Microbiology Automation Research Project (MARP)

U.S. Army Medical Research and
Materiel Command Award No.
W81XWH-04-1-090

Introduction

- Project Goal
- Project Approach
- Project Tasks & Status
- Phase II Proposal

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Project Goal

- To develop a specimen transport system that allows incubation to begin at the time of specimen collection, while the patient is in transport
- To Create an optimized and automated process for Microorganism culture, identification and sensitivity.

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Project Approach: Research

- Industry Searched to Prevent Duplication
- Created a Database of Current Technology
- Evaluated the Work Flow of the Manual Process
- Determined the Variance in Manual Process
- Identified Applicable Standards

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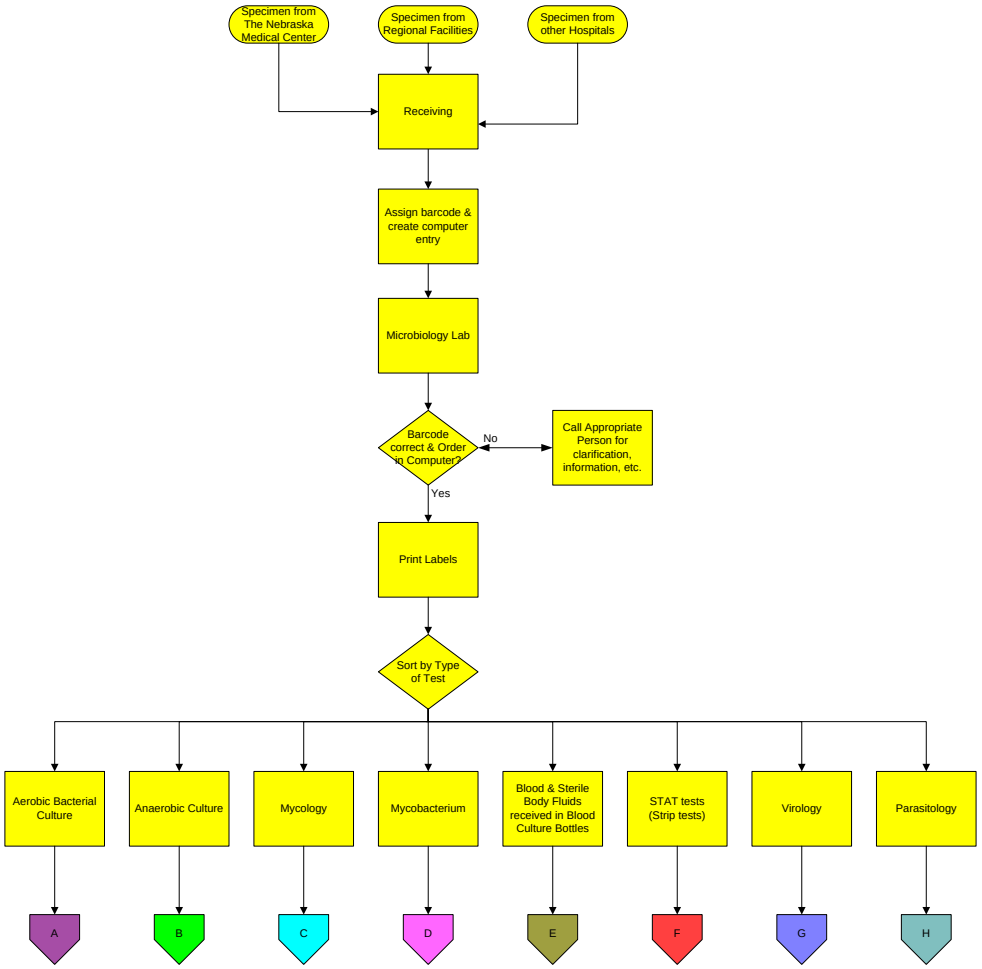
Microbiology Manual Process Flow



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Microbiology Workflow Engine

- Standardization Approach
  - Dictionary of terms
  - Definition of processes
- Overall architecture
  - Action Process Flow
  - Method Process Flow
  - Technique Process Flow

high level approach

in depth level approach

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Simulation Modeling Approach

- Simul8 Modeling Software
  - Real time computer model that mimics the micro lab
  - Visualize the impact of future MARP prototype
  - Accurate numerical result collection
- Manual Process Flow vs. Automatic Process Flow
- Instrument Integration
- MARP Prototype Integration

