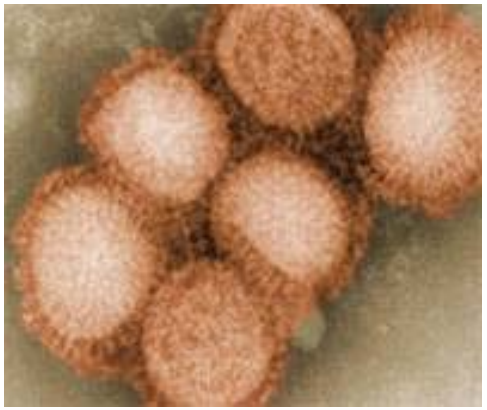
Modeling Influenza Capacity and Surveillance Costs



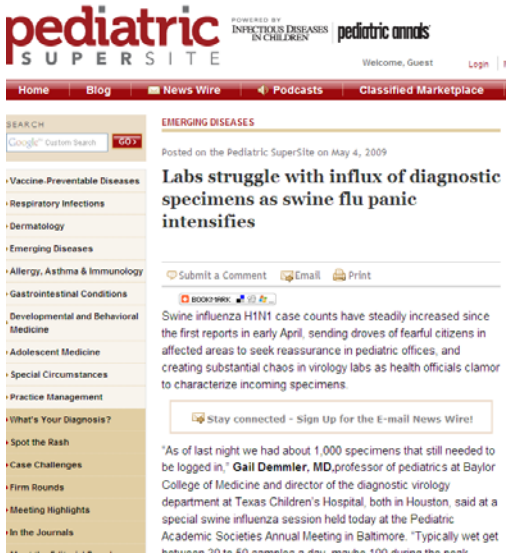
Michael Pentella, PhD, D(ABMM)
Director, Bureau of Laboratory Services
The Commonwealth of Massachusetts

2013 APHL ANNUAL MEETING & 7TH GOVERNMENT ENVIRONMENTAL LABORATORY CONFERENCE

Pandemics & Pandemic Alerts
19th, 20th & 21st Centuries

Historical accounts:

- 1891 H3
- 1918 “Spanish flu” H1N1
- 1957 “Asian flu” H2N2
- 1968 “Hong Kong flu” H3N2
- 1976 Fort Dix “Swine flu”
- 1977 “Russian Flu” H1N1
- 1997 Avian influenza A (H5N1)
- 2004-05 Avian influenza A (H5N1)
- 2009 “2009 Novel” H1N1
- 2013 Avian Influenza A H7N9


pediatric SUPERSITE

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EMERGING DISEASES

Posted on the Pediatric SuperSite on May 4, 2009

Labs struggle with influx of diagnostic specimens as swine flu panic intensifies

Swine influenza H1N1 case counts have steadily increased since the first reports in early April, sending droves of fearful citizens in affected areas to seek reassurance in pediatric offices, and creating substantial chaos in virology labs as health officials clamor to characterize incoming specimens.

“As of last night we had about 1,000 specimens that still needed to be logged in,” **Gail Demmler, MD**,professor of pediatrics at Baylor College of Medicine and director of the diagnostic virology department at Texas Children’s Hospital, both in Houston, said at a special swine influenza session held today at the Pediatric Academic Societies Annual Meeting in Baltimore. “Typically wet get

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Influenza Virologic Surveillance Right Size Project: Modeling Initiatives

- Influenza Laboratory Resource and Process Modeling Project
- Influenza Cost Estimation Models
- Right Size Pilot Study: Sample Size Calculators

How are these modeling initiatives related to the Right Size Project?

- Virologic surveillance testing performed is often driven by lab capacity
- Each state should do a cost analysis of the surveillance testing performed to determine the most cost effective and efficient model
- Accurate cost analysis is critical to prioritize funding

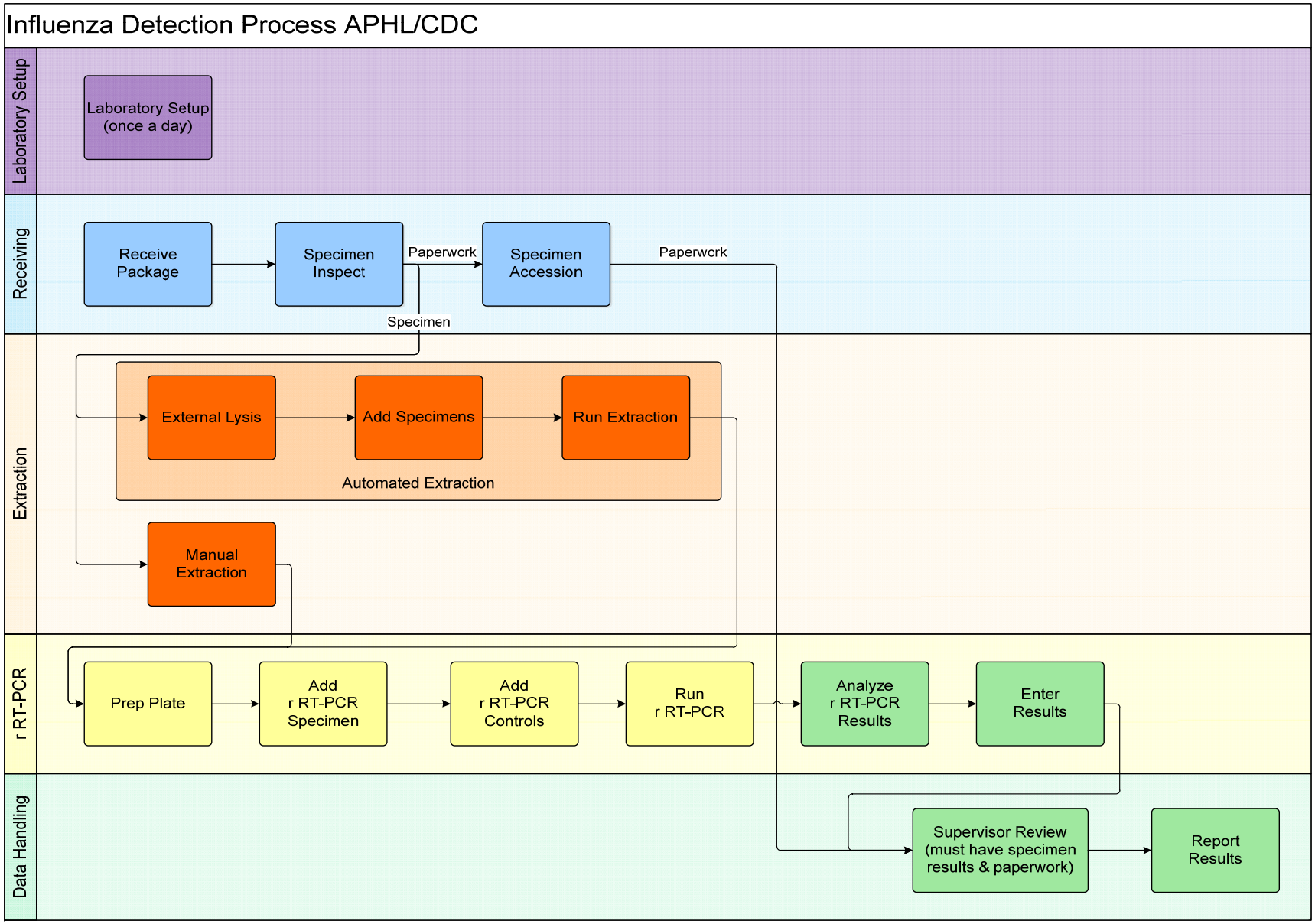
Influenza Laboratory Resource and Process Modeling Project

