniotic Fluid, Whole Blood
- Sample volume: 10-80 μ L
- Sample capacity: 60 samples
- Disposable tip metering verifies sample aspiration and dispense and addresses carryover and cross-contamination concerns
- Clot, bubble, low and high viscosity, thin layer fluid and short sample
- Sample trays accommodate:
 - 10mL, 7mL, 5mL collection tubes
 - 1.5mL micro-collection containers
 - VITROS Microsample cups and 0.5mL and 2.0mL cups

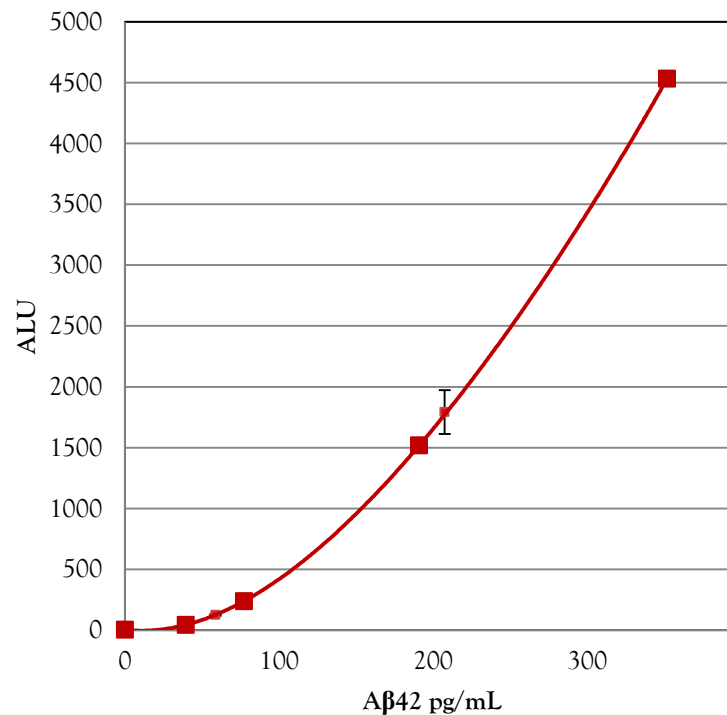
CSF Ab42 ASSAY Update

STANDARD CURVE FOR CALIBRATION OF A β 42

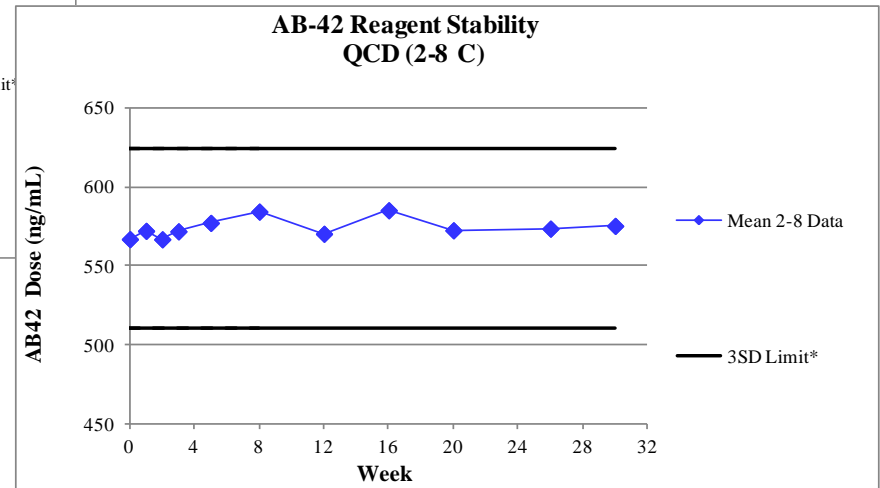
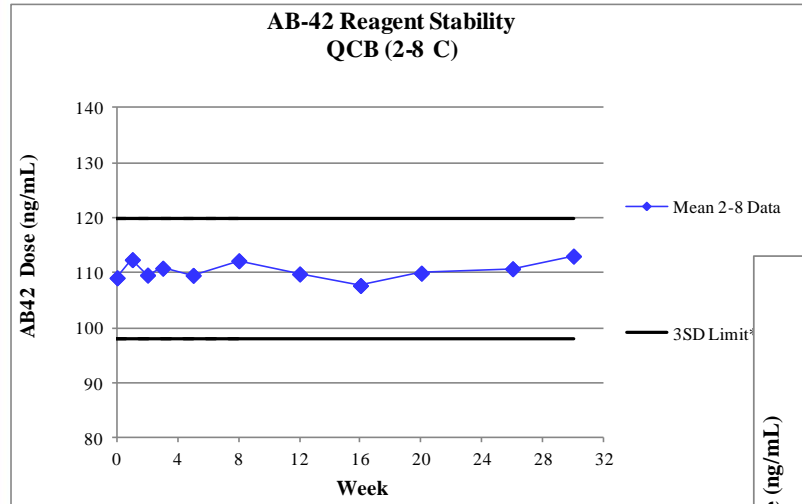
Test Range
 $\pm 2SD$ on control ALUs