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Site Visits (1/2)

- Nebraska Medical Center – Omaha, NE
- Creighton University Medical Center – Omaha, NE
- Alegent Health System – Omaha, NE
- Washington Hospital Center – Washington, DC
- Nebraska Public Health Laboratory – Omaha, NE
- University of Chicago Hospital – Chicago, IL
- Rush-Presbyterian-St. Luke's Medical Center – Chicago, IL
- Northwestern Memorial Hospital – Chicago, IL
- Ehrling Bergquist Hospital – Offutt AFB, NE
- Mayo Clinic – Rochester, MN
- Fairview-University Medical Center – Minneapolis, MN
- The Cleveland Clinic – Cleveland, OH
- William Beaumont Hospital – Royal Oak, MI
- Henry Ford Hospital – Detroit, MI

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Site Visits (2/2)

- University of Colorado Hospital – Denver, CO
- National Jewish Medical and Research Center – Denver, CO
- Colorado Department of Public Health and Environment – Denver, CO
- Quest Diagnostics Inc. – Denver, CO
- Barnes-Jewish Hospital – St. Louis, MO
- Parkland Memorial Hospital – Dallas, TX
- Walter Reed Army Medical Center – Washington D.C.
- Johns Hopkins Hospital – Baltimore, MD
- University of California, San Diego, Medical Center – San Diego, CA
- VA Medical Center – San Diego, CA
- Naval Medical Center – San Diego, CA
- Centers for Disease Control and Prevention – Atlanta, GA

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Applicable Standards

Clinical Lab Standards	Information Data Type Standards	Regulation Standards	Electrical and Mechanical Standards
College of American Pathologists (CAP), CLIAA	Health Level 7 Interface Standards (HL7)	Food and Drug Administration (FDA) Medical Device Design	Underwriters Laboratory (UL)
Centers for Disease Control (CDC)	American Society for Testing and Materials (ASTM)	International Organization for Standardization (ISO)	Radio Frequency Identification (RFID)
World Health Organization (WHO)	Clinical Data Interchange Standards Consortium (CDISC)	Institute of Electrical and Electronics Engineers (IEEE)	Occupational Safety and Health Administration (OSHA)
American Society of Microbiology (ASM)			Canadian Standards Association (CSA)
Clinical and Laboratory Standards Institute (CLSI)			

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Project Approach: Requirements

- Following FDA Development Methodology
  - Telelogic DOORS©
    - MAP (Microbiology Automation Platform) System Requirements
    - SCV (Specimen Culture Vehicle) Product Requirements

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Project Approach: Design

- Microbiology Automation Platform (MAP)
  - Software
    - Telelogic TAU© UML/SysML Modeling Software
      - End-to-End Development Lifecycle Solution
      - Requirements linked from Design through Testing
    - DODAF (formerly C4ISR AF) Compliant
    - Develop modular design
  - Hardware
    - Determine Optimal Detection Mechanisms
    - Develop modular hardware design
- Specimen Culture Vehicle (SCV)
  - Develop an engine model for versioning

