



BBITM

Solutions

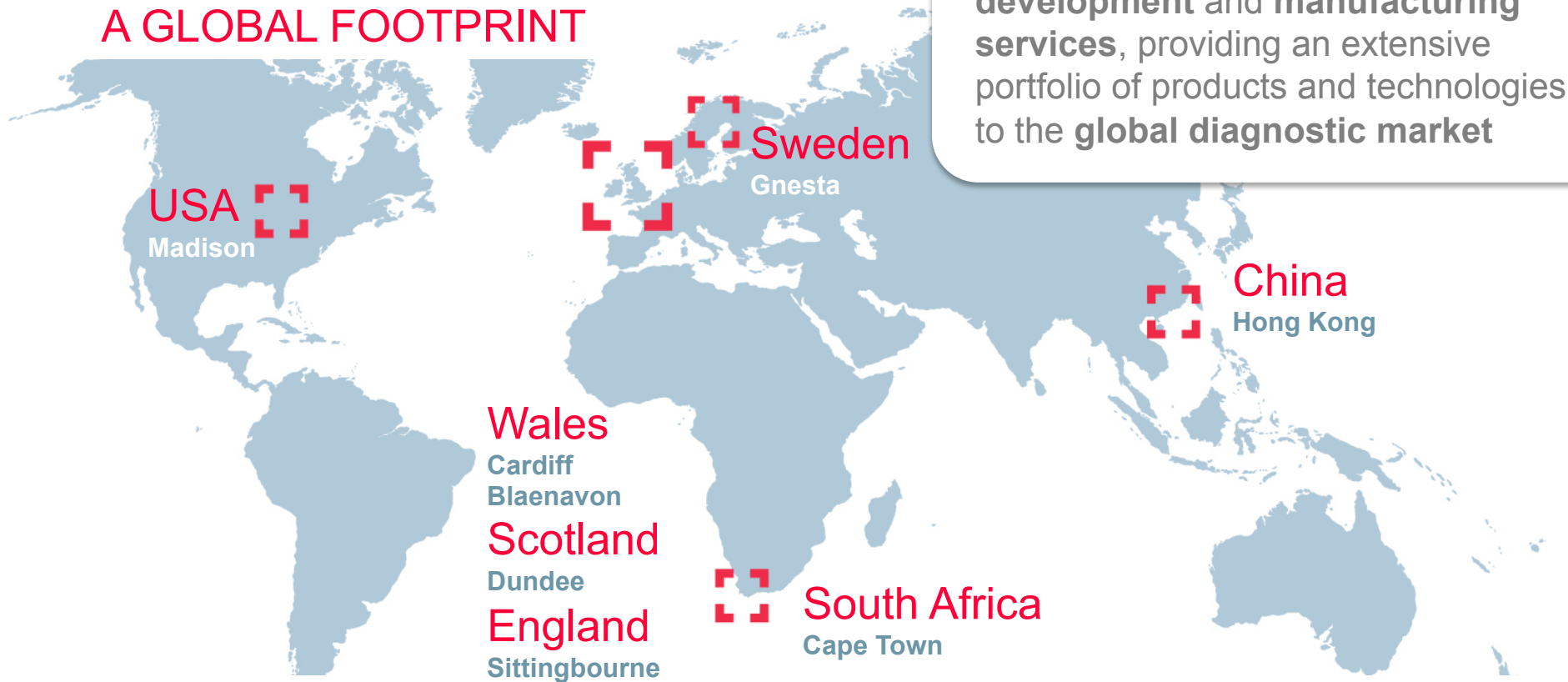
SHAPING THE FUTURE OF LATERAL FLOW

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Introduction to BBI

A GLOBAL FOOTPRINT



A leading expert in immunoassay **development and manufacturing services**, providing an extensive portfolio of products and technologies to the **global diagnostic market**

7 SUPPLY SITES
GLOBALLY

30 YEARS
EXPERTISE

FDA &
ANVISA QUALITY
STANDARDS

Reagents

Lateral Flow
Development

Lateral Flow
Manufacture

“We’re proud to have supported our customers with over 250 lateral flow development projects”

