

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



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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

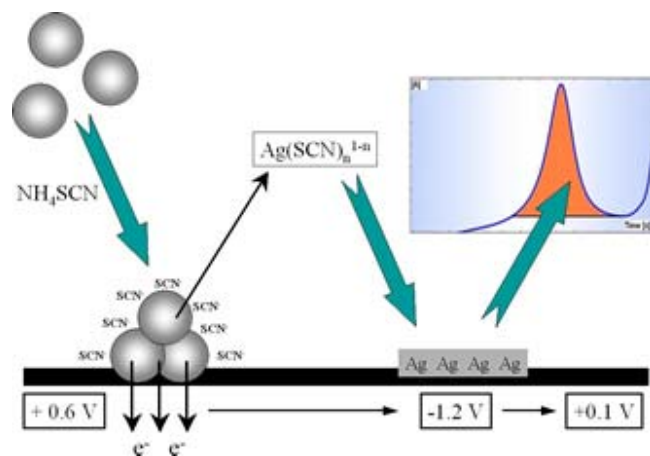
Saliva – the diagnostic challenge

- 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



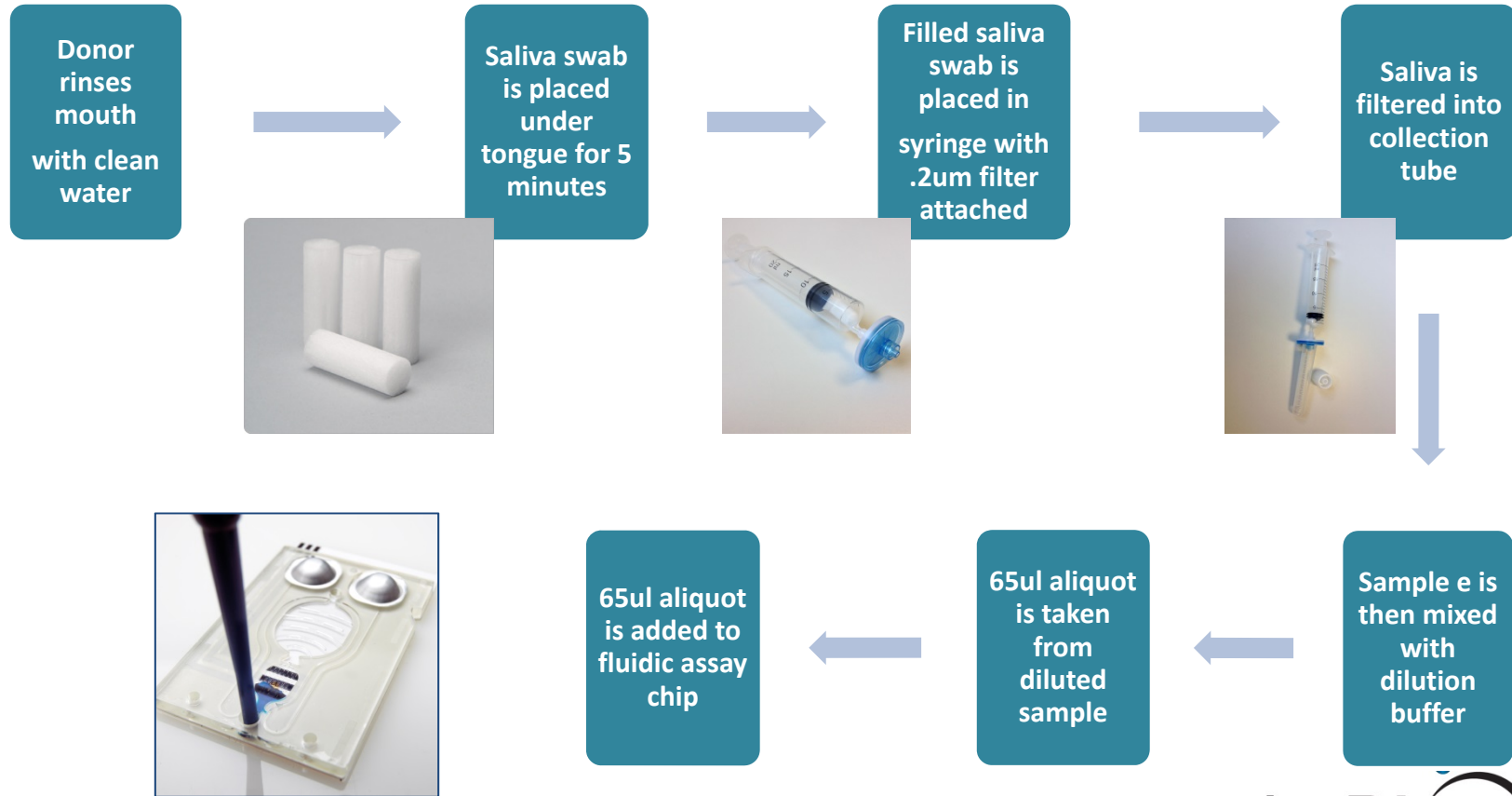
Fluidic assay chip