Lower Concentrations
 $\pm 2SD$ on control ALUs

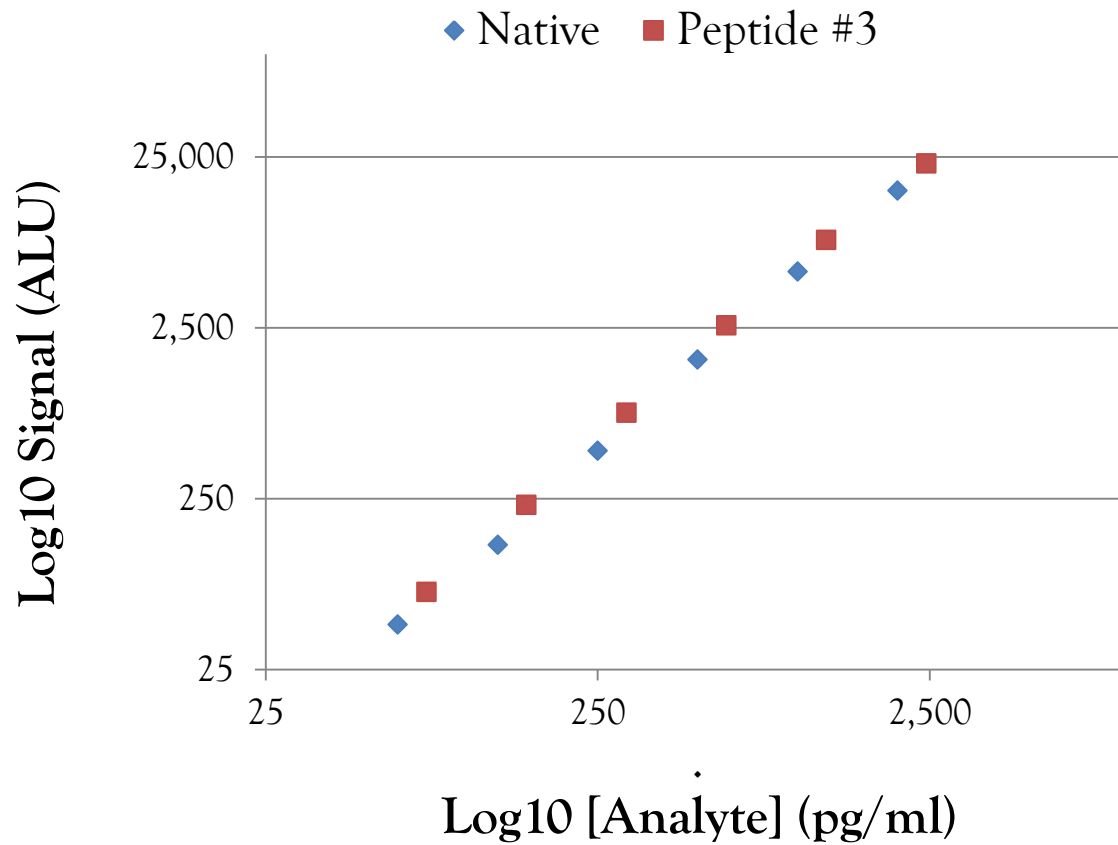


Ab42 REAGENT STABILITY

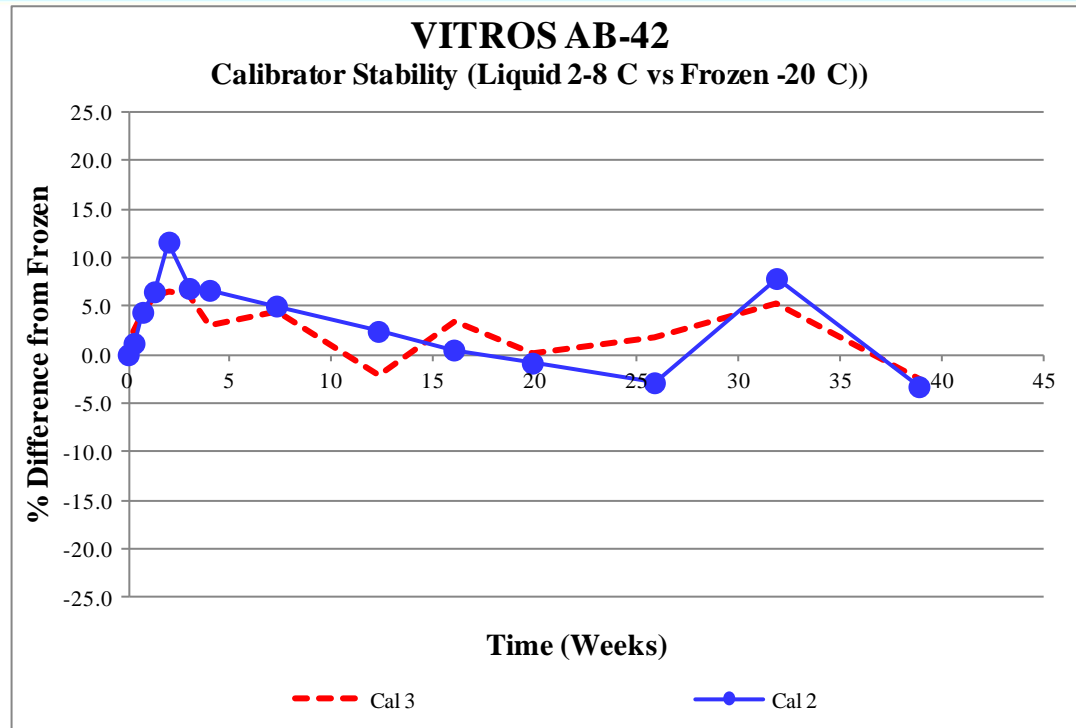


- The proposed reagent formulations are stable at 2-8 °C for up to 7 months
