

QUANSYS BIOSCIENCES

Clinical Case Studies

PRESENTATION OUTLINE

- AVIIR
- West Penn
- ASI
- ARUP
  - Streptococcus
  - Tumor Biomarkers
- Simon Frasier University
- OHSU

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CASE STUDY # 1

- AVIIR (Irvine, CA)
  - Case Study **demonstrates correlation to other multiplex clinical panels**
  - Proprietary panel used to assess cardiac health/risk of patient
  - Used both LUMINEX and MSD products for a single point diagnostic score
  - Needed more convenient platform to integrate both panels and add additional markers: 7-Plex
  - Quansys built a single panel for their CLIA use
  - Manufactured in GMP setting
  - Saved money by compiling three panels into one panel
  - Presented by AVIIR at Emirates Cardiac Society Congress, November 7-9, 2013, UAE.

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CASE STUDY # 1

AVIIR

- AVIIR: Intra-Assay: (QBS) 2.3% vs 4.8%
  Inter-Assay: (QBS) 5.7% vs 7.3%

Analytical Sensitivity and Precision

Analyte	xMAP / MULTI-SPOT	Q-Plex
	Limit of Detection (LOD) (pg/mL)	
CTACK	3.4	6.2
Eotaxin	2.8	1.4
Fas Ligand	4.9	2.3
HGF	3.4	3.3
IL-16	1.4	7.4
MCP-3	0.5	0.2
sFas	5.5	202

	xMAP/ MULTI-SPOT	Q-Plex	xMAP/ MULTI-SPOT	Q-Plex	xMAP/ MULTI-SPOT	Q-Plex
Assay	Process Control Mean Concentration, n=19 (pg/mL)	Process Control Mean Concentration, n=10 (pg/mL)	Mean Intra Assay CV, n=2 (%)	Mean Intra Assay CV, n=2 (%)	Inter Assay CV n=19 (%)	Inter Assay CV n=10 (%)
CTACK	442	360	5	1	6	6
Eotaxin	83	73	5	4	7	6
FASL	112	77	7	2	8	5
HGF	278	350	3	2	7	8
IL-16	356	311	3	3	8	6
MCP-3	11	7	7	3	9	5
sFAS	6408	6606	4	1	6	4

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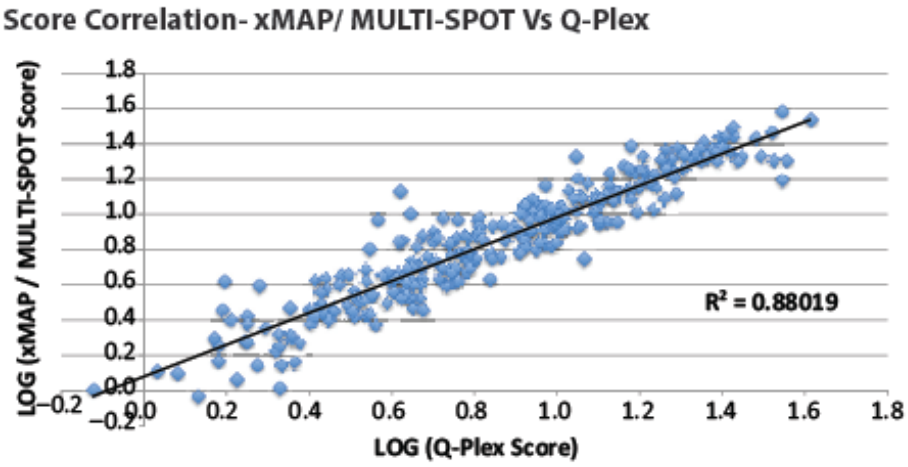
CASE STUDY # 1

- AVIIR: Luminex/MSD : Q-Plex



- Conclusions: While providing a more cost effective technology than xMAP/MULTI-SPOT, Q-Plex also combines the seven protein assays of the MIRISK VP test in one format, streamlining the testing and minimizing the hands-on time to obtain a patient's CHD risk score.