- 2009 H1N1 pandemic underscored the need to thoroughly understand PHL testing capacity in order to effectively plan and prepare for a rapid and sufficient laboratory response to future pandemics.

- APHL, CDC and Booz Allen Hamilton engaged in simulation and modeling to analyze current PHL capacity, optimize processes and resource allocations, and recommend improvements for response to unexpected increases in demands for specimen testing in PHLs.

- In 2011 and 2012, **38** labs participated in the modeling project.

Influenza Process Map



Capacity Models

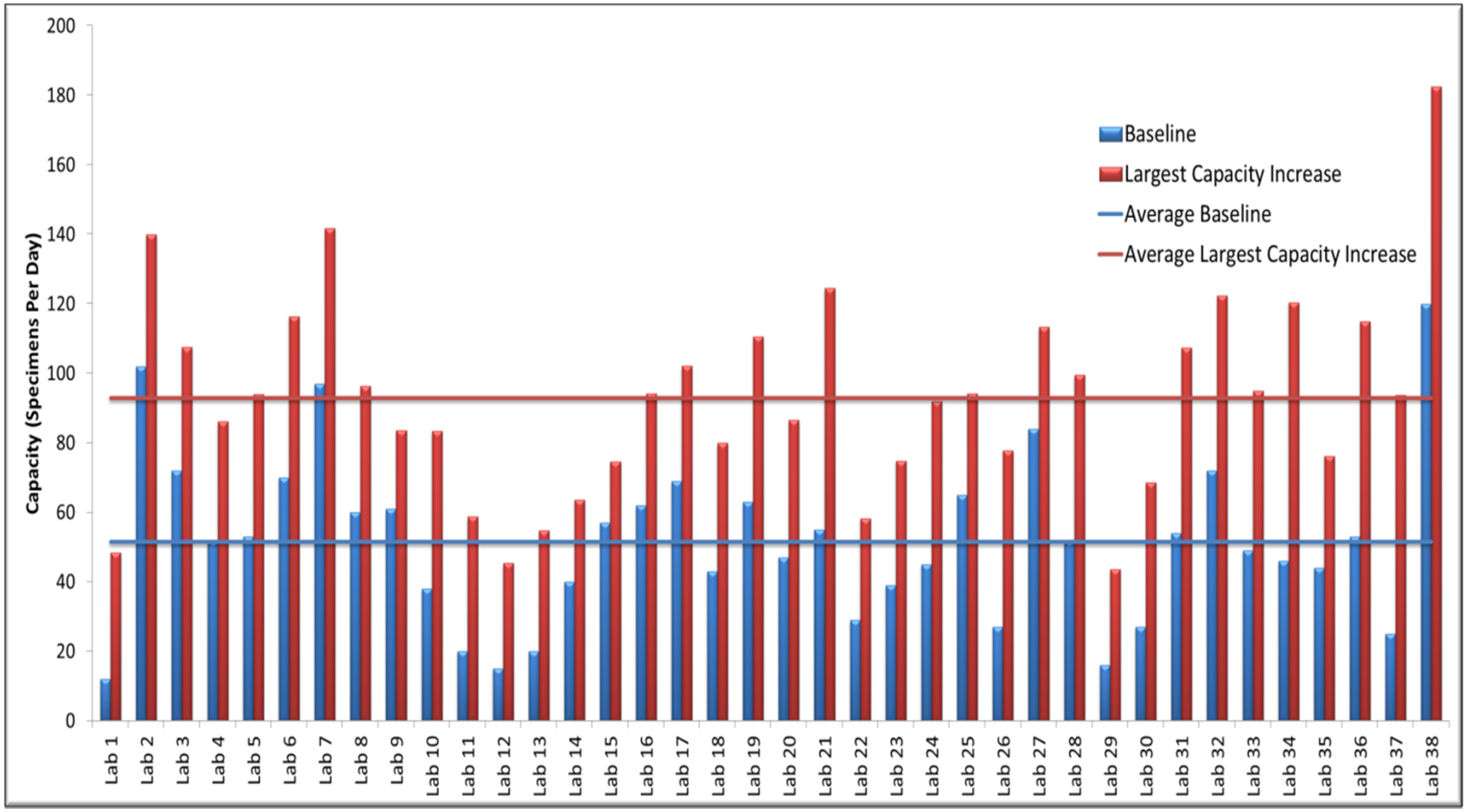
1. Influenza A/B Typing Assay with full Influenza A Subtyping using baseline resources (9 specimens per plate)
2. Influenza A/B Typing Assay with reflex Influenza A Subtyping using baseline resources (19 specimens per plate for typing; 9 specimens per plate for subtyping)
3. Influenza A/B Typing using surge resources (19 specimens per plate)