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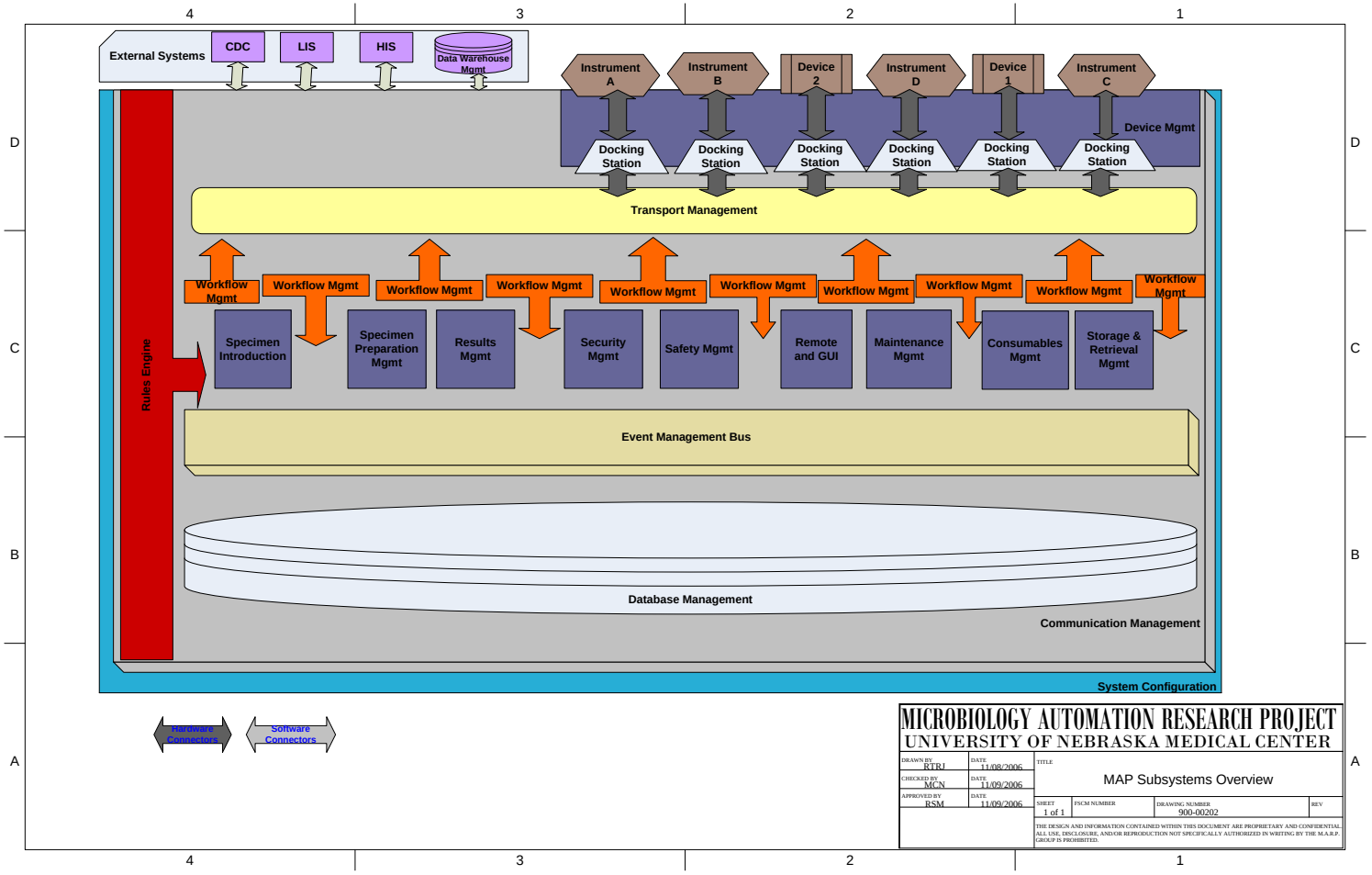
MAP Subsystems Architecture Overview



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SCV (Specimen Culture Vehicle) Development

- Develop size, shape and usability
- Materials consideration
- Vendor Search-materials and media
- Cost estimates of various approaches