CASE STUDY # 2

- West Penn

WEST PENN ALLEGHENY HEALTH SYSTEM
A proud part of the Allegheny Health Network

Allegheny Health Network

  - Case Study **demonstrates custom development and manufacture to clinical standards.**
  - Panel of 4 assays called B-AMP panel; screened 3700 biomarkers to find these 4
    - (biglycan, myeloperoxidase, annexin-A6 and protein S100-A9
  - Proteins involved in Esophogeal Cancer diagnosis
  - 5 year survival rates are less than 15%
  - Other diseases diagnosed as well: Gastroesophogeal Reflux Disease, Barrett's Esophogus and high-grade dysplasia
  - Product to be used in CLIA lab

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CASE STUDY # 2

WEST PENN ALLEGHENY HEALTH SYSTEM
A proud part of the Allegheny Health Network

Allegheny Health Network

- Precision: 5.3-14.5% Inter-assay CV,
  6.8-13% Intra-assay CV
- Recovery: +/- 20%
- "We are excited and very optimistic about how this biomarker panel could be used to help patients, from early detection in at-risk patients, to risk-monitoring for patients with conditions that may lead to esophageal cancer, to monitoring the disease course in patients with cancer," said Ali Zaidi, MD, Director of Research at the AHN Esophageal and Thoracic Institute.

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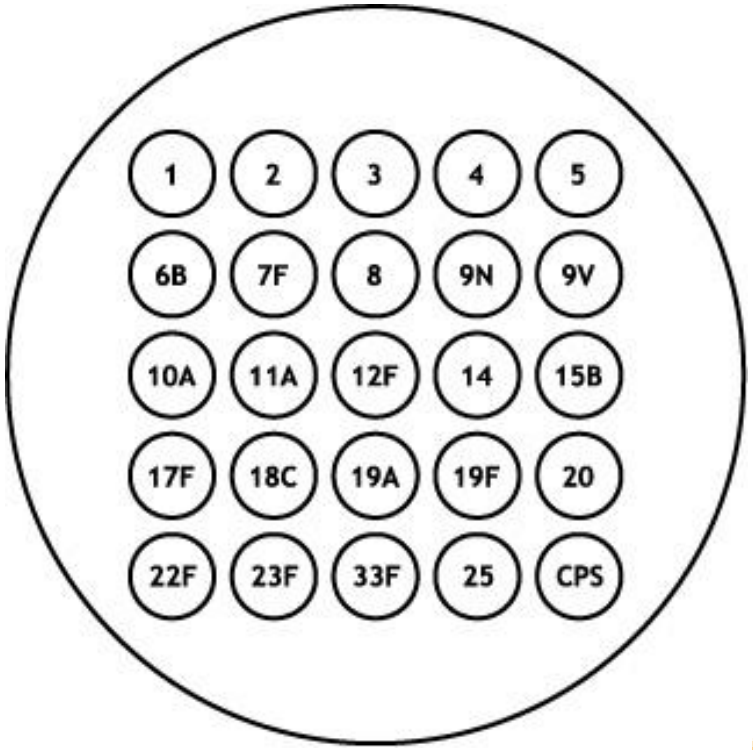
CASE STUDY # 3

ARUP

- Case Study **demonstrates custom development and manufacture to clinical standards.**
- Collaboration with ARUP Laboratories Inc. Salt Lake City, Utah
- Testing for antibodies to each of the different serotypes of *S. pneumoniae*
- Tested standardized Goldblatt samples in comparison to Luminex and WHO standardized ELISA
- Specs: Custom Software and Imager built
- Rapid Assay Time: 15 minute array