Capacity Model Inputs

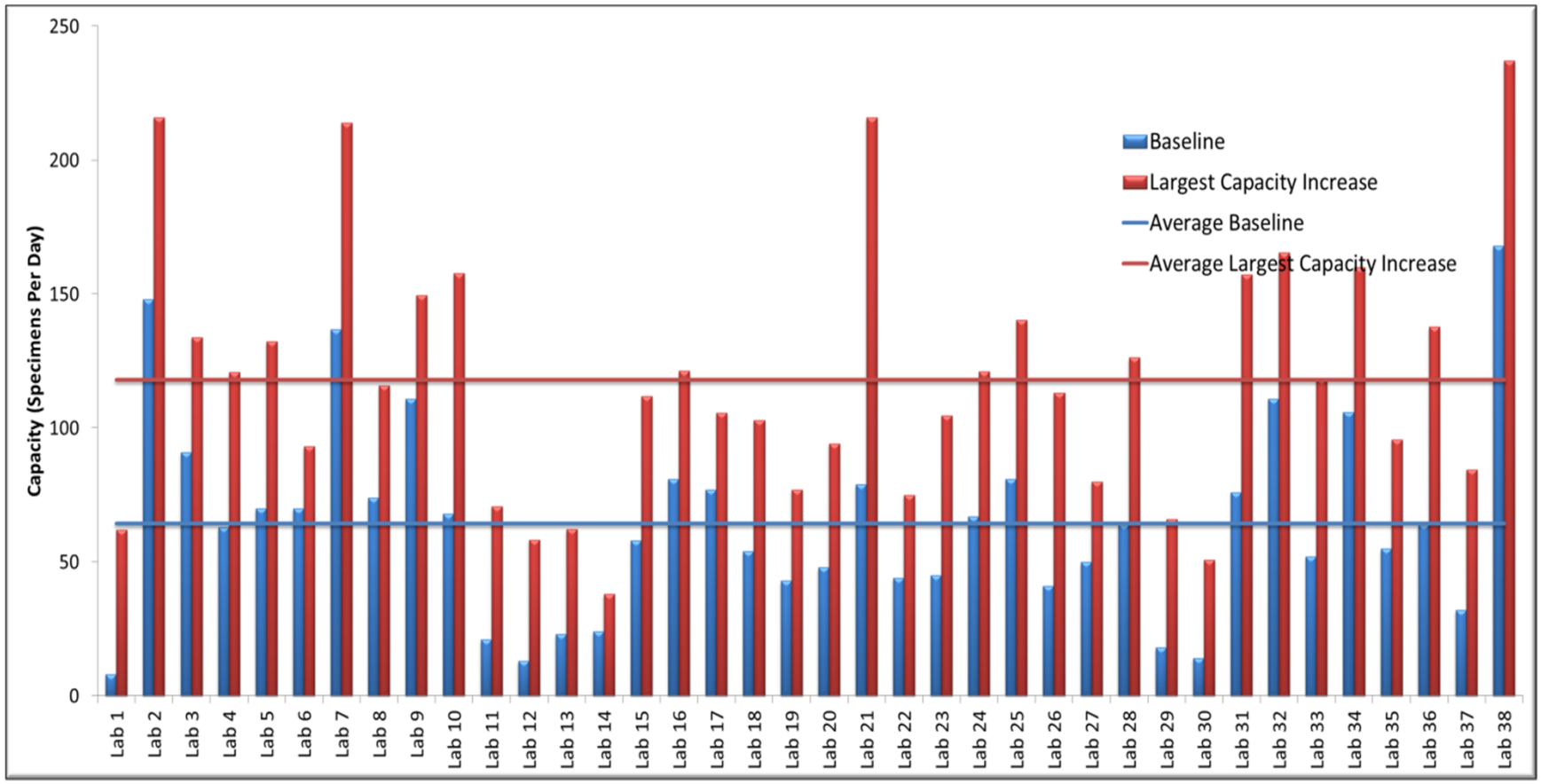
- Staff
- Primary Equipment
- Secondary Equipment

Model #1: Influenza A/B Typing with full Flu A Subtyping Assay:

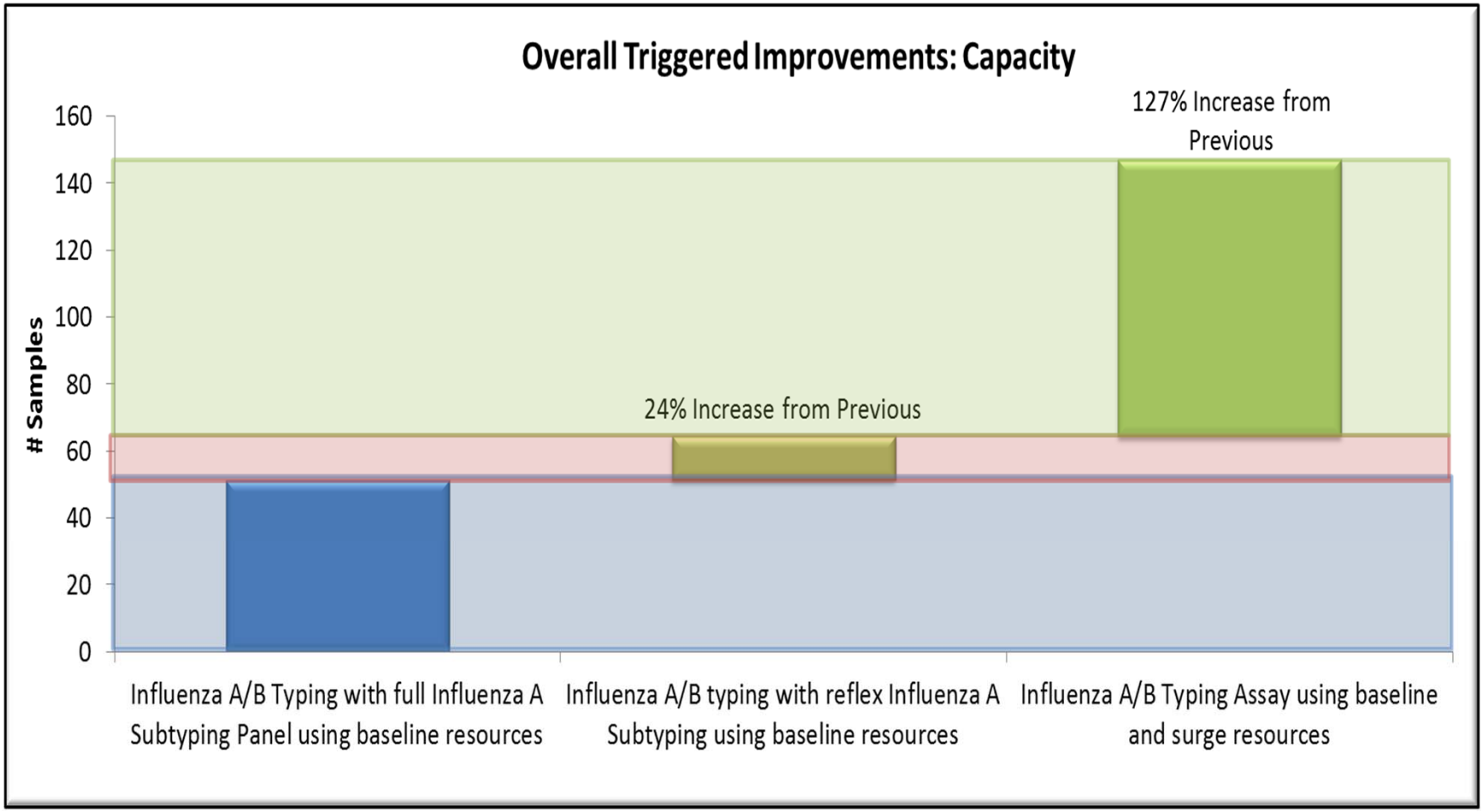
By modeling of various resource and process optimizations, potential improvements were identified that could increase capacity and on average by 80% for each laboratory.



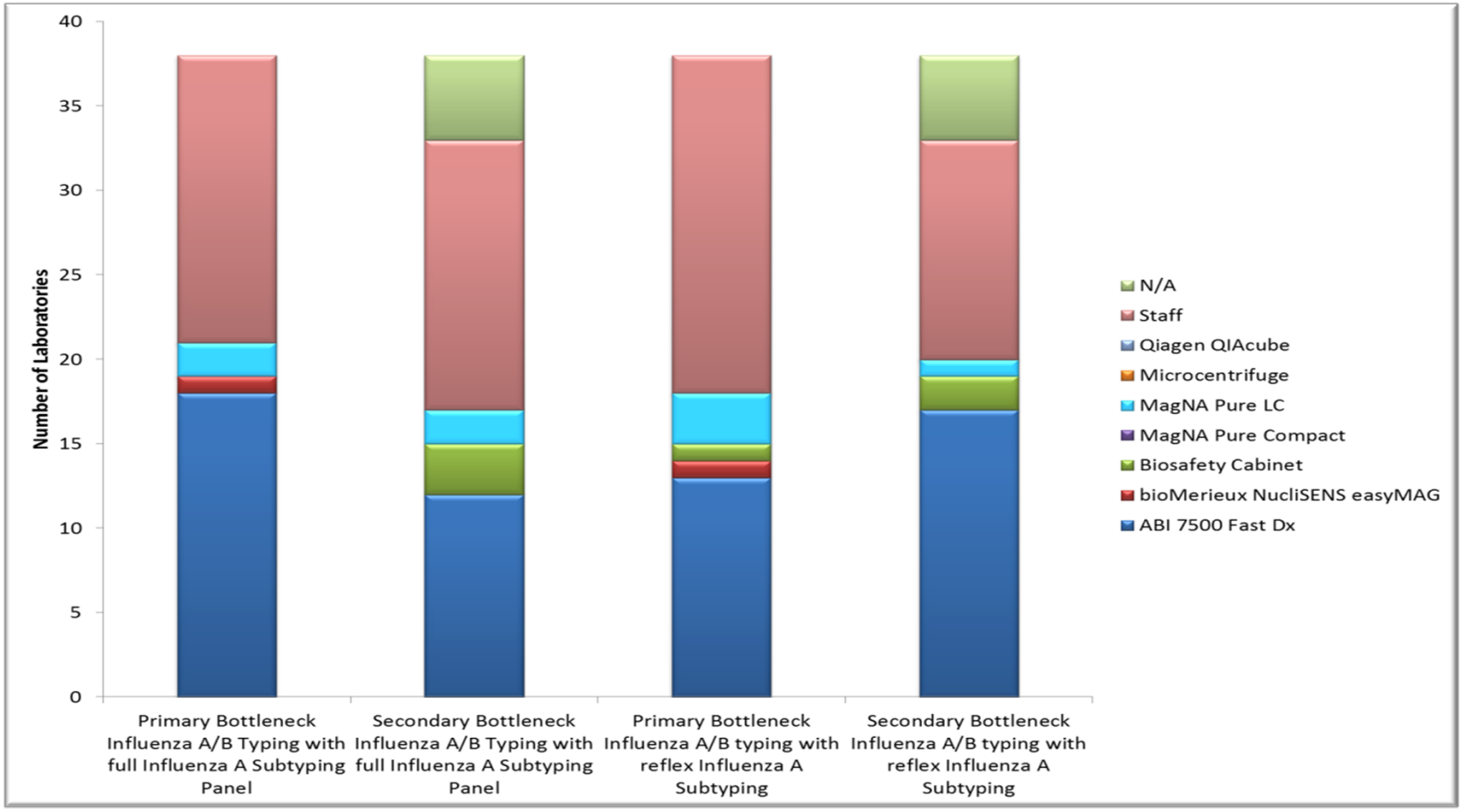
Model #2: Influenza A/B Typing with reflex Flu A Subtyping Assay: Potential improvements were identified that increase capacity for each laboratory on average by 83%