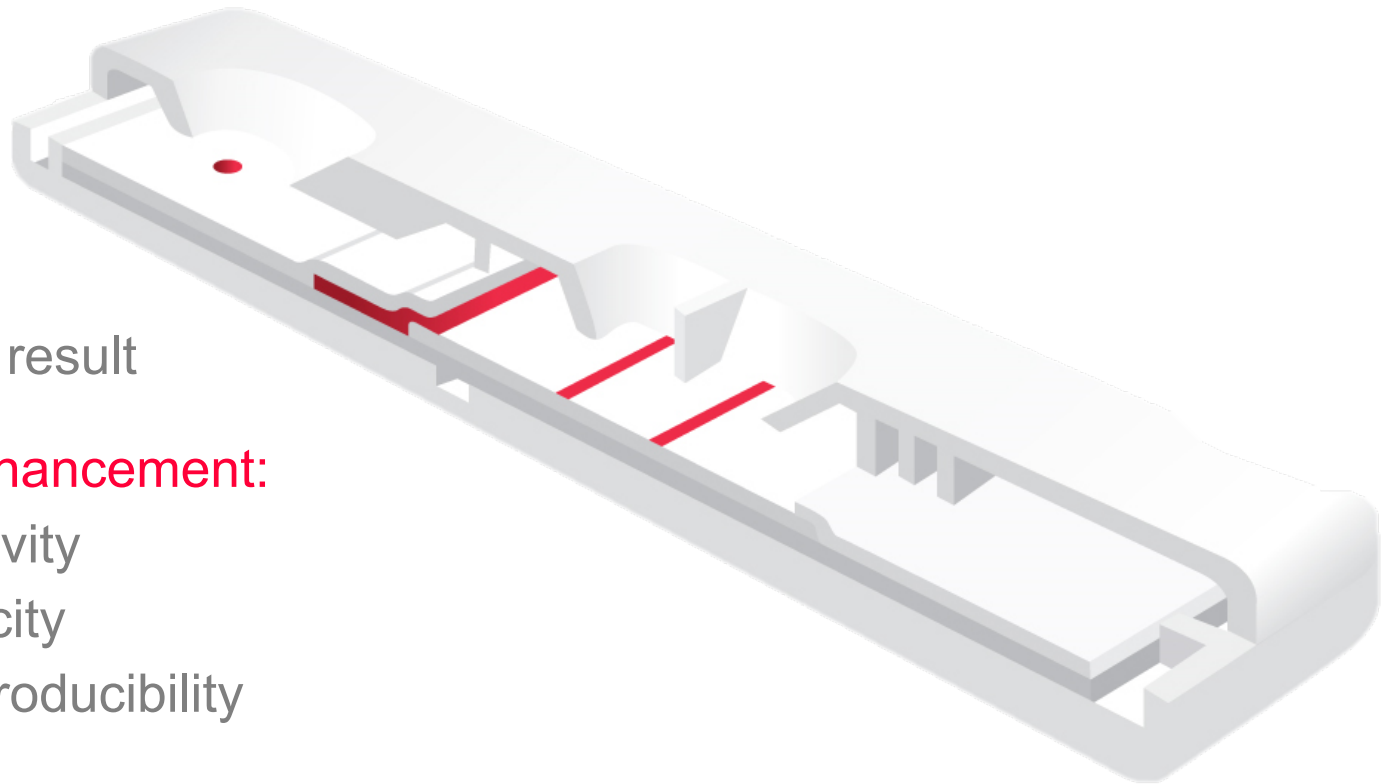
Challenges for Lateral Flow Immunoassays

Current Status:

- Cost effective
- User friendly
- Deliverable
- Rapid time to result


Performance Enhancement:

- Higher sensitivity
- Better specificity
- Improved reproducibility



Market Response

- Development of increasingly complicated tests
- Focus on improving assay sensitivity and limit of detection
- Drive for increased accuracy
- Develop enhancement technologies – need to maintain the original simplicity of the rapid test



“We’re looking for innovation around sensitivity”

Director of Operations

“I want to see next-generation technology, so we can offer something new to our customers allowing them to compete in their market place”