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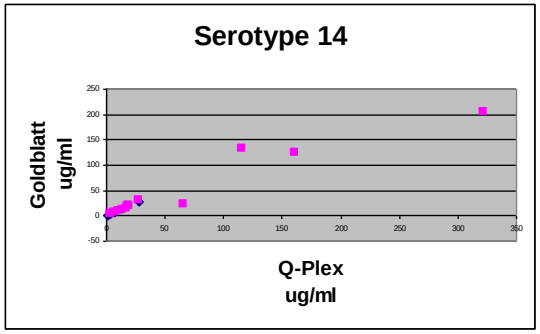
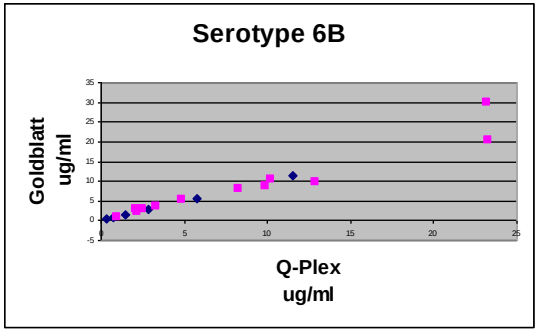
CASE STUDY # 3

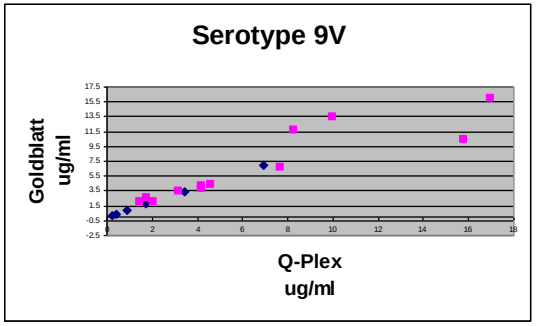
ARUP

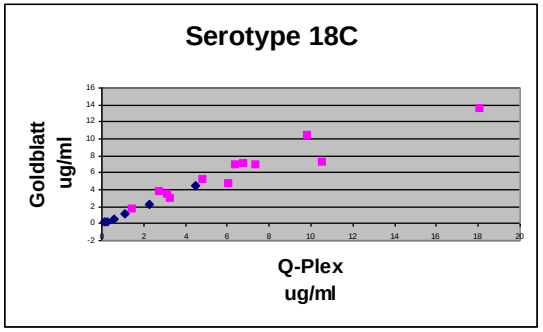
WHO Comparison Data

- Goldblatt samples: 12 sera samples used as standards
- Pneumococcal testing for WHO protocol validation
- Acceptance 8/12 samples <40% error









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CASE STUDY # 3

- ARUP

WHO Comparison Data

Quansys & Luminex Comparison Data (R^2)

	PnPs 4	PnPs 6B	PnPs 9V	PnPs 14	PnPs 18C	PnPs 23F	PnPs 19F
Quansys to WHO	0.77	0.90	0.82	0.92	0.90	0.69	0.97
Luminex to WHO	0.71	0.44	0.60	0.89	0.09	0.20	0.95

Quansys R^2 average = 0.85

Luminex R^2 average = 0.55

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CASE STUDY # 3

- ARUP

WHO Comparison Data

	4	6B	9V	14	18C	19F	23F	
A	12	12	10	12	11	12	11	95%
B	11	12	12	10	11	9	11	90%
C	9	6	11	12	11	9	12	83%
D	7	11	12	9	8	12	10	82%
E	11	7	9	8	11	7	9	74%
ARUP-Luminex	7	11	10	9	9	8	7	73%
Quansys	9	11	12	11	11	10	10	88%

