

Getting to the Heart of Cardiac Disease Tests



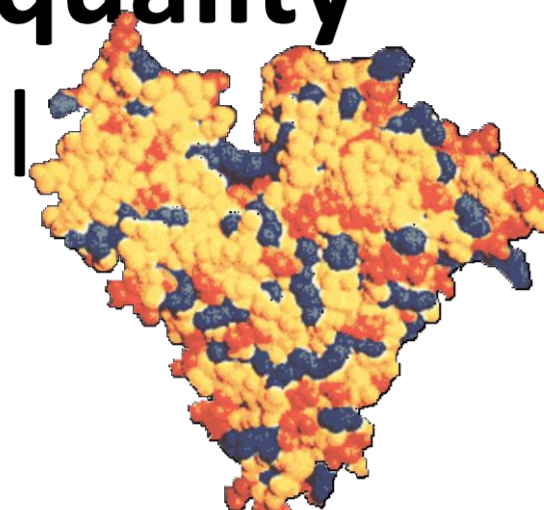
Tess Saltmarsh, PhD

Cardiff University & Ortho Clinical Diagnostics

Ortho Clinical Diagnostics
a Johnson & Johnson company

KTP Project

To determine the **role** and **critical-to-quality** characteristics of the key raw material Bovine Serum Albumin (**BSA**)



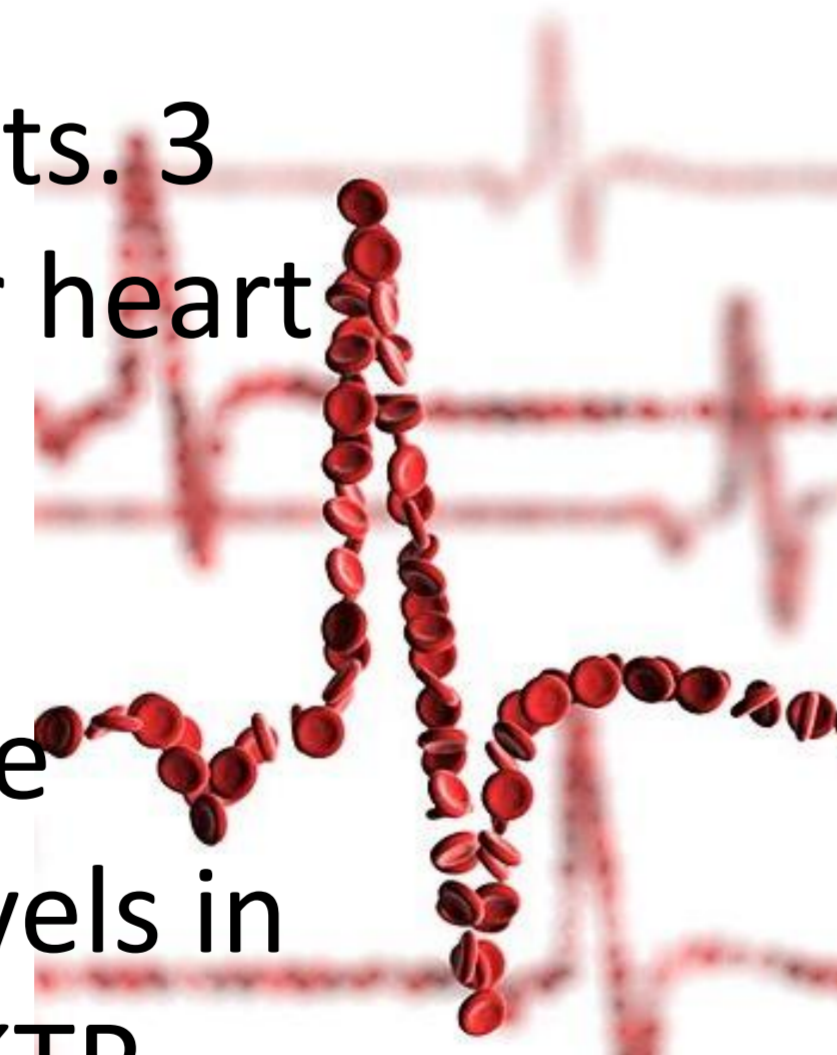
Ortho-Clinical Diagnostics (OCD) make tests for ~50 different disease conditions, ranging from cancer markers to hormone levels.