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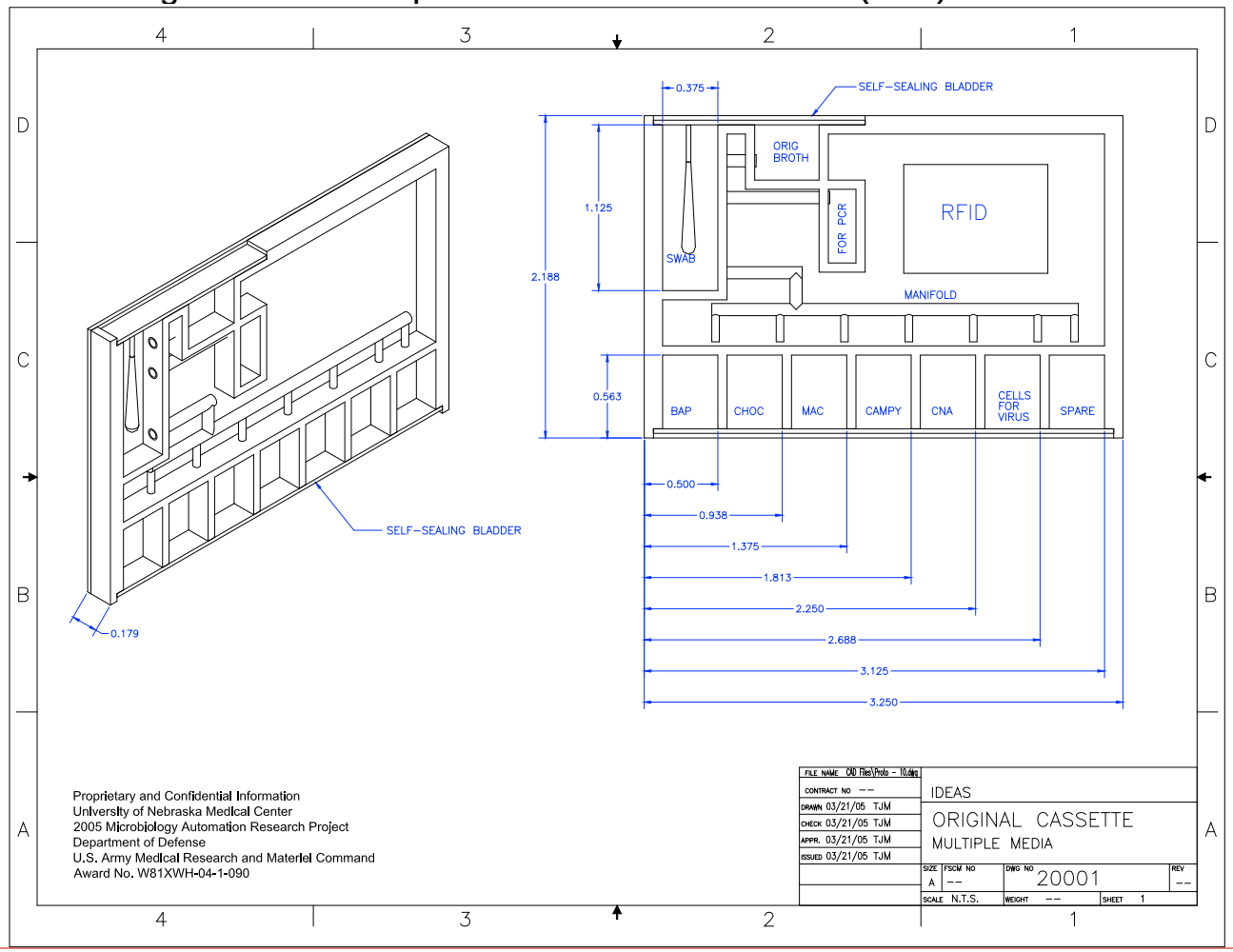
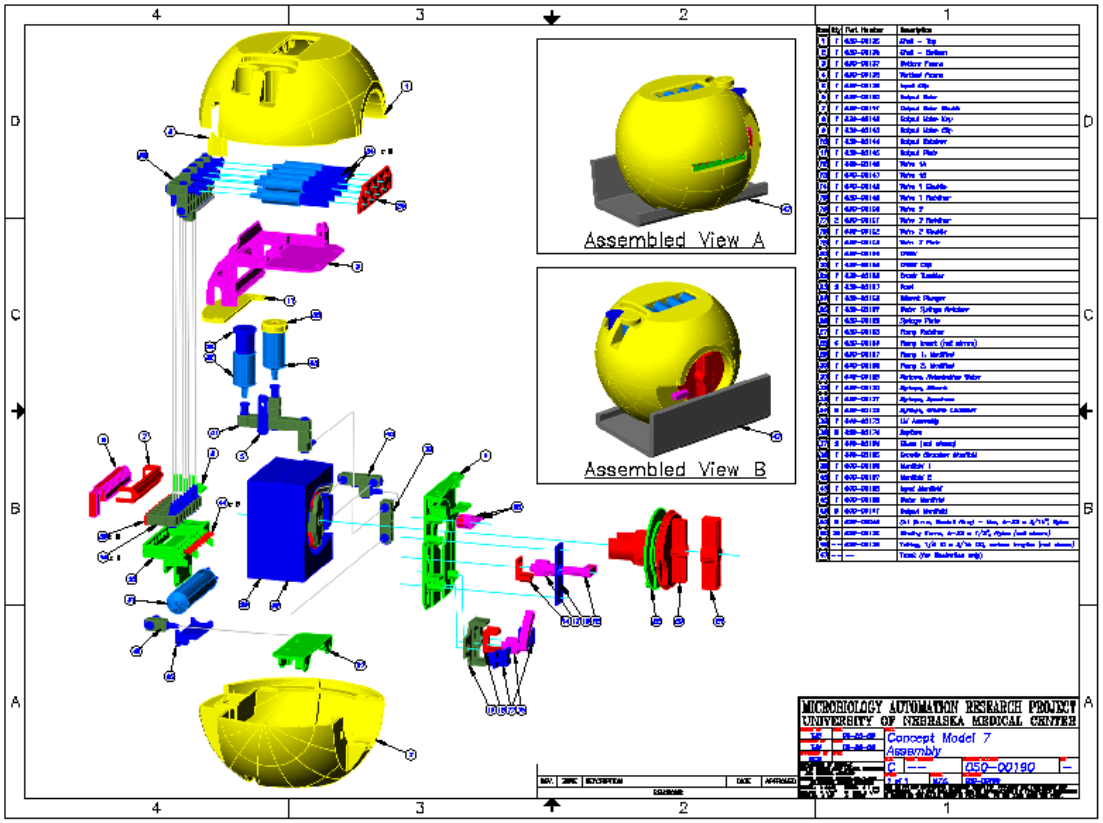
Initial Design Ideas for Specimen Culture Vehicle (1/3)



