Northrop Grumman and Biodetection
A demonstrated history of success with PCR-based systems

- **Biohazard Detection System (BDS) for USPS**
  - Over 1000 instruments built and deployed
  - Extensive testing and qualification performed
  - In service for nearly a decade

- **Autonomous Pathogen Detection System (APDS)**
  - Supported field operation of APDS units in live operation in NYC
  - Built 24 units to demonstrate initial autonomous detection capabilities

- **Next Gen Automated Detection System (NG-ADS)**
  - Evolution of APDS technology
  - Over 20 units built under Gen-3 Phase 1 contract with DHS
  - Completed comprehensive testing program including both lab and field testing

- Experience with other autonomous biodetection systems using alternate detection technologies (UV-LIF, Protein assays, MS), as well as chem/trace and R/N detection

Northrop Grumman has over a decade of experience focused at designing, deploying, and maintaining autonomous biodetection systems.
Biohazard Detection System (BDS)
The first national scale automated biodetection network

- Autonomous Biodetector - “Lab in a Box”
  - Fully automatic; samples, analyzes & reports results
  - Built-in diagnostics/controls to ensure test validity
  - Seamlessly integrated into USPS mail flow

- Sensitive and Accurate
  - Polymerase Chain Reaction (PCR) based identification
  - Thoroughly validated by USPS, DoD, CDC, others
  - 11*M tests without a false positive

- Mature – TRL 9
  - National deployment complete in 2005
    - Over 1000 instruments at hundreds of sites
  - National monitoring & support network in place
  - SAFETY Act Designation & Certification
  - Established and exercised CONOPS/Response plans

BDS screens mail as it enters USPS network & provides warning before contaminated mail is distributed through the mail network
BDS Network – Not Just a Sensor
Fully integrated logistics network provides national visibility & control

Fully Integrated Support Infrastructure
- Redundant communications for reliability
- Centrally monitors equipment health & status
- Manages field service representatives
- Manages consumables, spares & repairs
- Trend analysis for continuous improvement
- Technical reach-back to support 1st responders

National Field Monitoring Center
- The ‘nerve center’ of the network
- National view down to specific site/instrument
- Real-time visibility of equipment status
- Archives all test results
- ‘Closed Loop’ servicing & repair process

BDS Operations & Maintenance Support Network evolved over time to meet program needs & to ensure reliable system operation
Next Gen Autonomous Detection System (NG-ADS)
Robust, modular platform for environmental surveillance

- **Autonomous Operation and Reporting**
  - 24/7/365 indoor and outdoor operation
  - Local and remote command and control capability
  - End-to-end integrated sample processing

- **Confidence in Results**
  - Proven multiplexed PCR-based assays with high sensitivity and specificity
  - Integrated process controls
  - Viable archive samples available for offsite analysis
  - Continuous network monitoring to assure transmission of results
  - Automatic notification of alerts

- **Mature Solution**
  - Over 15 years of development and testing
  - Multiple tests at 3rd party and Government labs
  - More than 50 units built since 2006
  - Modular, open architecture allows insertions of new technologies
  - Over 130,000 hours of operation in the field
NG-ADS Assay Design
Specific, sensitive and low false positive rate

- Multiplex-PCR assay coupled to a liquid array-based COTS assay reader detects multiple agents simultaneously in a single sample
- Highly multiplexed, expandable detection platform
  - Up 50 discrete targets can be detected in a single sample
  - 4 controls run with every sample to increase confidence
  - Multiple signatures (3+) used per agent to increase specificity and minimize false alarm rate
  - Additional targets can be added without significant assay changes

Assay Controls

- **System Process Control (SPC)** – verifies that all assay processes are successful
- **Negative Control (NC)** – verifies that there is no non-specific hybridization
- **Fluorescence Control (FC)** – verifies that the fluorescent reporter molecule and labeling is functioning properly
- **Instrument Control (IC)** – verifies that the assay reader instrument is functioning properly