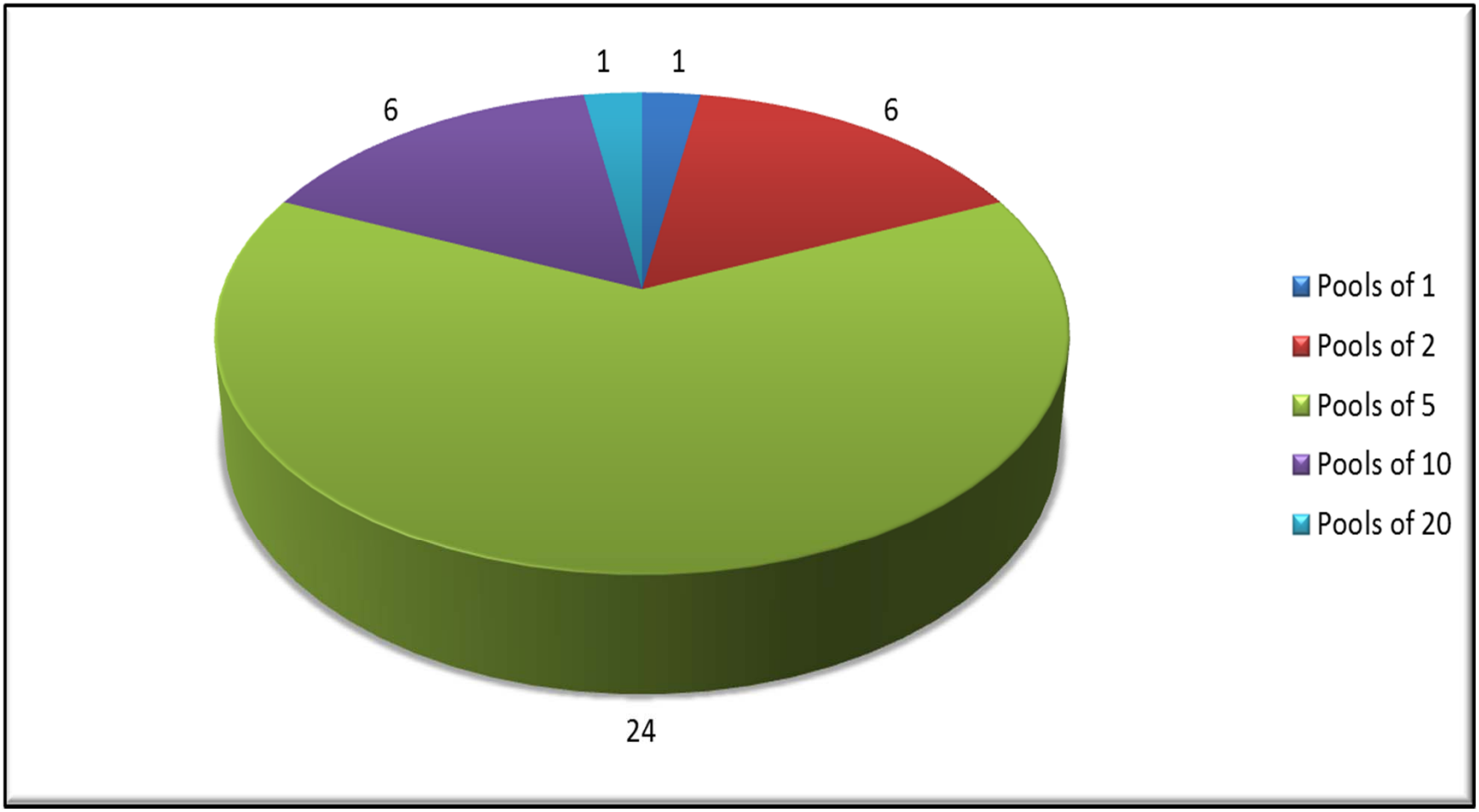
Predicted increase in capacity that may be achieved by implementing changes to testing algorithms



Staff and ABI 7500 Fast Dx were the most significant primary and secondary resource bottlenecks, respectively, for laboratories, regardless of algorithm.



Pools of 5 specimens provided the greatest capacity increase across all prevalence levels for 24 of the 38 laboratories modeled



Conclusions of Capacity Modeling

1. The national capacity for influenza specimen testing by PHLs is approximately 5,000 samples per day.
   - By implementing specific types of resource improvements, such as the ones identified for each study laboratory in their individual reports (e.g., cross-training of staff), would raise the extrapolated national forecasted capacity to 9,000 samples per day.
   - Pooling samples in pools of 5 at a 5% prevalence would increase the national forecasted capacity to approximately 9,350 samples per day.
   - Switching to an A/B testing only protocol would further increase forecasted capacity to approximately 14,250 samples per day.
2. For 82% of laboratories, utilizing the Influenza A/B Typing with reflex Influenza A Subtyping Assay resulted in a greater daily forecasted capacity then the Influenza A/B Typing with full Influenza A Subtyping.

Conclusions of Capacity Modeling cont.

3. Utilizing the surge algorithm (Influenza A/B Typing) with surge resources (e.g., additional staff identified in surge/emergency plans) can result in a 128%-148% increase in forecasted capacity over baseline.