Concept Model



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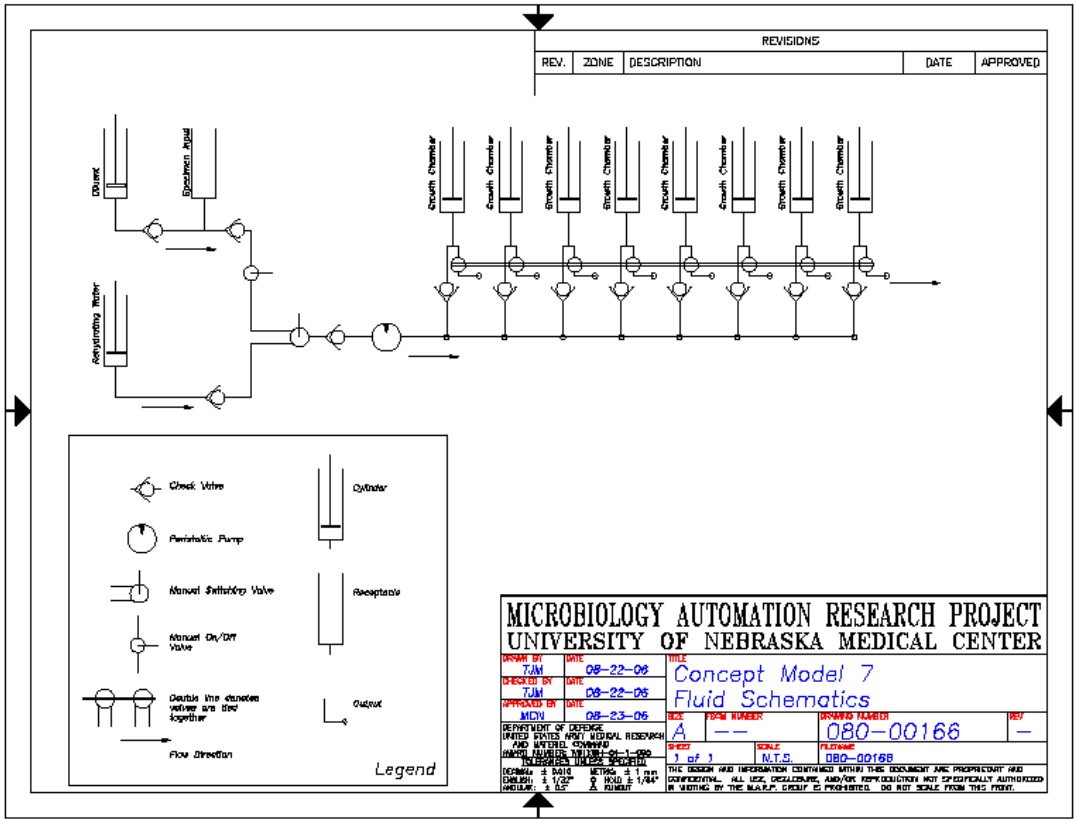

Concept Model

Implementation of specimen incubator

- For use in conjunction with existing detection equipment, e.g. mass-spectroscopy
  - 1 year, $3.5 Million
- For use in conjunction with a total microbology automation system.
  - 2 years $8 Million

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