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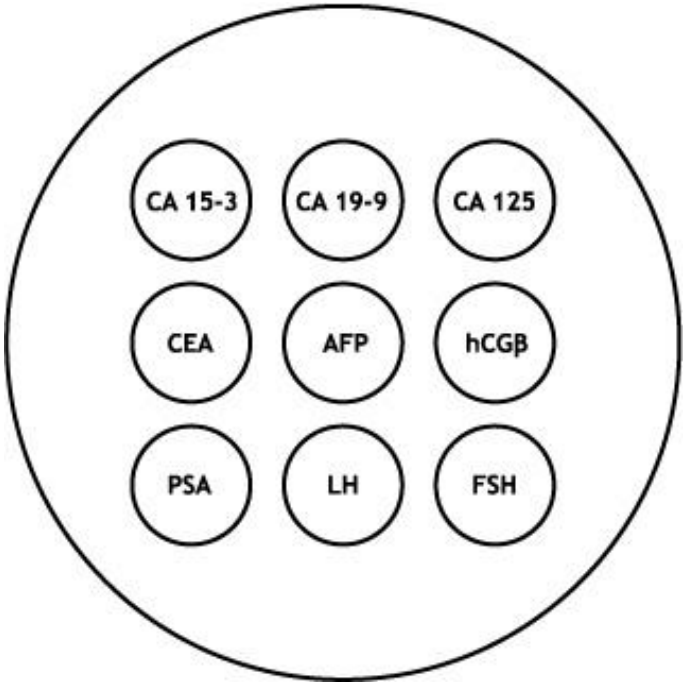
CASE STUDY # 4

- ARUP
  - Case Study **demonstrates custom development and manufacture to clinical standards.**
  - 9 tumor markers: CA 15-3, CA 19-9, CA 125, CEA, AFP, hCGβ, PSA, LH and FSH
  - Blindly tested 414 pre tested serum samples from ARUP Laboratories, SLC, Utah
  - Compared Quansys results to ARUP to validate assay



* Biotechniques. 2007 Mar;42(3):327-8, 330-3

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CASE STUDY # 4

- ARUP

Problem: Specificity of current markers. False positive and negative responses

