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© 2020 Axxin All rights reserved D002771v12 Axxin provides platforms and diagnostic products for biomedical applications that bridge the gap from research to market with world leading innovation, capability and cost effectiveness. The company's products are used worldwide in research and diagnostic applications.

Axxin is ISO 13485 registered.

The company's goal is to take the complexity and cost out of point of care diagnostics and near patient testing applications. Founded in 2007, Axxin has extensive experience with innovative instrument design and sensor technologies and has applied these to both molecular diagnostics and immunoassay rapid testing applications. Axxin has established itself as an early leader in commercializing diagnostic delivery systems in partnership with leading biomedical and pharmaceutical companies.

Axxin's experienced team has detailed expertise in product design, development and manufacturing in high technology products for worldwide markets, including regulatory approvals such as IVDR and FDA.



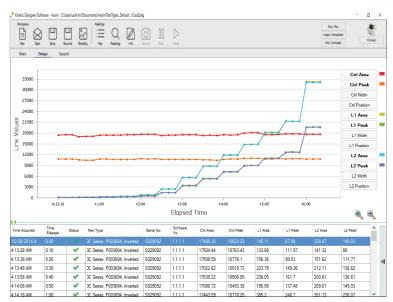
# **Immunoassay, Lateral Flow Instruments**



# AX-2X-S Visual & Fluorescence Lateral Flow Instruments

The Axxin AX-2X-S instrument is a portable, highly flexible, easy to use rapid testing instrument platform designed to provide qualitative and quantitative results for visual colorimetric and fluorescent immunoassays.

Key features include rapid result calling, multiplexing capability, automated workflow management, flexible tray design, colour touch screen interface, networking and communication options, internal memory storage, cloud sync data solutions and LIS/LIM integration connectivity.



**Graphical Analysis Display** 

# \*\* Control Colorigan Software - Auton - Coloridation (Coloridation Coloridation Col

Assay Designer Display

# **Real Time Kinetic Analysis R&D Software Tools**

- Assay Optimization and Design
- Validation and Verification of Assay Studies
- QC monitoring of Assay performance
- 2D and 3D Assay visualization in real time
- Replay Assay kinetics
- Histogram Views
- Visual and Fluorescent capability
- Qualitative and Quantitative Analysis
- Rich export of data including graphs, CSV files and images

# **Test Type Configuration Management**

- Configure Lateral flow strip tests
- 2 line or multiline analysis
- Qualitative & Quantitative Decision Algorithms
- Sophisticated image analysis of assay performance
- Configuration management and deployment

# **Molecular Instruments**











T16-ISO Instrument



**T8-ISO Instrument** 

# Isothermal Instruments

Axxin Isothermal instruments are highly flexible, benchtop and field portable instrument platforms designed to provide qualitative and quantitative results for molecular isothermal applications.

### **T16-ISO Instrument**

- Supports 16 tube testing in a single test run
- Three channel fluorescence detection per tube
- Standalone operation or PC connected modes
- Desktop Software supports two T16 instruments simultaneously enabling 32 tube testing.
- Testing temperature range of 37°C to 65°C
- USB and Ethernet connectivity for Data transfer

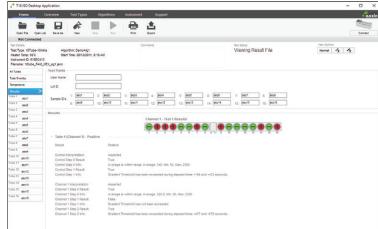
### **T8-ISO Instrument**

- Supports 8 tube testing in a single test run
- Two channel fluorescence detection per tube
- Standalone operation or PC connected modes
- Testing temperature of 37°C to 65°C
- USB and Ethernet connectivity for Data transfer
- Real Time result calling during test
- Real Time on screen curve analysis

# **Isothermal Software Application Tools**

- Real Time data presentation for Assay analysis
- Detailed tube result screens and overlays
- Data export and printed test result reports
- Thumbnail view in real time up to 16 tubes simultaneously
- Test Type workflow management
- Test Configuration and delpoyment to instruments
- Real Time algorithm and decision logic definition





Result Graphs Display

# **Axxin Capabilities Statement**









Axxin was founded in 2007 as a biomedical design and development company focused on medical devices with point of care applications using leading edge processor and bio-sensor interface technology. Axxin's outstanding team of engineers provide fully integrated services required to design, develop, test and transfer to manufacture your medical device. Axxin's experienced team has detailed expertise in product design, development and manufacturing in high technology products for worldwide markets, including regulatory approvals such as IVDR and FDA.

Axxin's company systems are ISO 13485 compliant and its internal product quality control processes, procedures and capabilities ensures the manufacturing of quality and reliable products with long operational life cycles.

### **Expertise includes:**

### **Design and Development Services**

- Product Consulting including detailed specifications
- Concept and feasibility assessment
- Product Requirements capture and analysis
- R & D Lifecycle services
- Prototyping and Proof of Concept
- Advanced testing expertise for Standards Certification
- Design for test and manufacture
- Industrial Design services
- Program Management
- Design History File Management for Regulatory Submission

# **Cartridge and Consumable Design**

- Injection moulded cartridge design
- Fluidics development
- Instrument integration
- CAD design and package integration

## **Hardware and Electronics Design**

- Design Management
- Schematic and Multilayer PCB design
- Embedded Systems design
- Biosensor design and integration
- Advanced system on chip design

## **Software and Systems Development**

- Software Architecture and design
- Software Validation and Verification
- User Interface and Human Factors Development
- C#, C++ development including .NET framework
- ASP, .NET server applications and APIs
- Embedded WinXP, WinCE and Linux development

# **Manufacturing Management Services**

- Design for test and manufacture
- Procurement management including supplier evaluation
- Bill of Materials Life Cycle Management
- Test fixture design and development
- Test Rig development and volume manufacturing
- Quality Assurance management
  - Engineering and Production support

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