49 Adlyfe

...innovation is in our blood....

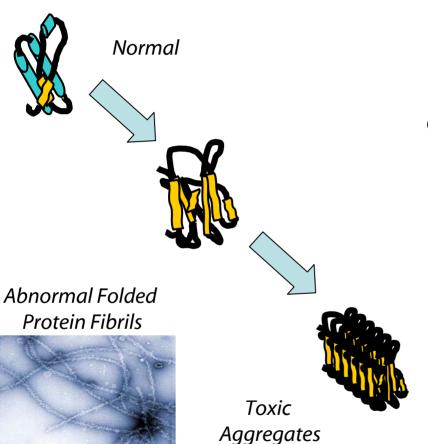


- Founded in Summer 2003, located in Rockville, MD.
- We have 12 employees, 6000 sq ft blood lab
- Revolutionary diagnostic and therapeutic blood products for improved <u>safety</u>, <u>testing</u> and <u>availability</u> of blood
- Near term opportunity in protein misfolding technology and products





Earlier Detection & Treatment of Neurodegenerative Wastings Diseases

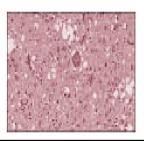


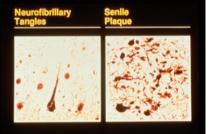
Problem:

Proteins misfold, aggregate and form fibrils and plaques



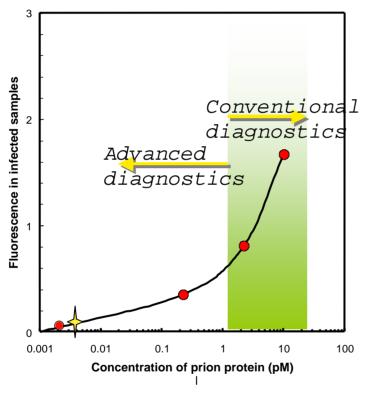
These deposit in brain tissue and are correlated to dementia, loss of brain functions and death







Conventional Diagnostics Currently Don't Meet Requirements

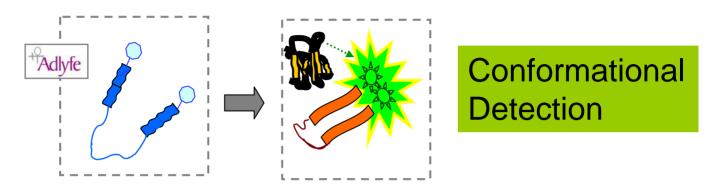


e.g. : 1 IU = 3 fM = 200,000 PrP

- Predicted levels of target proteins are too low early in the timecourse of disease for current tests
- Poor characterization of Protein 'state' in early stage disease
- Adlyfe technology measures protein misfolding events in pre-clinical and presymptomatic stage



A New Paradigm in Early Detection of TSE Diseases



Adlyfe's proprietary reagents:

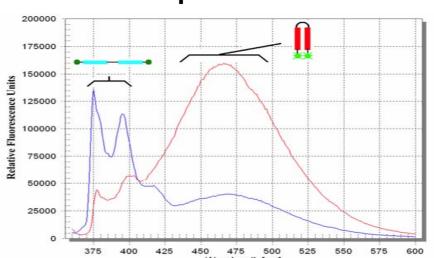
- -Are sequence matched peptides that mirror conformational regions that fold on target protein
- -Mimic protein folding events and transduce and amplify a fluorescent signal to report aggregates in the blood before disease progresses

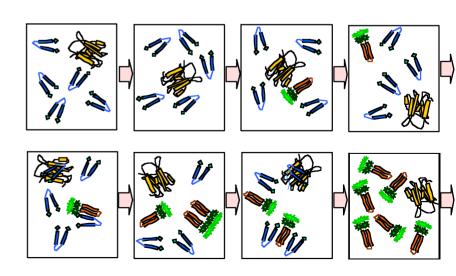


Unparalleled Sensitivity through Novel Amplification

- Adlyfe ligands associate with PrPSC and transduce signal
- •Ligands seed nucleation reaction throughout the peptide ensemble and amplify (propagate) signal
- •Thermodynamic studies published: Tcherkasskaya *et al* (2003) J. Biomolecular Structure and Dynamics 21:353-365.