- Stability studies are ongoing

SYNTHETIC A β 42 CALIBRATOR VS. NATIVE A β 42



Ab42 CALIBRATOR STABILITY



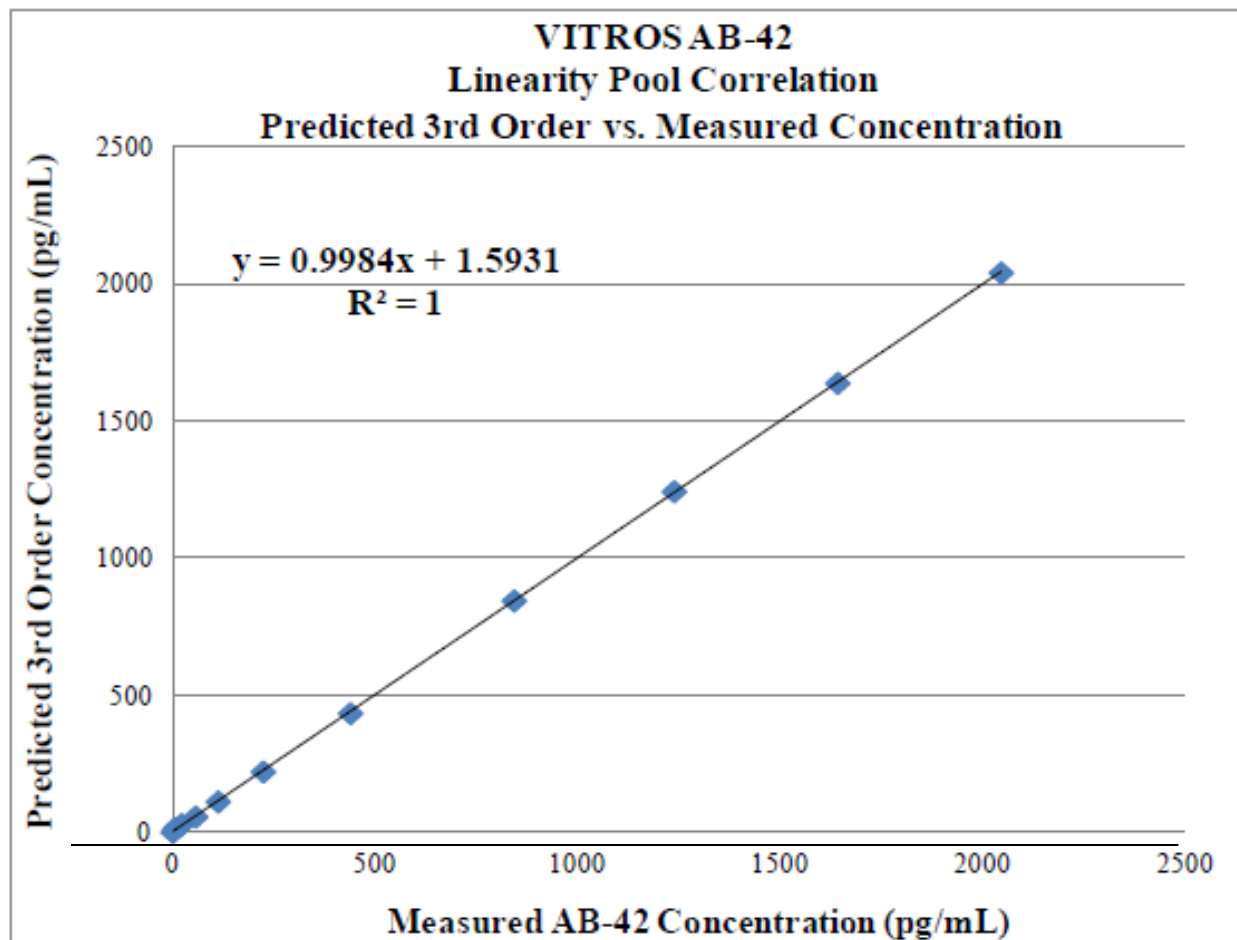
- The proposed calibrator formulation is stable at 2-8 °C for up to 39 weeks
- Stability studies are ongoing