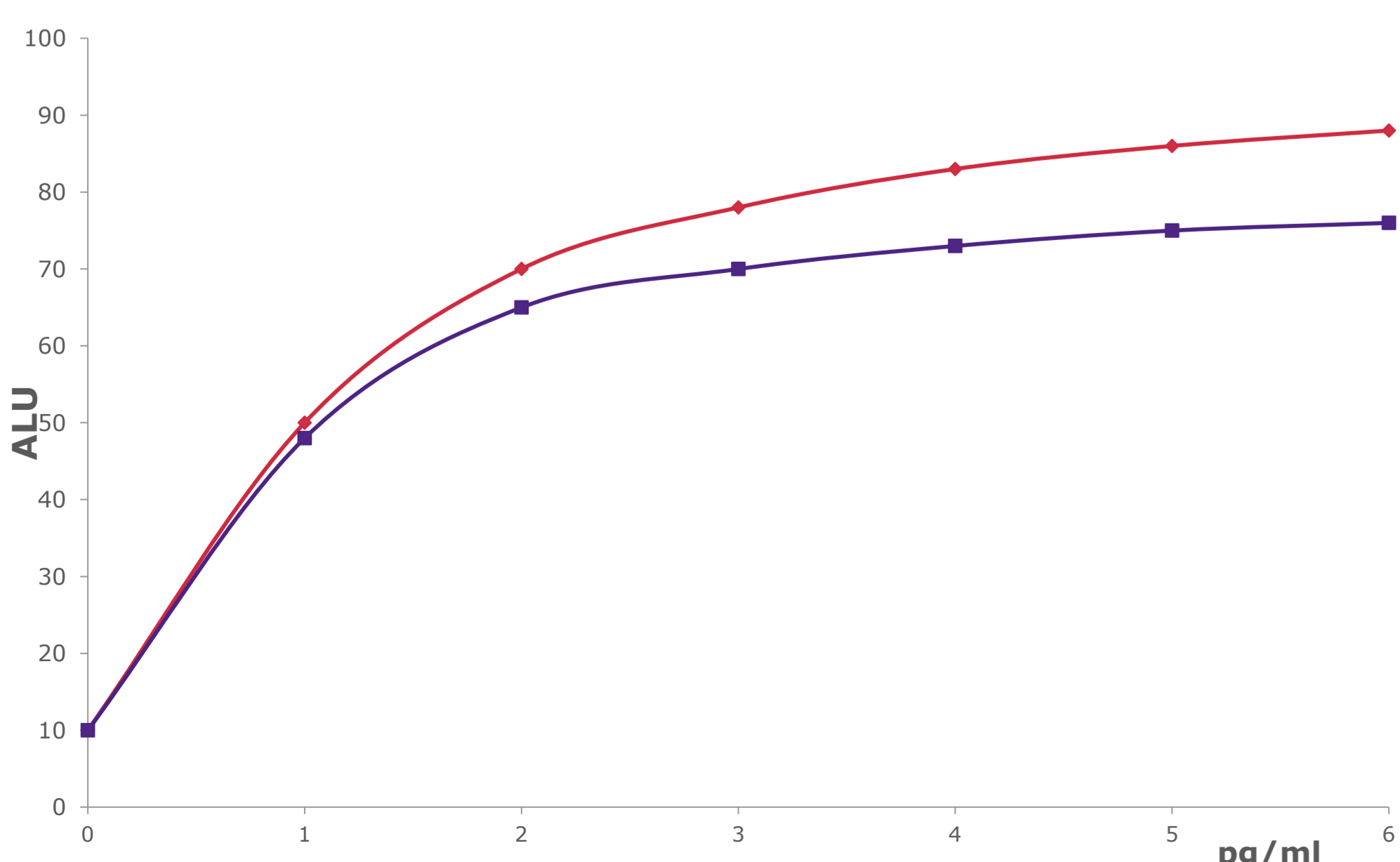
BSA is a key component in OCDs tests. It works to keep other components **stable** and maintain the **sensitivity** of the test.

Cardiac Disease Test

OCD make 4 different heart disease tests. 3 are for acute heart attack. The 4th is for heart failure – **NTproBNP**.



BSA affects stability of NTproBNP in the calibrators that are used to quantify levels in the test, but it is not known how. The KTP partners are investigating this.