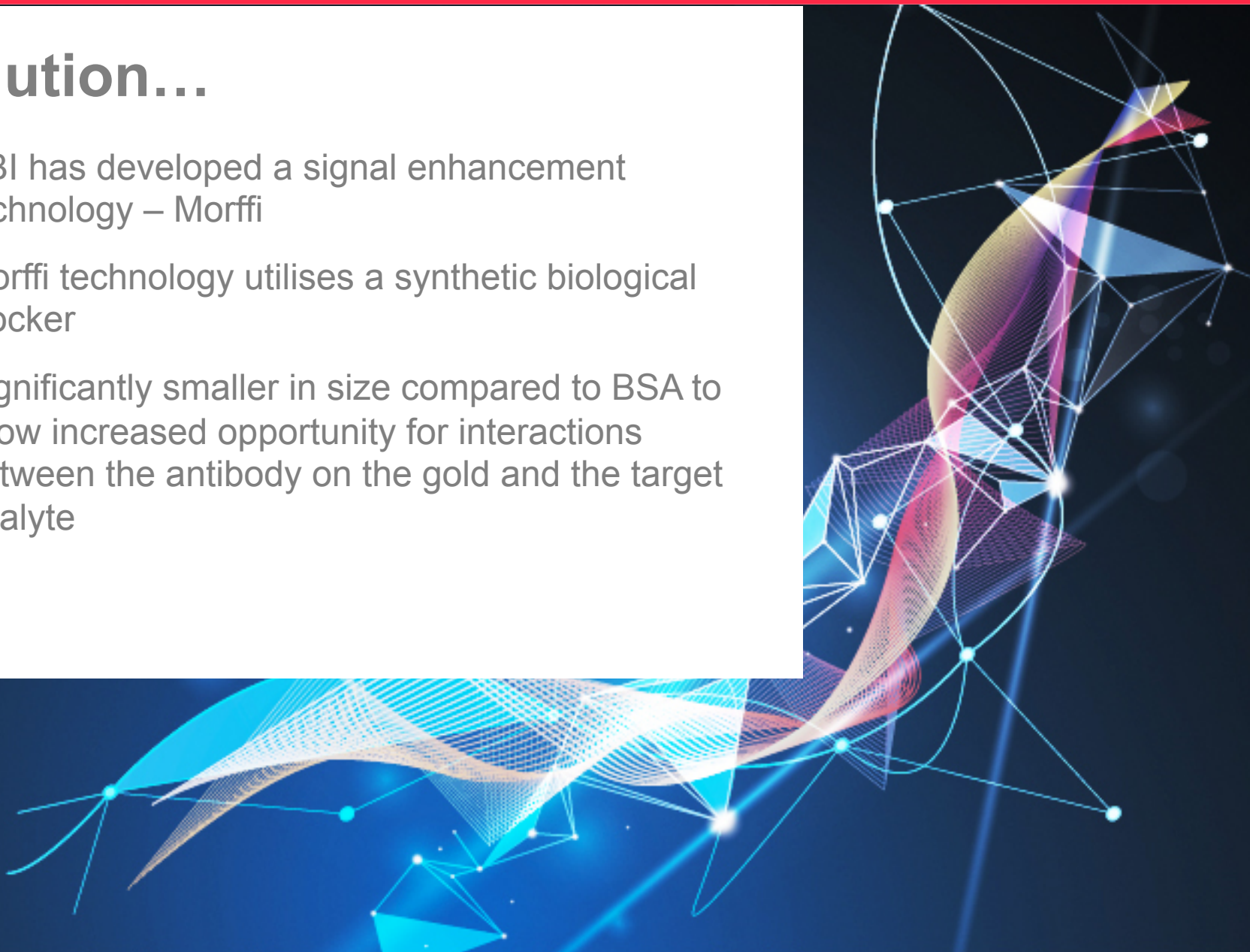
Deputy Director

Focus on Signal Enhancement

- **LF blocking technology** – in the conjugation process a blocking agent is used on the label after antibody/antigen binding to prevent NSB
- **Industry standards** – majority of conjugates are blocked with BSA
- **BSA problems**
 - Cross reaction
 - may hinder the availability of antibody on the label surface due to its size
 - Batch inconsistency
- **Alternative blockers** – agents such as fish gelatin, PEG and casein all suffer from lot to lot variability