Ab42 PRECISION PERFORMANCE

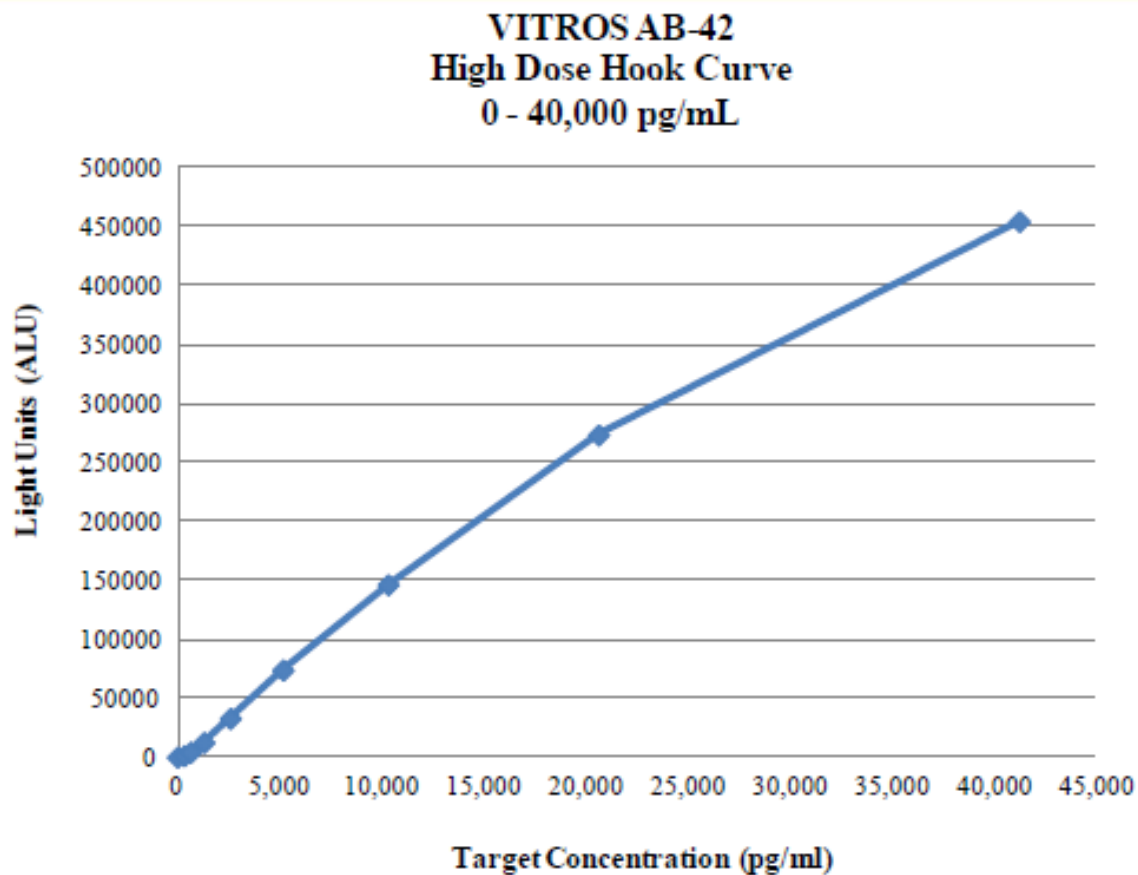
5-Day Precision Study – 4 individual CSF Samples and 3 Controls
 % CV pg/mL, n=20 (4 reps/day)

AB-42 Reagent with Hinged BJ/c					
Sample ID	Mean	SD	%CV	Within-lab Precision %CV	Repeatability %CV
CSF129	113	4.89	4.3	4.1	1.7
CSF220	847	28.7	3.4	3.2	1.1
CSF239	422	15.0	3.6	3.4	1.5
CSF278	244	14.9	6.1	5.8	1.5
QCB (R&D)	121	0.94	0.8	0.7	0.5
QCD (R&D)	614	5.07	0.8	0.8	0.6
QCE (R&D)	1167	9.27	0.8	0.8	0.5
CSF Mean				4.1	1.4
QC Mean				0.8	0.5