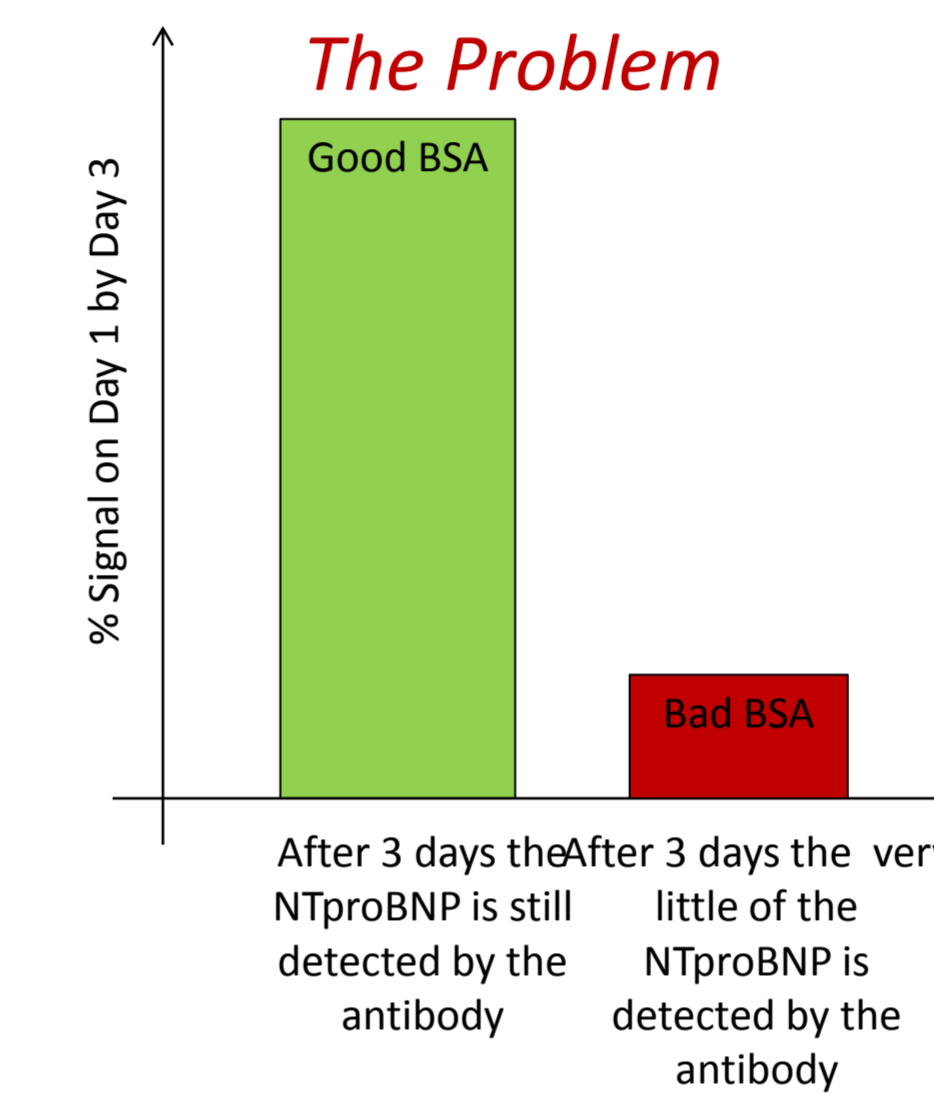
The Partnership

Investigating the role of BSA disease tests, including at the heart of cardiac tests
Each Partner brings skills and resources and gains benefits as outlined.