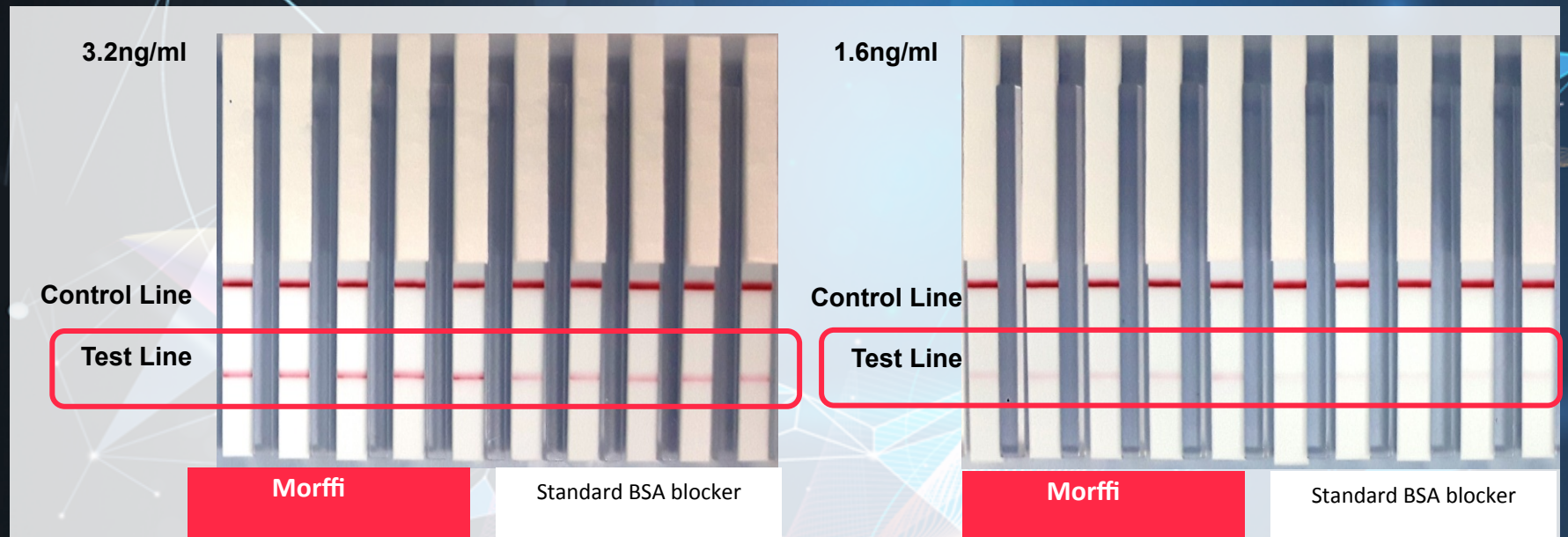
Solution...

- BBI has developed a signal enhancement technology – Morffi
- Morffi technology utilises a synthetic biological blocker
- Significantly smaller in size compared to BSA to allow increased opportunity for interactions between the antibody on the gold and the target analyte