4. Insufficient staffing and ABI 7500 Fast Dx instruments were the most common primary and secondary limitations to laboratory capacity, and the gain or loss of these resources had the largest impact on forecasted capacity; however, there were no direct correlations between the number of staff or ABI 7500 Fast Dx instruments and capacity.

5. Factory-style specimen processing was an improvement over shepherding-style processing in 67% of laboratories regardless of subtyping algorithm.

Conclusions of Capacity Modeling cont.

6. The current specimen pooling algorithm produced a significantly higher throughput in all but one laboratory studied; however, modifications to the current pooling algorithms could increase forecasted capacity by an additional 40%. We recommend putting together data for an Emergency Use Authorization (EUA) in the case that increased capacity is needed based on these modeling results.
7. Most laboratories had the largest increase in forecasted capacity with pools of 5 specimens; however, laboratories should utilize the analysis provided within this

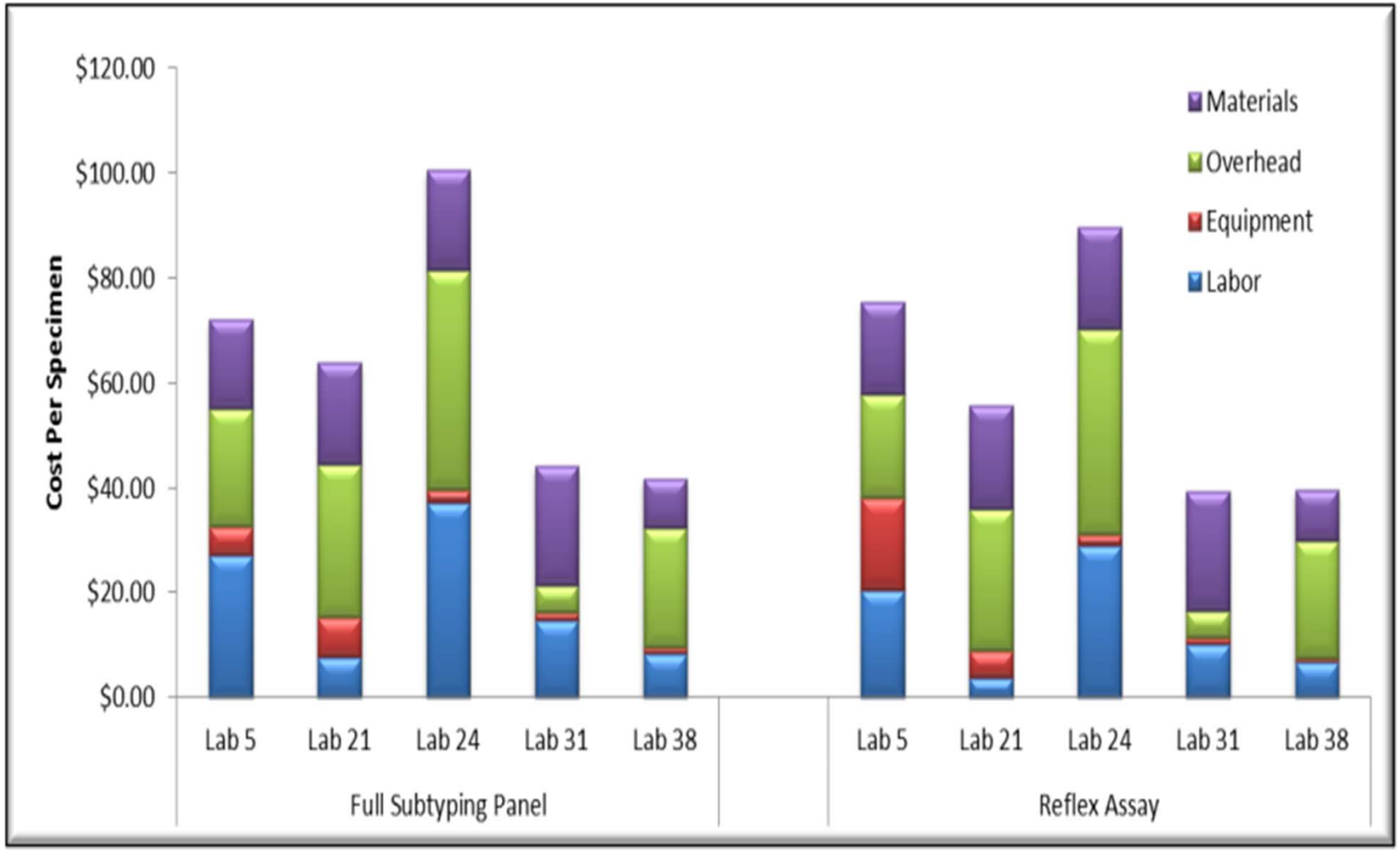
APHL-CDC Influenza Cost Estimation Models

- Model allows individual laboratories to understand a detailed breakdown of their influenza testing costs.
- Cost-per-specimen metric was based on operational and inventory-related costs, testing methodology and overall laboratory performance.
- This metric serves as a baseline for the cost of specimen testing, and allows the given laboratory, APHL, and CDC to identify cost-saving opportunities for future specimen testing.
- This analysis was conducted for 6 PHLs.