Increase in CA 125

- After Dialysis
- Endometriosis
- Obesity
- Mitral Valve Stenosis

Increase in CA 15-3

- After Dialysis
- Menstrual Cycles
- Primigravida Pregnancy
- Hypothyroid

"It is well known that the sensitivity and specificity of currently used tumor markers can be improved if multiple tumor markers are measured."

James T. Wu Ph.D. University of Utah
(Circulating Tumor Markers of the New Millennium, 2002)

* Biotechniques. 2007 Mar;42(3):327-8, 330-3

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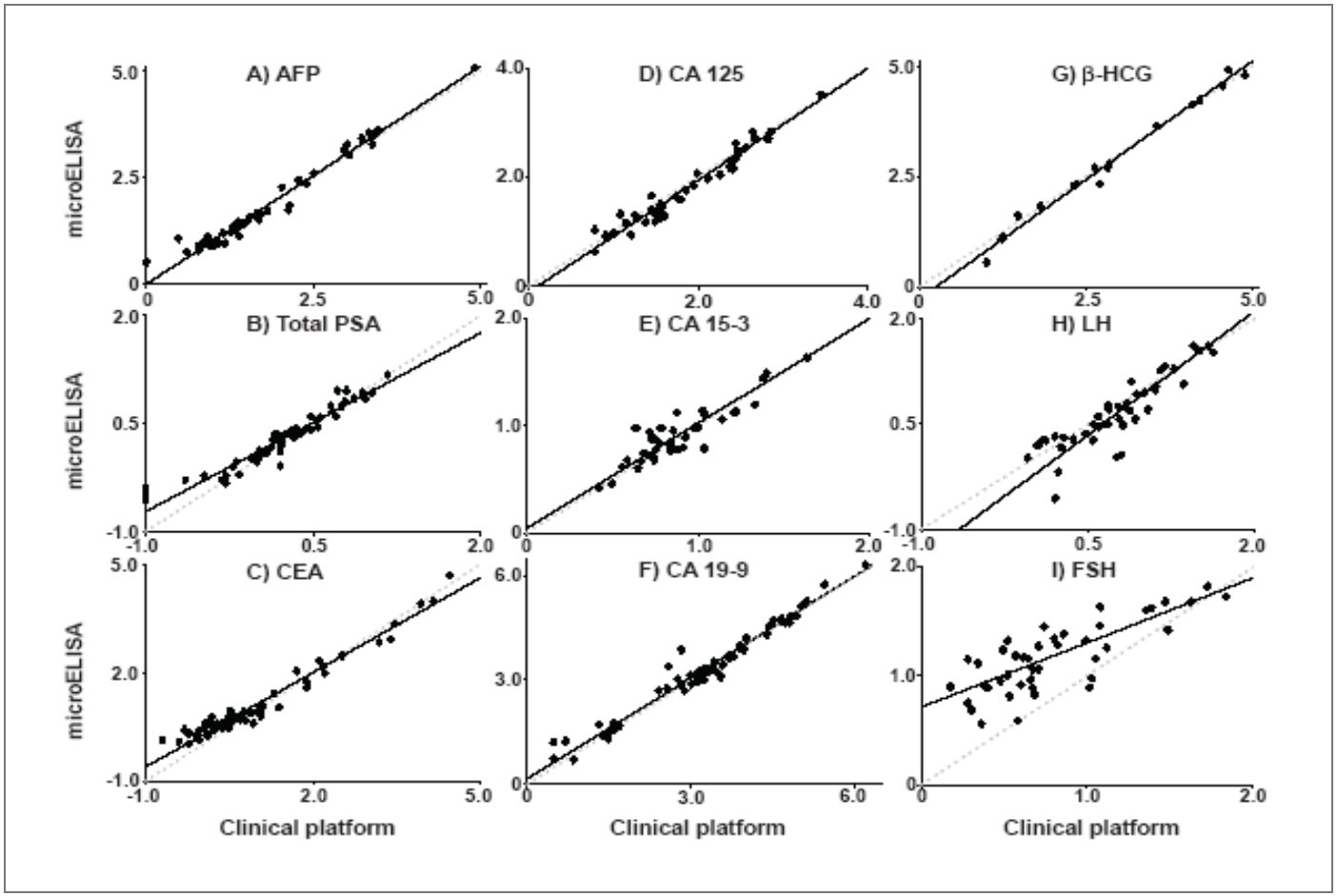
CASE STUDY # 4