VITROS AB42 ASSAY LINEARITY



AB42 ASSAY: HIGH DOSE HOOK

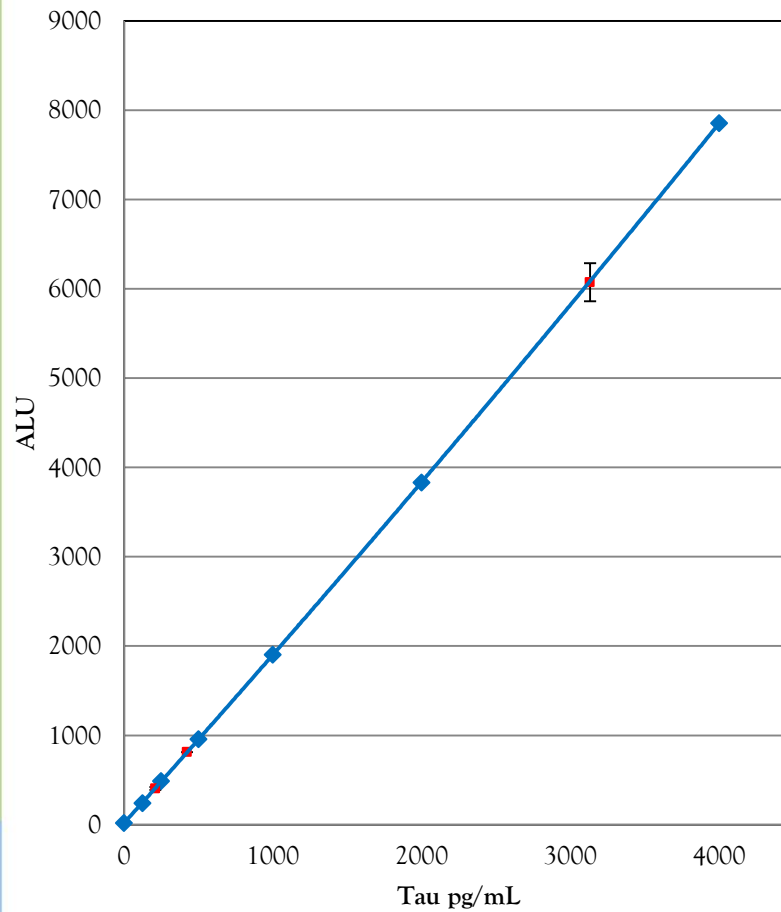


No high dose hook up to ~40,000 pg/mL

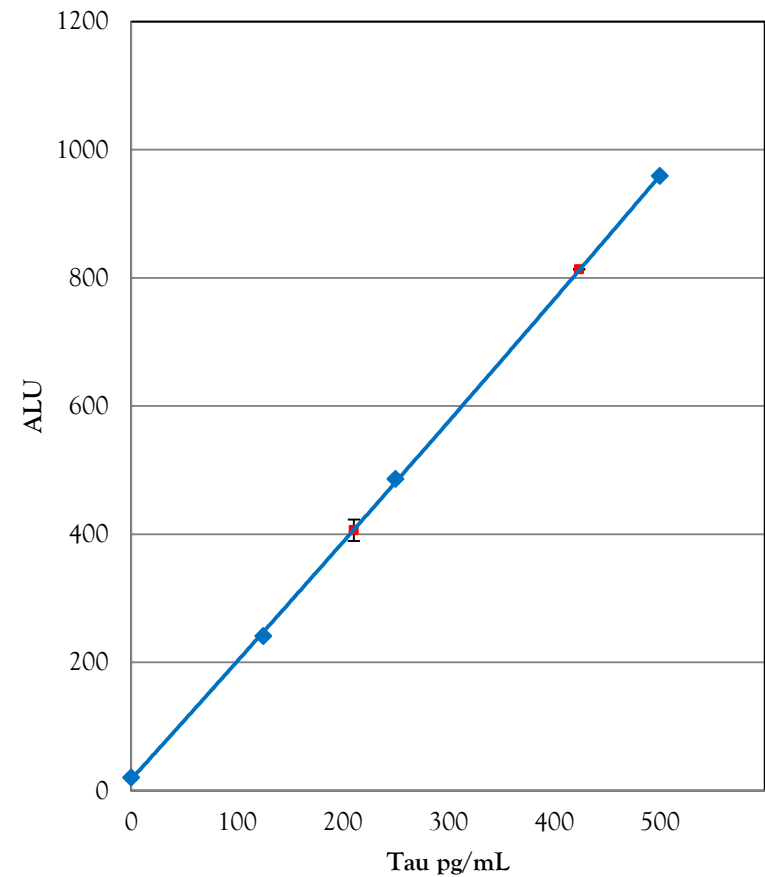
CSF Tau Assay Technical Performance

STANDARD CURVE FOR CALIBRATION OF TAU

