

CYTOVALE SEPTISCAN SEPSIS  
DIAGNOSTIC SYSTEM

## Medical & Life Sciences

Project  
Management



Mechanical  
Engineering



Systems  
Engineering



Electrical  
Engineering



Software  
Engineering



FTE

12

# CYTOMETRY SYSTEM & DISPOSABLE CARTRIDGE FOR CLINICAL DATA GATHERING

## APPROACH

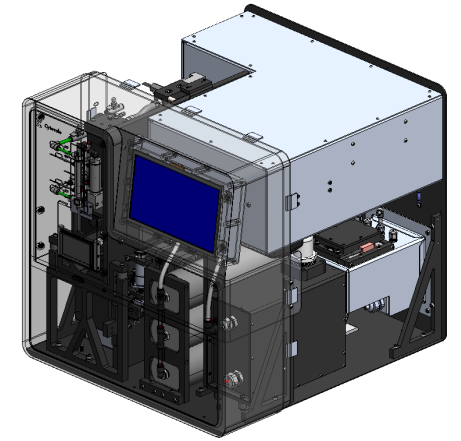
- Started with a feasibility prototype & fully designed a complete repeatable product for verification & validation
- Established baseline requirements for 61010 compliance
- Established key performance requirements to allow repeatable data & fast cycle time
- Ensured design minimized human error through automation
- Multidisciplinary team allowed for close communications with client & subcontractors

## RESULTS

- Achieved rapid sepsis diagnostic score rate – from sample to score in 5 minutes
- Designed precision pressure & dynamic temperature control system for faster results
- Completed regulatory manufacturing documentation
- Completed design of the disposable cartridge assembly transferred to manufacturer
- 16 months from initial concept to delivering 5 units for clinical testing
- FDA Clearance in 2023

## KEY TECHNOLOGIES

- OpenEmbedded/Yocto Linux, IMx6 Application Processors, Python
- Precision Optics, Temperature, & Pneumatics system
- Sub-micron 3 axis motion system with vibration isolation
- Volume manufacturing design of tooling & contract manufacturer setup for the disposable cartridge



ALTEN TECHNOLOGY