Ortho Clinical Diagnostics
a Johnson & Johnson company



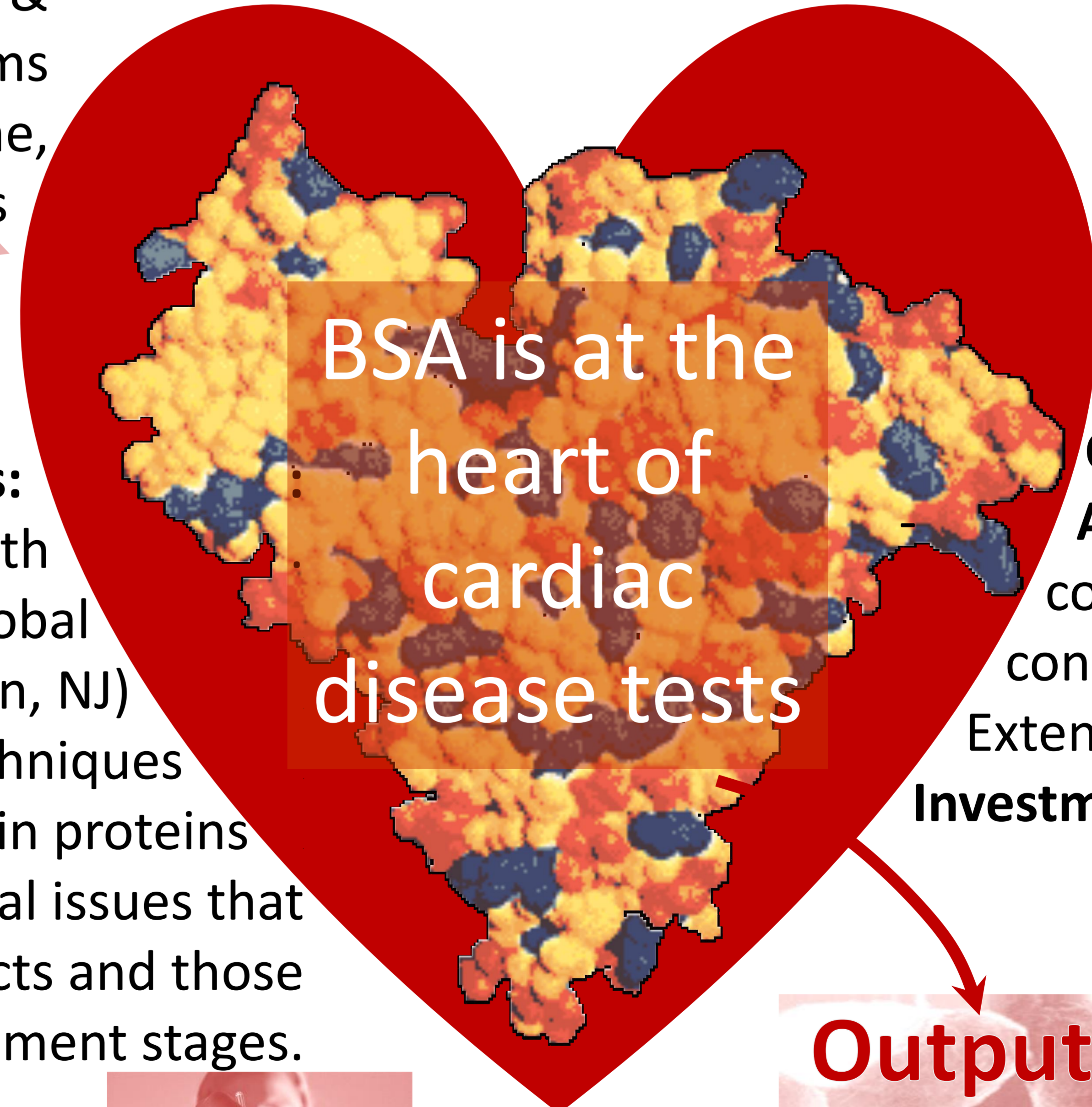
- OCD provide:**
- Expertise regarding the testing & history of problems
 - Resources – financial, time, people, technicians
 - Commercial awareness



CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD



- CU provide:**
- Expert **insight** in protein biochemistry
 - Cutting edge **techniques & tools**, e.g. microwave “speed” gel staining



- OCD benefits:**
- Extended **collaborations** with local (Cardiff Uni) and global partners (OCD – Raritan, NJ)
 - Access** to expertise, techniques and resources, especially in proteins
 - Understanding** of key technical issues that apply to current products and those at Research & Development stages.



- CU benefits:**
- Awareness** of commercial considerations in research
 - Extended **collaboration**
 - Investment** in research projects



Output

New discoveries – NTproBNP calibrator instability is related to BSA. The amount of **bacteria** present during BSA manufacture affects how it works in various OCD tests.

Acknowledgements:

Cardiff University, School of Bioscience – Prof John L Harwood, Prof Trevor Dale, Prof Bruce Caterson.
Ortho-Clinical Diagnostics – Dale Kay (UK), Chris Thomas (UK), Jonathan Crowther (USA), Patti Leinenbach (USA)