- ARUP

  Quansys Array verses ARUP Plot of Residuals



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* Biotechniques. 2007 Mar;42(3):327-8, 330-3

CASE STUDY # 5

SFU

- Case Study **demonstrates custom development and manufacture to clinical standards.**
- Simon Fraser University, BC, Canada
- Female Reproductive Health: Urine samples from Guatemala
- Adiponectin, Cortisol, E1G, FSHb, HCGb, and C-Peptide
- Three sandwich ELISAs and three competitive assay in one well
- Testing in parallel to Bayer ACS:180 Clinical Analyzer
  - Pearson Correlation Coefficient: (≥0.75)
- Am J Hum Biol. 2012 Jan-Feb;24(1):81-6. doi: 002/ajhb. 21229. Epub 2011 Nov 28.

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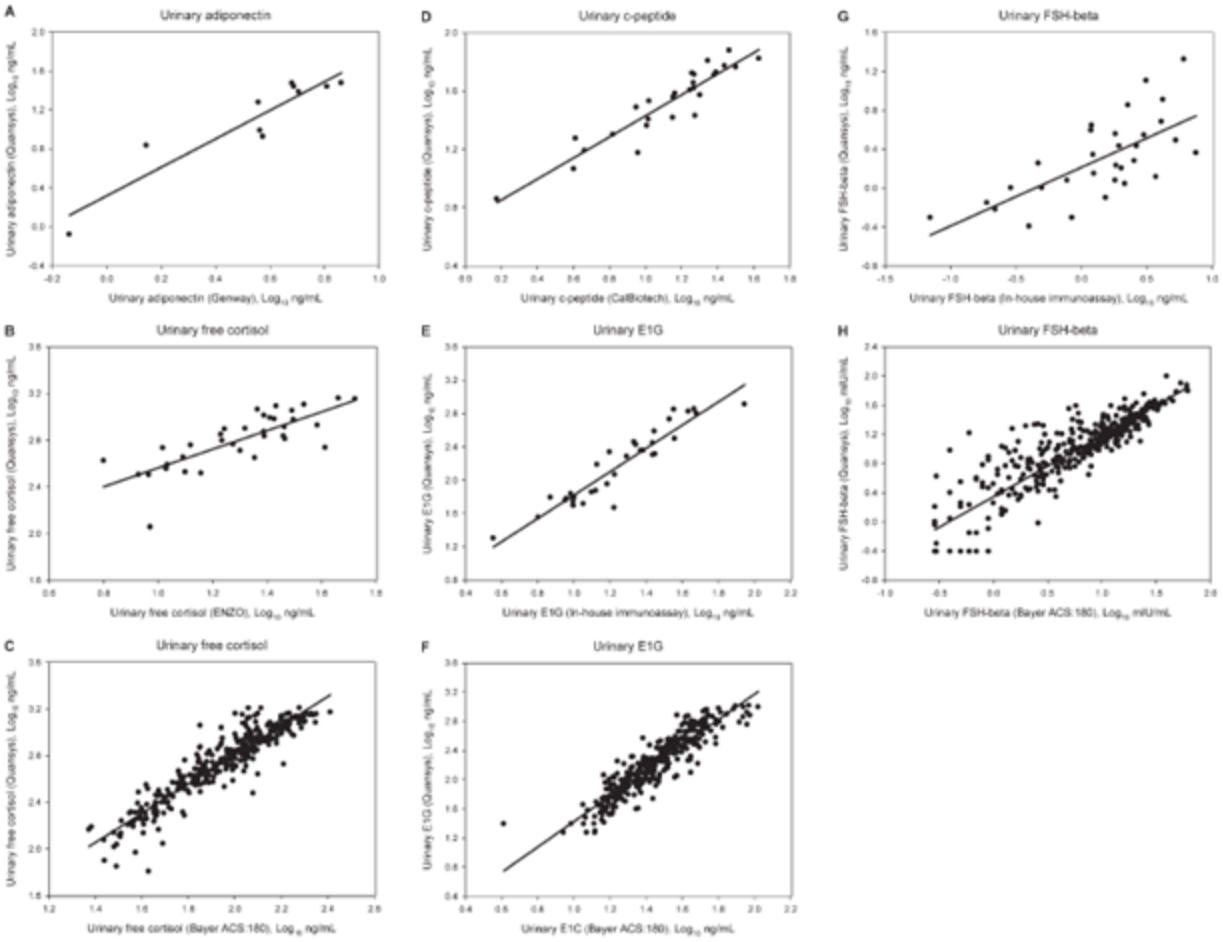
CASE STUDY # 5

SFU

- Correlation between two methodologies



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CASE STUDY # 5

SFU

- Assay Performance: Sensitivity and Reproducibility

	Quansys Multiplex			Traditional ELISAs		
	Sensitivity	Intra-Assay CV	Inter-Assay CV	Sensitivity	Intra-Assay CV	Inter-Assay CV
Adiponectin	0.023 ng/ml	10%	6.90%	0.156 ng/ml	4.4%	6.2%
Free Cortisol	0.343 ng/ml	7.30%	8.50%	0.057 ng/ml	10.5%	13.4%
C-Peptide	0.090 ng/ml	9.30%	7.70%	2 ng/ml	3.9%	8.5%
E1G	0.252 ng/ml	9.70%	8.20%	1.45 ng/ml	7.9%	8.5%
FSHb	0.017 ng/ml	7.20%	7.30%	0.143 ng/ml	3.8%	6.5%
HCGb	0.035 ng/ml	7.10%	7.50%	0.003 ng/ml	3.5%	5.8%

- Summary: “This multiplex technology provides a more economic, rapid, and ecologically sound alternative to individual assays for studies requiring the measurement of multiple biomarkers per biospecimen.”