**Luminex Bead Array**
- Color coding of beads define unique “bead class”
- A specific probe is attached to each “bead class”
- Different “bead classes” in a single mix create a uniquely identifiable “Bead Array”
NG-ADS Sensor Network
Provides real time alerts and data access to decision makers
NG-ADS User Interface – Remote Web Viewer

Real-time instrument data access and remote command and control

- Web Viewer application provides system users real time access to critical instrument and assay data to support response decisions
  - Assay test results, including controls
  - Status and history of key instrument performance parameters (temps, flow rates, pressures, etc)
  - Current instrument operational status
  - Command history

- Remote command and control capabilities
  - Remote start/stop
  - Remote diagnostic routines
  - Remote sampling interval changes

Real time data available to qualified users on variety of mobile and desktop platforms
## NG-ADS Specifications and Recent Testing

### NG-ADS Key Performance Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
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<tbody>
<tr>
<td>Maturity</td>
<td>TRL 7</td>
</tr>
<tr>
<td><strong>Operational Environment</strong></td>
<td>Indoor/Outdoor (rain, snow, wind, dust, etc)</td>
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<tr>
<td></td>
<td>Temp: -28 C to 50 C</td>
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<tr>
<td></td>
<td>Humidity: 5-100%</td>
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<tr>
<td>Agents</td>
<td>6 agents in current assay, expandable to 20 agents or more</td>
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<tr>
<td></td>
<td>Capable of detecting DNA, RNA and Protein threats</td>
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<tr>
<td>Sensitivity</td>
<td>100-600 org/m³ air</td>
</tr>
<tr>
<td>P_D / FAR</td>
<td>Probability of detection &gt;95%, FAR better than 1 in 10⁹</td>
</tr>
<tr>
<td>Size</td>
<td>28&quot; W x 35&quot; D x 70&quot; H</td>
</tr>
<tr>
<td>Weight</td>
<td>~600 lb with on-board consumables</td>
</tr>
<tr>
<td>Power</td>
<td>Standard 110/120VAC, 20A</td>
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<tr>
<td></td>
<td>Battery backup for ride-through capability</td>
</tr>
<tr>
<td>Comms</td>
<td>Cellular, 802.11x, Ethernet capable; VPN and other features for data security</td>
</tr>
<tr>
<td>Operational Availability</td>
<td>&gt;99.5%</td>
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<tr>
<td>Time to Result</td>
<td>2 hrs from end of sample collection</td>
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<tr>
<td>Collection Interval</td>
<td>Configurable collection periods up to 24 hr (or longer); compatible with triggered collections</td>
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</tbody>
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### Government Testing
- Aerosol Testing at ECBC
  - Collection & retention efficiency of inert particles and biological simulants
- Assay Testing at LANL
  - Assay sensitivity and specificity using extracted DNA and environmental confounders
- Analytical Testing at DPG
  - Analytical sensitivity using live and killed whole organisms
- System Testing at DPG
  - System sensitivity using killed whole organisms
- Field Testing
  - 12 units in Midwest city from Jan ‘11 thru Jun ‘11
    - ~40,000 operational hours; Availability ~98%
    - 4 units from Jun ‘11 thru Feb ‘12
  - 3 units in NCR from Sep ‘11 thru Dec ‘11

### Recent Testing at NG
- Limit of Detection
  - Analytical sensitivity with genomic and whole agent material to determine LOD
- Specificity Testing
  - Analytical specificity using near neighbor targets to demonstrate differentiation
- Aerosol Collector Testing
  - Sampling efficiencies with inert particles and biological simulants
Summary

• Effective and reliable PCR-based autonomous biodetection in indoor and outdoor environments is a difficult, but not impossible challenge

• Use of mature, COTS-based technologies reduces development risk, and allows more rapid transition from prototype to production

• There is no substitute for field testing experience – test early and often throughout development cycle

• PCR-based autonomous detection technologies are mature and ready to begin final testing and deployment in BioWatch applications