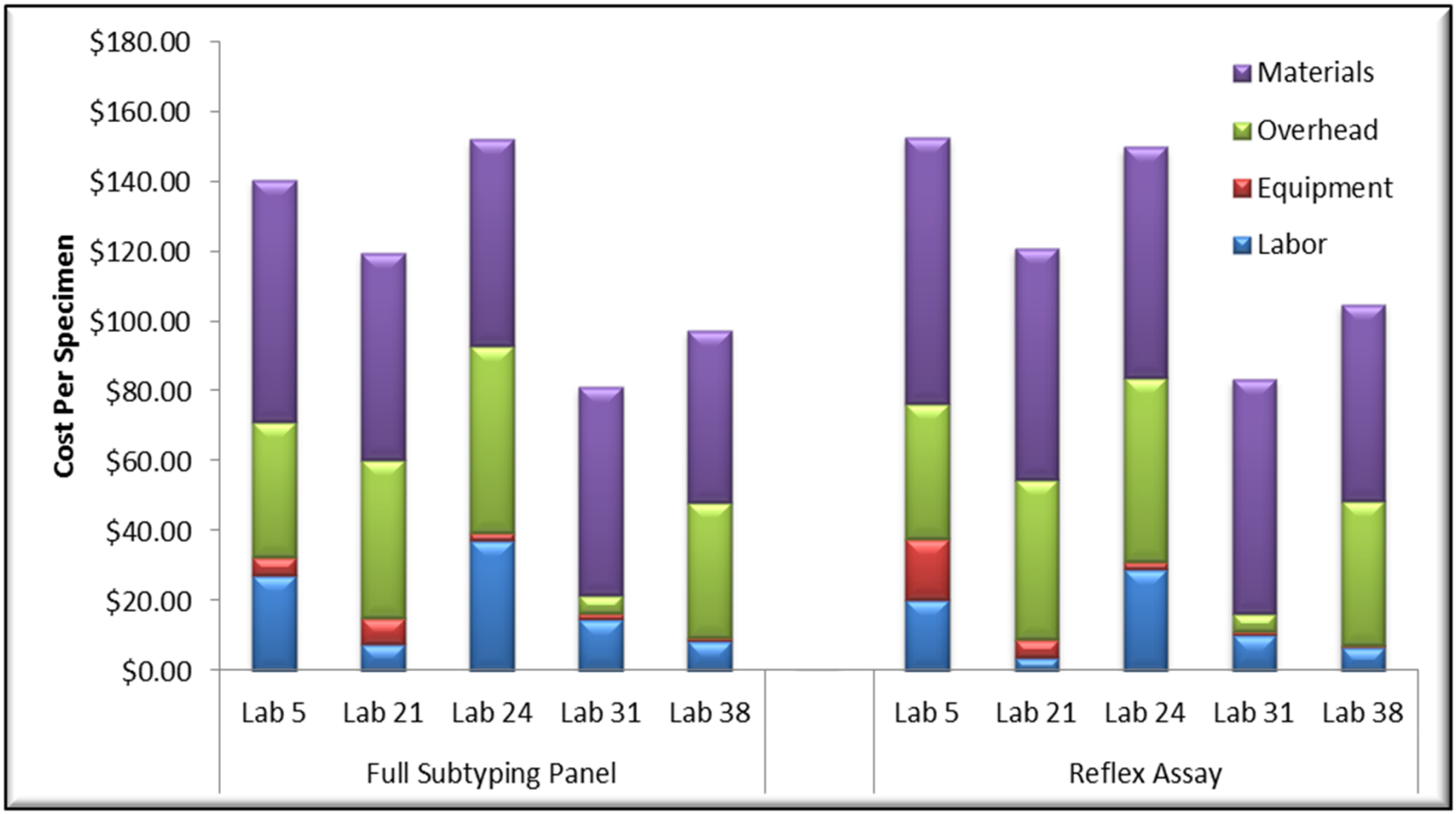
Costing Model Inputs

- Used data from the Influenza Laboratory Resource and Process Modeling Project.
- Collected additional data including:
  - Overhead and Shipping: cost of facilities, surcharges, utilities & transport of specimens. This could be done by
    - Itemized Price
    - Percentage of entire overhead for facility
  - Labor: salary + fringe etc. = hourly cost
    - rRT-PCR cost model
    - Viral culture
  - Equipment
    - Depreciation
    - Service contracts
  - Consumable Materials
    - Extraction
    - rRT-PCR
    - Consumables directly/indirectly associated with specimen testing

Total Cost per Specimen
(excludes IRR costs and 1 outlier lab)