Test Range
 $\pm 2SD$ on control ALUs

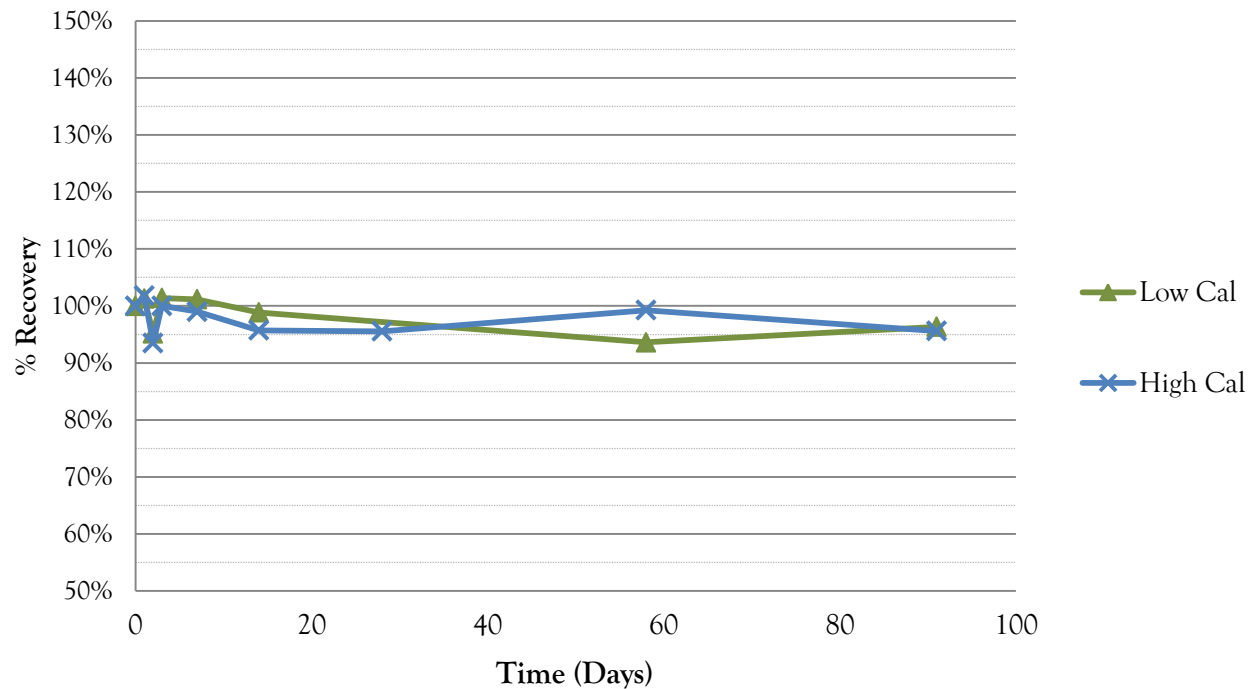


Lower Concentrations
 $\pm 2SD$ on control ALUs



TAU LIQUID CALIBRATOR STABILITY

Peptide Calibrator Stability At 4C

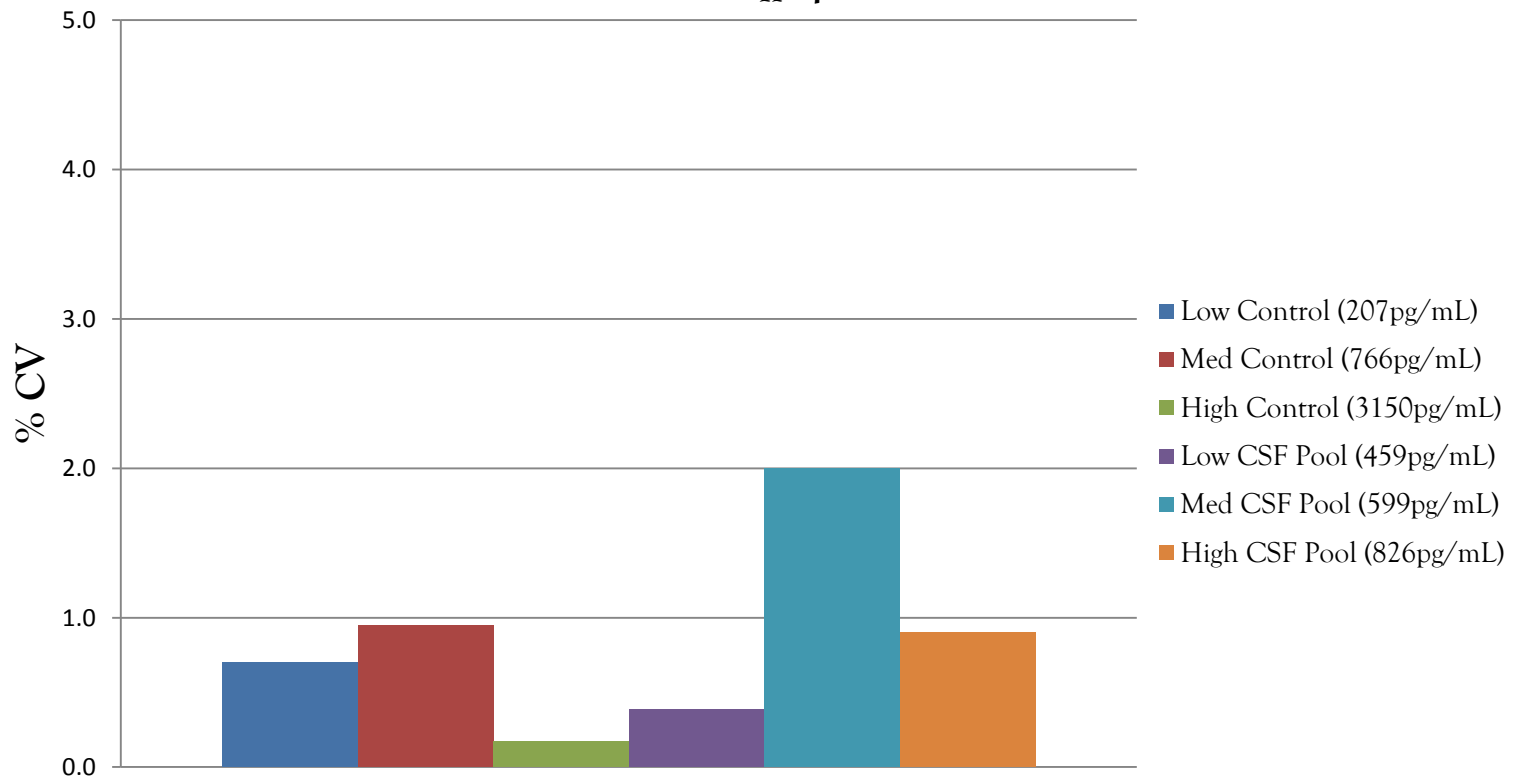