MPD Assay versus Gold Standards

MPD Assay

- No Proteinase K treatment
- Relative to healthy
- Ante- or post-mortem
- Rapid / inexpensive
- 2 hrs to answer

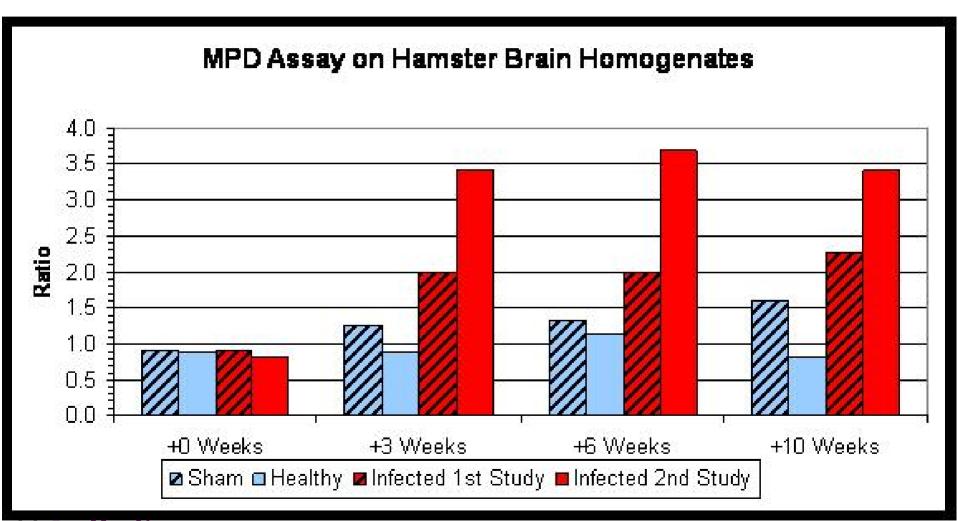
Gold Standard ELISA and WESTERN

- Requires Proteinase K*
- Post-mortem assay
- 6 to 8 hrs (ELISA)
- 8 hrs+ (WESTERN)

-*The requirement for proteinase K treatment will underestimate the amount of infectious material

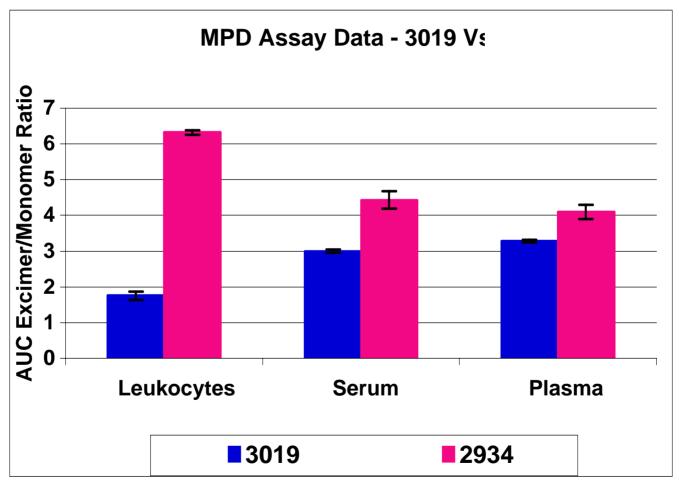


Pre-symptomatic Detection in Hamster Scrapie Model (strain 263K)



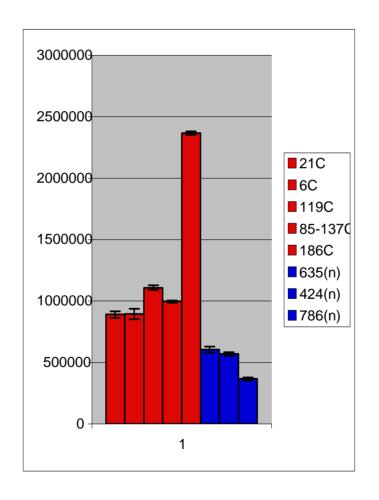


Detection in Sheep





Discrimination of sCJD in Human Plasma





Compiled MPD Assay Results:

Endemic Disease

	Diseased Sensitivity	Healthy Specificity
Sheep		
plasma	13/13	36/36
serum	39/39	9/9
Total	52/52	45/45
	100%	100%
Bovine		
plasma	20/20	19/20
	100%	95%
Human		
plasma	5/5	3/3
	100%	100%

Experimental Infection

	Diseased Sensitivity	Healthy Specificity
Hamster		
plasma	43/43	23/23
brain	88/88	50/50
Total	88/88	50/50
	100%	100%
Monkey	Coded sampes	
plasma	8/8	4/4
	100%	100%
Mouse		
plasma	5/5	
brain	1/1	1/1
	100%	100%



We are currently analyzing blinded samples in clinical and pre-clinical states of disease in sheep, humans and non- 11 primate monkeys

TSE Test Kit

- Multi-well polypropylene plate
 - target peptide
 - Reaction buffer
 - Extraction buffer
- Sequence specific ligands would create blood screen and diagnostic kits for BSE, vCJD and other neurodegenerative protein misfolding diseases
- Current focus on blood sample preparation for high throughput screening applications



