

Saliva as a sample matrix for rapid, quantitative diagnostics in low resource settings



AACC Emerging Technologies Conference
San Jose, April 24, 2014
Courtney Nicholson



Overview

- Low resource requirements
- Saliva as a sample matrix
- AgPlus platform
- Results



Company

- 9 staff (6 science based)
- Compliant to ISO13845
- Business to Business commercial model
- Working across human, vet, sports, wellness diagnostics



AgPlus technology

Ag+ have developed a

- Handheld diagnostic platform technology
- Patented electrochemical immunoassay biosensor
- Delivering the next generation in rapid, quantitative diagnostics



Development objective

Develop saliva based assay that

- Removed mains powered mechanical sample processing
- Can be used in Point of Care setting
- Can be carried out by unskilled/semi-skilled users
- Delivers quantitative results
- Time to result <10 minutes
- Can be operated in variety of environments



ASSURED Criteria

Characteristics	Specification	AgPlus system
Affordable	<\$500 for hardware <\$10 per test	
Sensitivity/Specificity	Low detection limits (assay specific)	
User friendly	1-2 days training, easy to use	
Rapid and robust	<30mins for diagnosis	
Equipment free	Compact, battery powered, on-site analysis, no sample handling, no cold chain	
Deliverable	Portable, Handheld	

Saliva as a diagnostic fluid

- Easy to obtain matrix
 - Does not need specialist training or facility
- Diagnostic relevance
 - Many biomarkers can be detected in saliva
- Abundance of matrix
 - Repeat testing samples easily taken, non invasive
- Cost effective
 - Sample can be obtained with low tech devices



Saliva – the diagnostic challenge

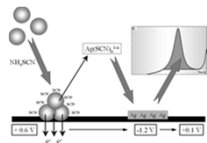
- Mucins and other high abundant proteins
- Method of removal of interfering substances
- Low concentration of target markers
- Sensitivity achieved on saliva assays

- Clinical Challenge
 - Correlation of biomarker levels to serum assays



AgPlus system

Working, integrated, portable, rapid quantitative diagnostic technology



Assay chemistry



Handheld reader



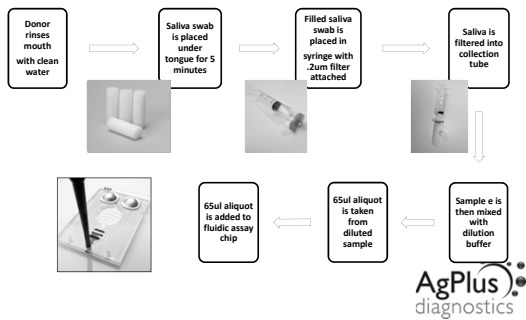
Fluidic assay chip



Technology overview

Sensitivity	Tnl – 0.1ng/ml (serum) Testosterone – 15.6pg/ml (saliva) Progesterone – 1ng/ml (plasma) Cortisol – 1ng/ml Avian Flu virus – 20 virus particles/ml Human alpha thrombin – 6ug/L ⁻¹
Analyte analysis	Monoplex and multiplex assays
Sample type	Whole blood, serum, plasma, saliva
Speed of analysis	<10 minutes
Portability	Handheld reader, battery powered. Assay chips stored at room temperature
Multiple detection formats	Immunoassay and molecular detection
Ease of use	Simple, touch screen interface

AgPlus saliva collection and preparation



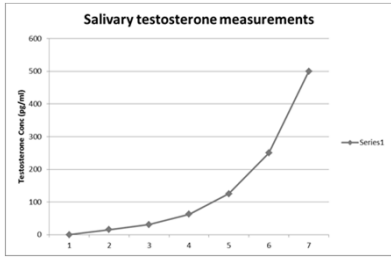
Handheld device for low resource settings



- Communication enabled
- Full assay control
- Results analysis
- Portable
- Hand-held
- Battery powered
- On-board information storage
- Customisable interface



Saliva assay results



Testosterone
Competitive assay
format



Summary

- Achieved removal of traditional mechanical sample preparation through buffering reagents
- Delivered a quantitative, portable assay using saliva matrix
- Simple to use system that can be used by variety of operators
- System achieves key ASSURED criteria for low resource settings



Thanks

- Acknowledgments
 - AgPlus staff who carried out assay development:
Fairclough L, Hutchinson E, Chard M, Penfold Y
- Contact
 - Courtney.nicholson@agplusdiagnostics.com
 - www.agplusdiagnostics.com