- The proposed calibrator formulation is stable at 2-8 °C for up to 90 days
- Stability studies are on-going

TAU PRECISION PERFORMANCE

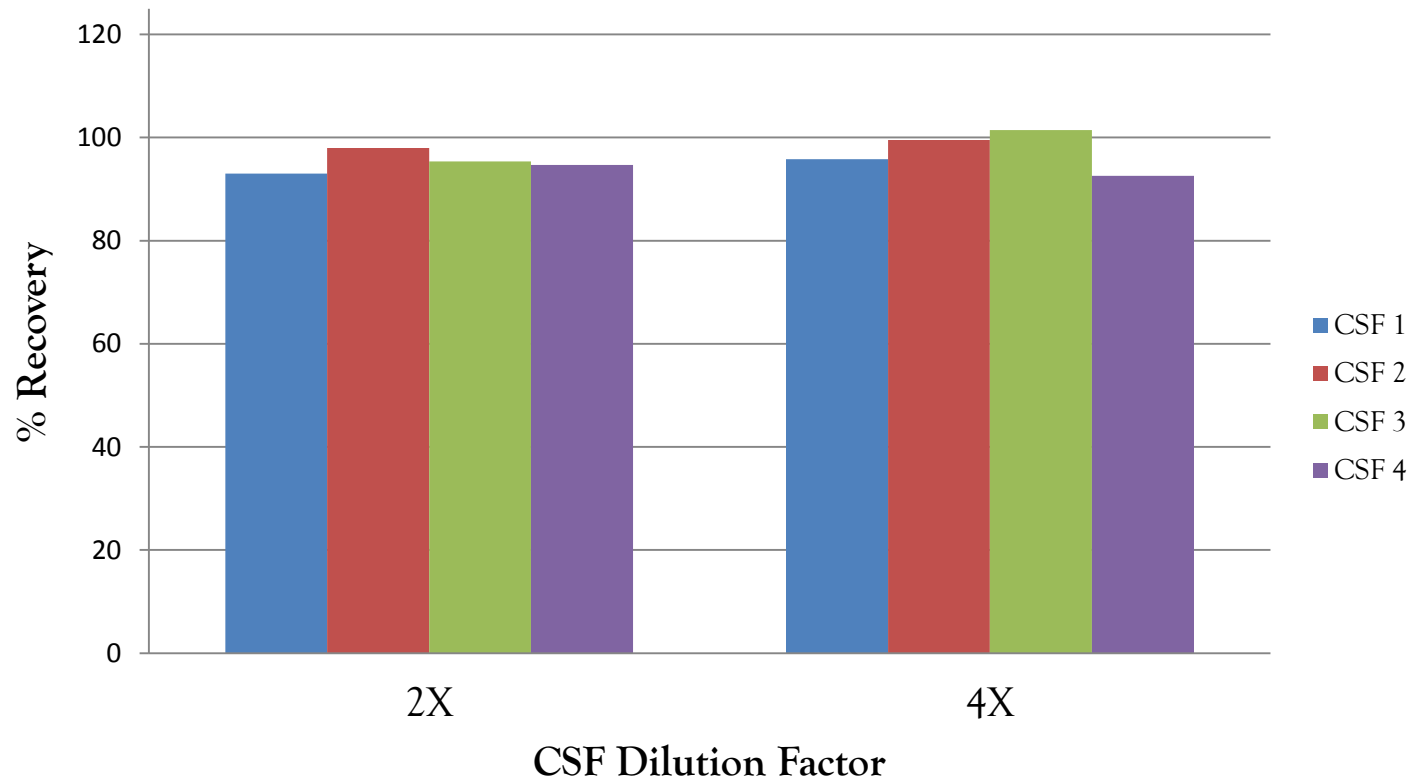
Tau Assay Precision (% CV) of Buffer Controls and Pooled CSF

