Flu Diagnostics
Program Goals

- Goals for development of rapid, accurate diagnostic tests:
  - Inform patient care
  - Inform outbreak and pandemic control, guide public health interventions and monitor spread within communities.
  - Inform earlier antiviral therapy; targeted therapies, especially for antiviral resistant infections
  - Reduce antibiotic over-prescribing

- Key Strategies:
  - Move diagnostics closer to point of patient care, including physician's office, pharmacies, and home settings
  - Increase utility of influenza diagnostics for informing pandemic response
  - Simplify use of sequencing technology so appropriate for clinical lab use
# Current Flu Diagnostics Program Line-up

<table>
<thead>
<tr>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18</th>
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<tbody>
<tr>
<td>Becton Dickinson – POC Antiviral Res</td>
<td>18 Month Extension</td>
<td>InDevR – Influenza Genotyping Array</td>
<td>Automated platform</td>
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<td>Johns Hopkins University (Coop. Agreement)</td>
<td>Additional Clinical Study</td>
<td>Alere – POC Molecular, Flu A&amp;B+</td>
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<td>Test Evaluations – Medical College of WI</td>
<td>4-month no-cost extension</td>
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- **Existing**
- **FY16/17 new start**: 510(k) CLIA waiver
- **New BAA award**

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InDevR star: Automated platform

Alere stars: Automated platform
AoI #3: Influenza and Emerging Infectious Diseases - Test Systems and Diagnostic Tools

- Technical Point of Contact: Rodney Wallace; Rodney.Wallace@hhs.gov
- Priorities:
  - Consumer and patient-oriented diagnostic products for point of care, pharmacy, and home testing
  - New technologies: simpler/easier to use sequencing platforms for clinical labs, pandemic + seasonal strain ID & subtype
  - Clinical value studies
  - Novel Marker Identification – symptomatic & pre-symptomatic
- Data Expectations:
  - TRL 6 (most sub-areas)
  - Prototype / preliminary assay data, design history file, commercialization plan, regulatory & manufacturing plans
3.1 Improved specimen collection materials and methods

3.2 Advanced sequencing methods:
   3.2.1 Methods for identifying novel influenza viruses
   3.2.2 Simplification of Next Generation Nucleotide Sequencing Platforms

3.3 Antiviral drug resistance Dx

3.4 Prognostic Dx marker(s) of influenza infection

3.5 Home use or point of care diagnostics

3.6 Studies to demonstrate the value of using Influenza diagnostics