

Development of diagnostics instrument



Design and development of a central laboratory diagnostic instrument incorporating immunoassays.

Expertise and domain knowledge

- In vitro diagnostics
- Medical product development
- Mechanical design
- Fluidics
- Assay chemistry
- Mathematical modelling
- Optics
- Magnetics
- Industrial design





Our client asked:

For a partner to progress the design and development of a central laboratory diagnostic instrument.

The project story:

Sagentia Innovation used mathematical modelling to develop design rules for the control of paramagnetic beads in the magnetic wash module and used its optics expertise to develop the concept for the highly sensitive detection module. We next performed proof of principle testing to validate the analysis and address potential issues that might have reduced assay sensitivity or specificity. We were then invited to join the program as our client's development partner, focused on the hardware design for the instrument modules controlling reagent storage and dispensing, sample transfer and processing, through to assay reaction and detection. Throughout the development, there was a focus on high levels of assay performance, sample throughput and instrument reliability. The development progressed through the following activities under our ISO13485 compliant quality management system:

- Electro-mechanical component selection and testing
- Detailed hardware design
- Input to software design for hardware control
- Risk management using FMEA and critical component analysis
- Design for Manufacture and Assembly
- Prototype builds and configuration control
- System integration and functional testing
- Life testing and environmental testing
- Pre-verification testing
- Design transfer and support

Results: deliverables and outcomes

- Grounding of designs in a thorough understanding of the underlying science
- Accelerated progress through detailed design and development
- Controlled product release following CE marking

Contact us

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