

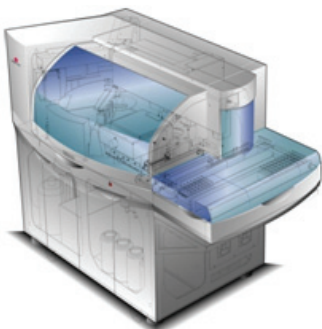
## IN VITRO DIAGNOSTICS

Quest establishes strong relationships by providing outstanding technical expertise, innovation, and superior value. Over the last 20 years we have worked on:

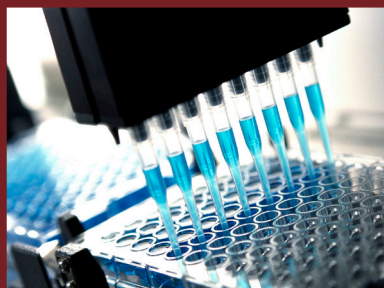
### Point-of-Care, Disposables, Immunodiagnostic/Coagulation, & Differential Diagnosis

#### Sample Program

A highly complex serum based immunoassay system was architected, designed and built in just a little over two and a half years. The design embodied 11 PowerPCs running PSOS that communicated via Ethernet/RS-485 to 70+ peripheral controllers. The team for this program grew to 60 people and embodied mechanical, electrical, software and optics. Some of the key technical challenges included:



### System Architecture, Fluidics, Thermal Control, Finite Element Analysis of Mechanical Designs, & Optical Recognition/Quantification of the Florescent Signal



## IN VITRO DIAGNOSTICS

Quest Product Development understands the critical elements in the design and development process of In Vitro Diagnostic products. Some of those areas include:

### ■ Automation Demands That Vary on Assay Type

- › Immunoassays (*FIA, EIA, ELISA, Luminescence*)
- › Molecular Diagnostics
- › Microarrays
- › Cytology
- › Differential Assays

### ■ Specific Automation Areas

- › Cellular Imaging
- › Sample Tube Handling Robotics
- › Fluid Handling, Pipetting, Wash Delivery Systems, etc.
- › Cuvette Design & Handling
- › Detection Systems (*PMT, CCD Arrays/Cameras*)
- › Disposable & Industrial Design (*Floor Model, POC*)
- › Software Architecture (*Embedded, User Interface, Laboratory Information Systems HL7, HIPPA*)
- › Fluorescence Microscopy

### ■ IVD Industry Standards & FDA Regulations

- › CLSI Standards (*Formerly NCCLS*)
- › IVD Directive (*Directive 98/79/EC*)
- › 61010-1
- › FDA 21 CFR 820
- › FDA 21 CFR 809