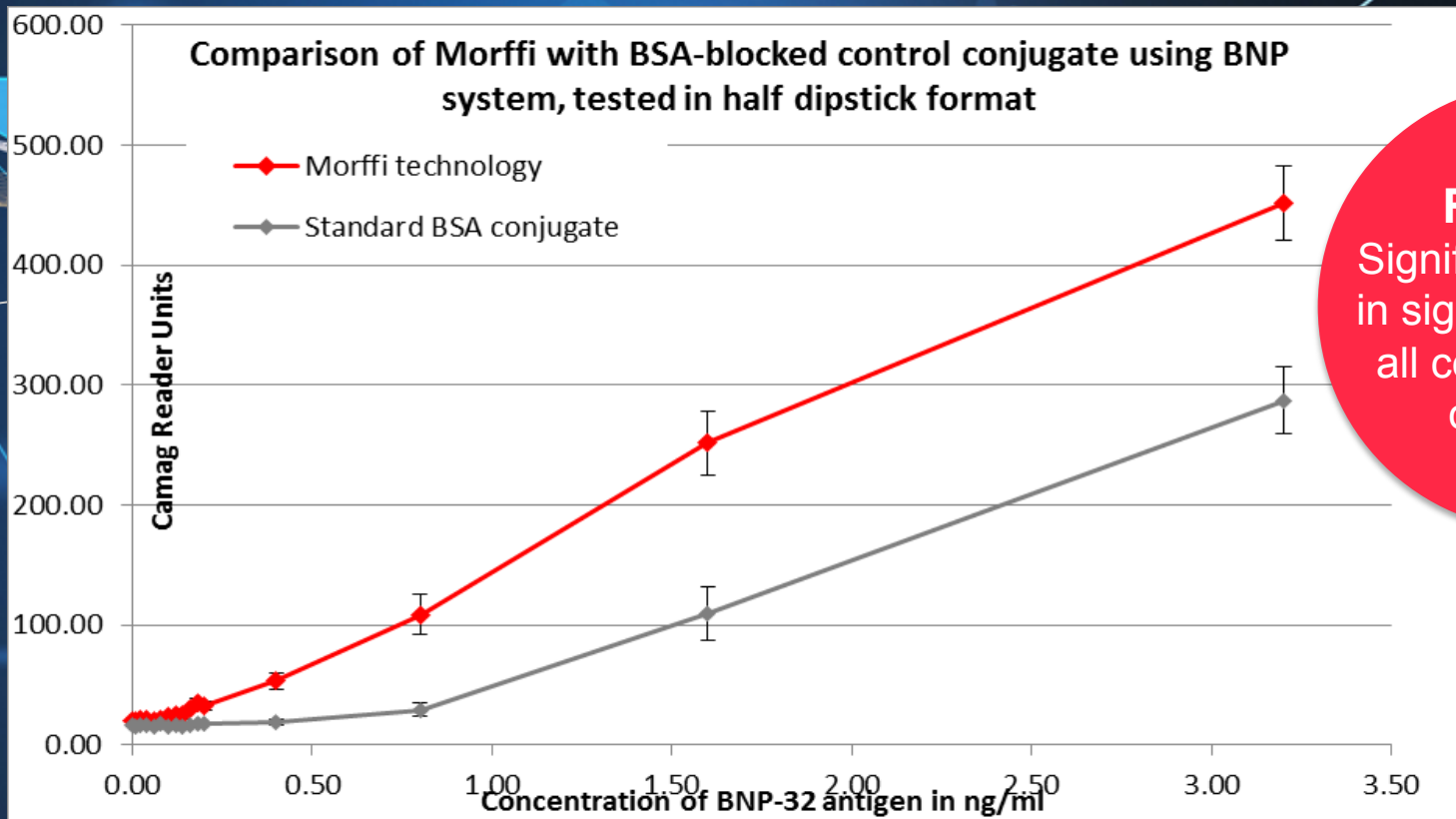


Improved signal intensity

Morffi conjugate and BSA blocked conjugates were run using a half dipstick method n=5