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CASE STUDY # 6

- Case Study **demonstrates advantages to other multiplex panels**
  - Quansys and Aushon (plate based)
  - RayBiotech (slide based)
  - Milliplex (bead based)
- Oregon Health Sciences University (OHSU), Portland, OR
- Samples from inner and middle ear tissues from mice.
- Evaluated assays: IL-1a, IL-1b, and IL-6, TNFa, GMCSF and IL-10.
- Hear Res. 2011 May;275(1-2):1-7. Epub 2010 Dec 7
- Evaluated:
  - Sensitivity
  - Linearity
  - Concordance to R&D Systems ELISAs
  - Cost effectiveness
  - RT-PCR correlation (SA Biosciences)

CASE STUDY # 6

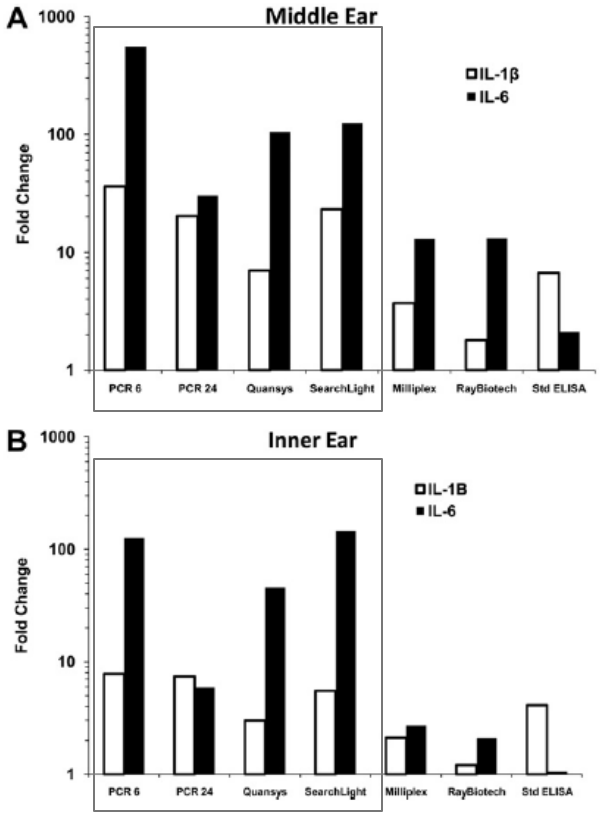
- Array Performance:

Test	Quansys	Aushon	Milliplex	RayBiotech
Sensitivity	“greatest sensitivity”	“greatest sensitivity”	“lower sensitivity”	“lower sensitivity”
Linearity	“reliably measured”	-	-	-
R&D ELISA Concordance	“greater sensitivity”	“more sensitive”	“more sensitive”	“more sensitive”
RT-PCR	“matched closely”	“matched closely”	-	-
Cost Effectiveness	“Cost Effective”	-	-	-

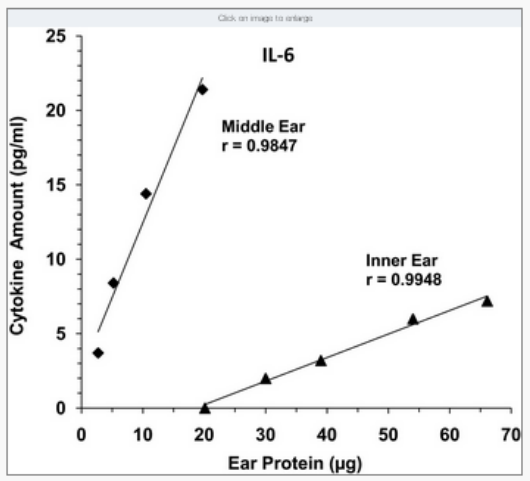
CASE STUDY # 6

OREGON HEALTH & SCIENCE UNIVERSITY

- RT-PCR correlation



- Linearity at low range of IL-6 for Quansys



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CASE STUDY # 6

- Conclusions

  "Thus, the multiplex ELISA procedures appear suitable and reliable for the study of hearing related proteins, providing accurate, quantitative, reproducible results with considerable improvement in sensitivity and economy."

Questions?

Please contact Quansys at
1-888-782-6797
or info@quansysbio.com

Thank You!

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