n=4



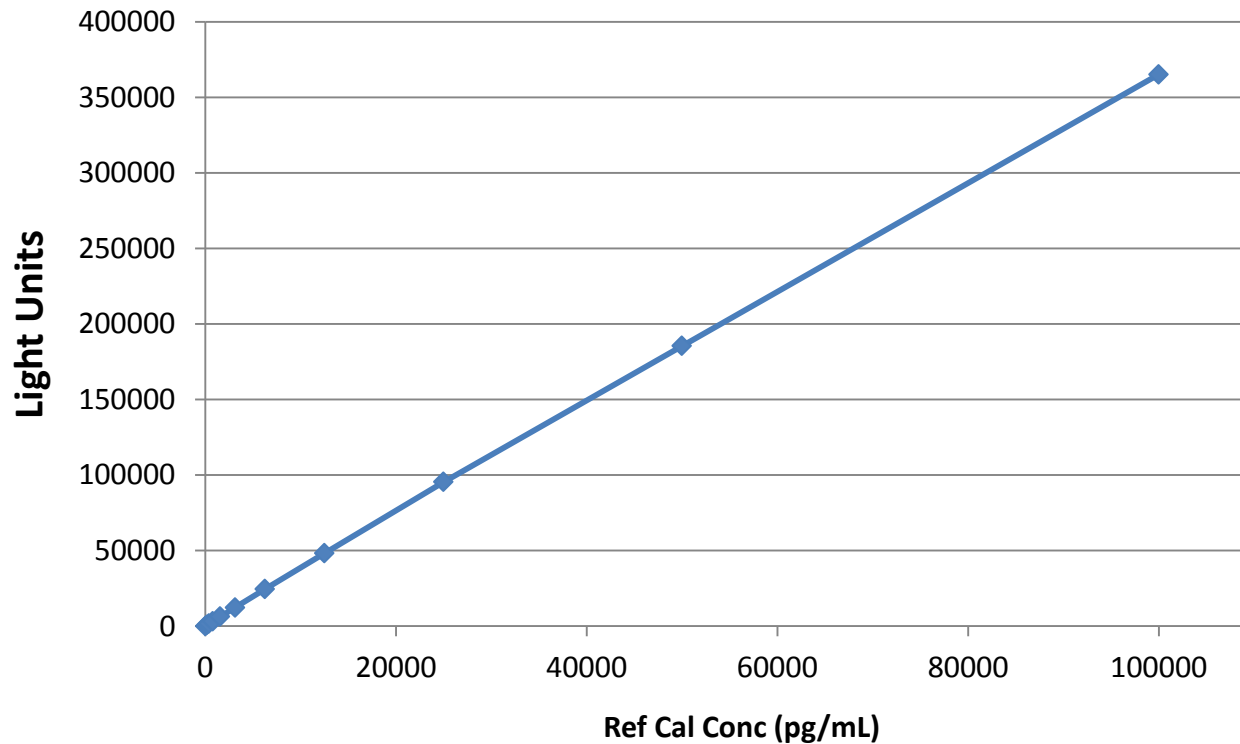
TAU CSF DILUTION LINEARITY

Dilution Of Four Individual CSF's Using OCD
High Sample Diluent B



TAU ASSAY: HIGH DOSE HOOK

Tau Assay High Dose Hook Curve



No high dose hook up to ~100,000pg/mL

UPDATE SUMMARY

- **Both assays are in Design Lock**
- **Assays exhibit linearity upon dilution**
- **No evidence of a “hook effect”**
- **Calibrators and reagents show good real time stability at 4°C**
- **Reagents and calibrators are in process development at production facility**
- **Poster at this meeting on Wednesday:
P4-346**

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