



INFLUENZA DIAGNOSTIC PROGRAMS

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Division October 14, 2015

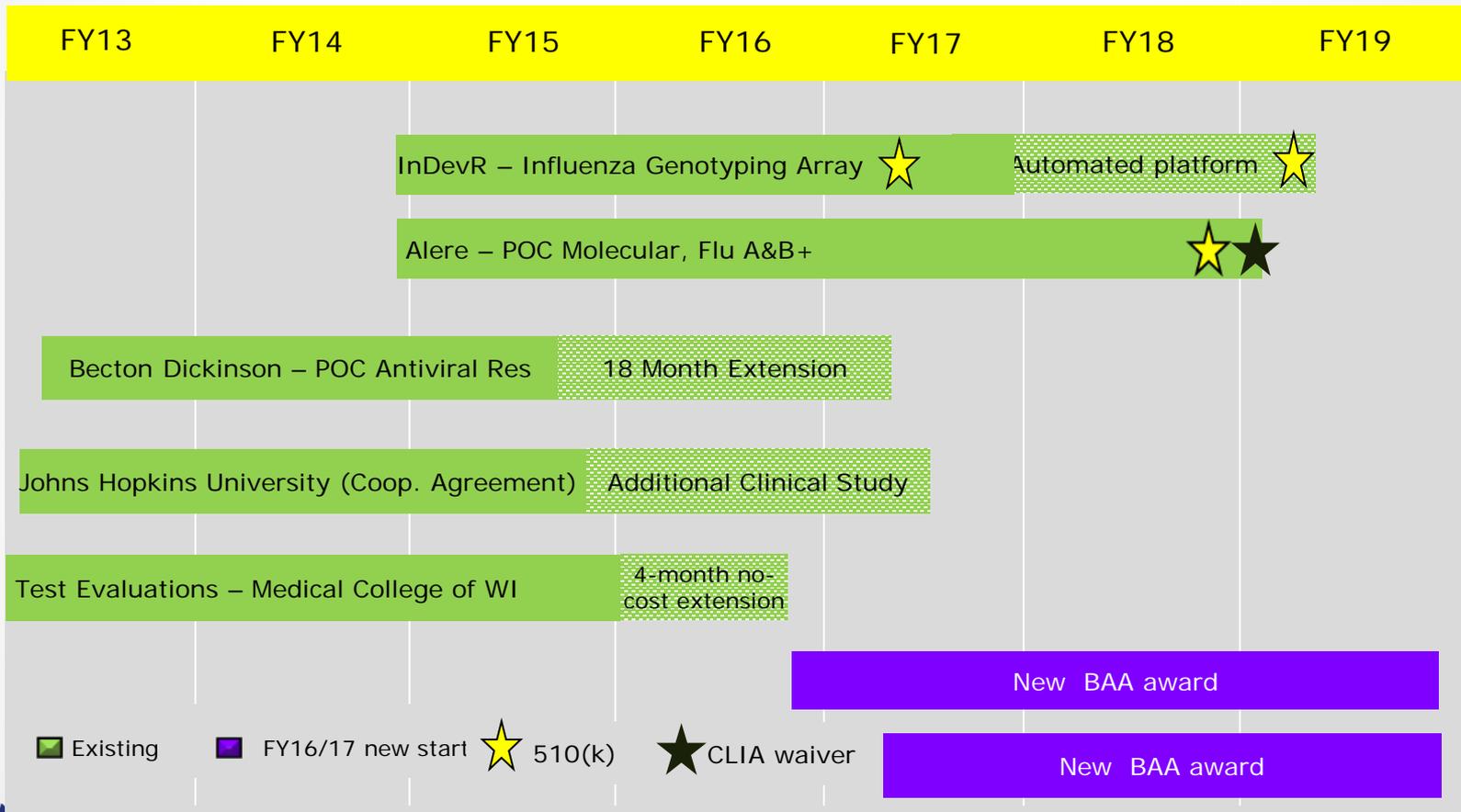
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Flu Diagnostics Program Goals

- 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



AoI #3: Influenza and Emerging Infectious Diseases - Test Systems and Diagnostic Tools

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- 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



Flu BAA AoI #3

Sections

- 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***