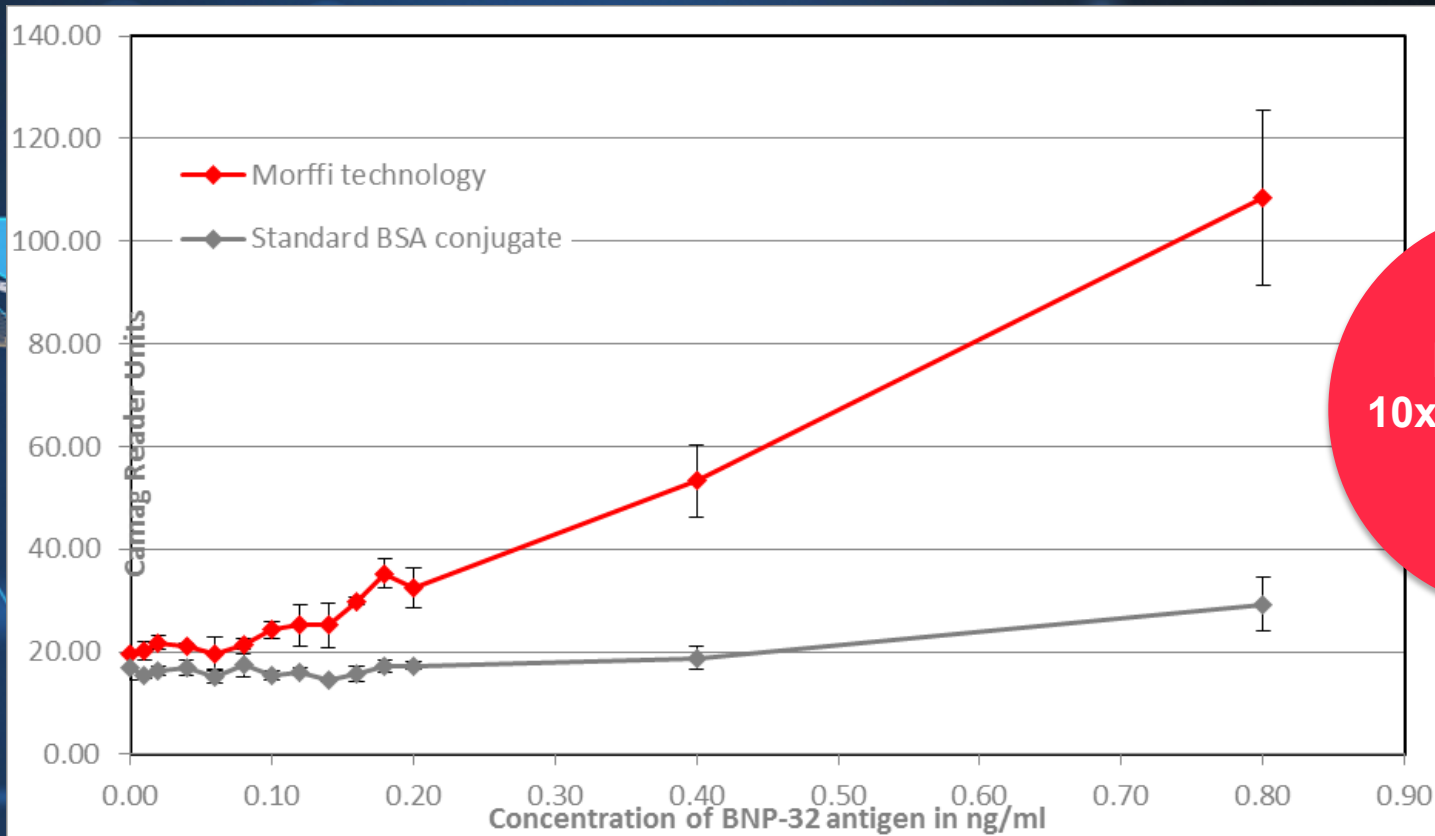


Improved Signal Intensity



RESULT:
Significant increase in signal intensity at all concentrations of antigen

Improved Limit of Detection



RESULT:
10x improvement
in LOD

The Limit of detection produced using Morffi™ is 0.08ng/ml BNP-32 antigen, whilst the BSA-blocked control conjugate allowed a Limit of detection of 0.8ng/ml BNP-32

Morffi Advantages:



Up to 10x increase in sensitivity



Improved signal intensity

Stronger signals generated at the current limit of detection for your test



Faster time to result

Stronger signals gives faster rate to result



BSA Free

No cross reaction



Simple, fast and inexpensive development

No requirement to change assay format, materials or complexity

Morffi Application

- Demonstrated on polyclonal and monoclonal antibodies
- Assessed in sandwich and competitive assay formats
- Robustness of different batches of conjugate
- Large scale conjugate manufacture demonstrated
- Excellent stability of conjugates comparable to BSA blocked



Examples where Morffi can be utilised

- Need for lower LOD in existing test – simple swap out
- Qualitative assay where no requirement for LOD but stronger test line signal beneficial
- Veterinary test where BSA will cross react
- Bio-warfare test where time to result is critical to limit potential exposure



Morffi joins our Lateral Flow Portfolio alongside:



AtomoRapid™



no-varum™
mobile reader solutions

Conclusion

- Lateral Flow market is evolving into:
 - Quantitation of results
 - Improved **sensitivity** and **specificity**
 - Requiring increasing assay reproducibility
- Exciting opportunities for innovation in the market
- BBI Solutions are...

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