Technology overview

| | |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sensitivity | TnI – 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

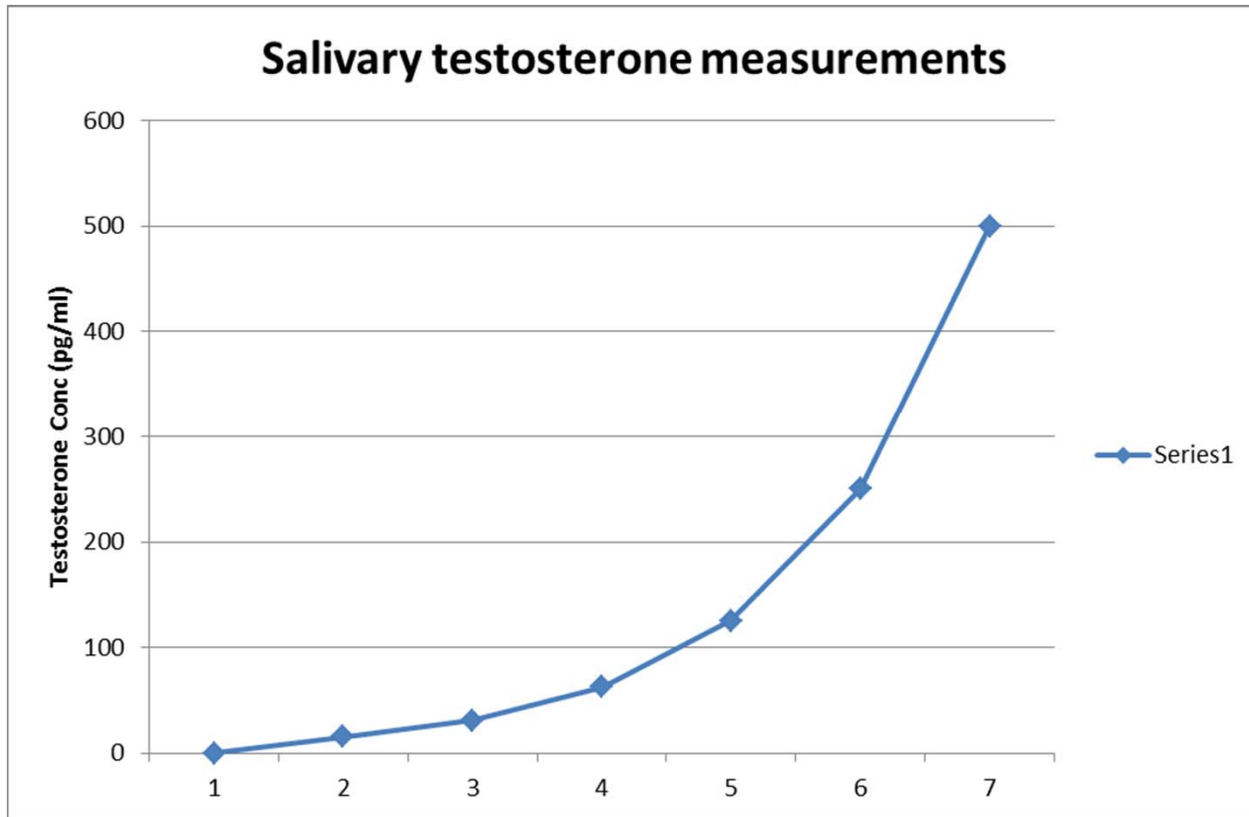


Handheld device for low resource settings



- 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

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