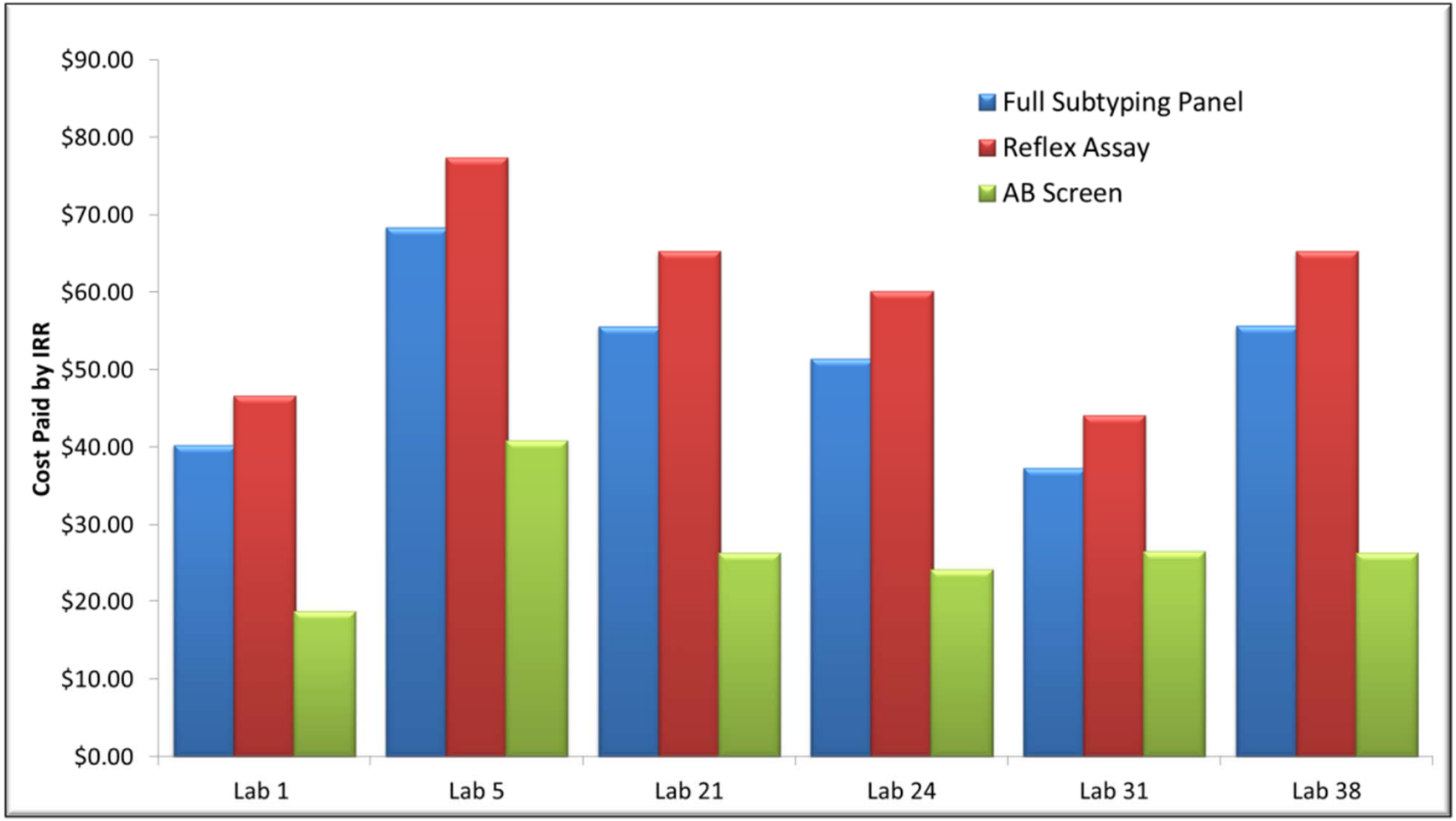


Total Cost per Specimen
(includes IRR but minus outlier lab)



Material cost per specimen paid by IRR

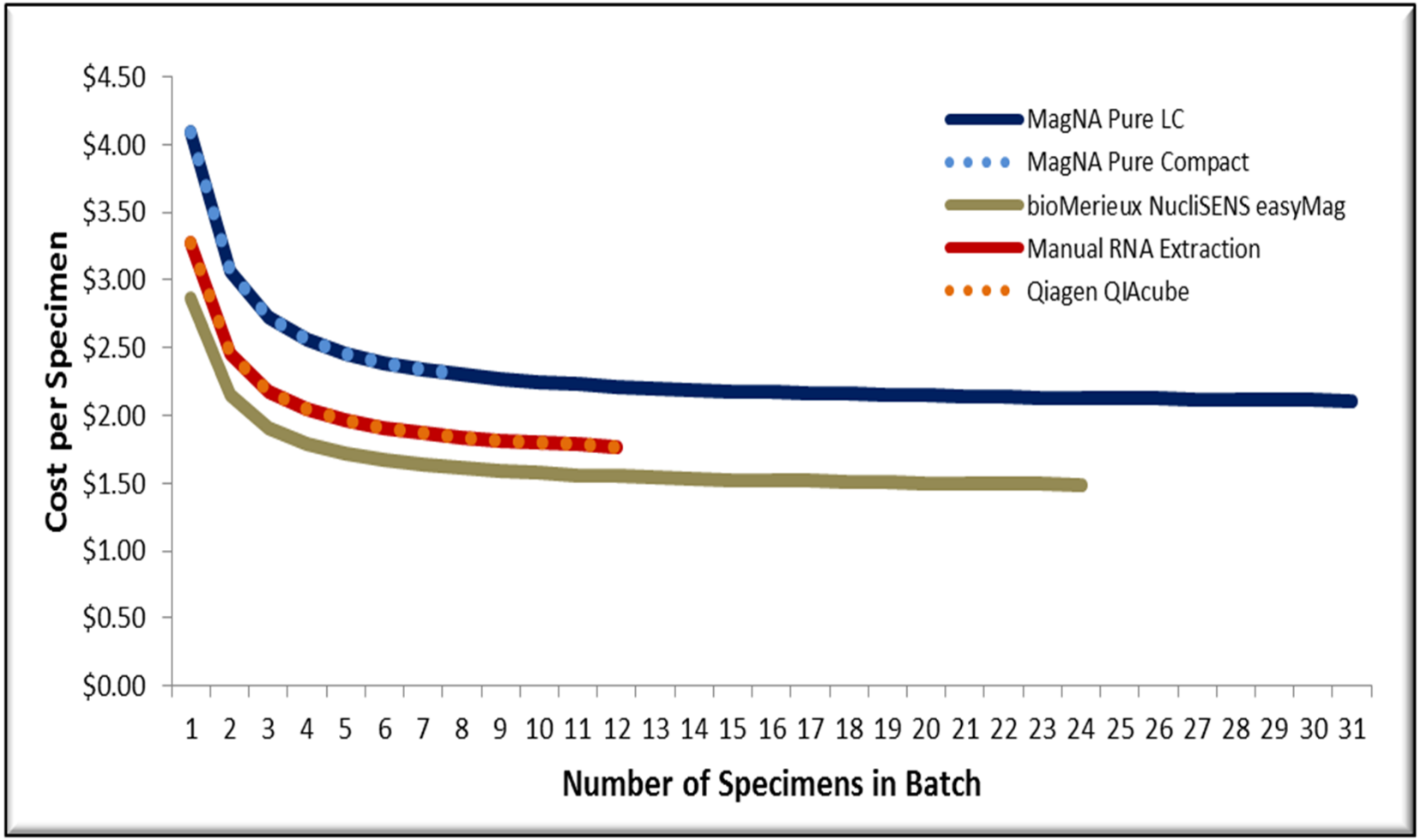
Full subtyping algorithm is most cost efficient



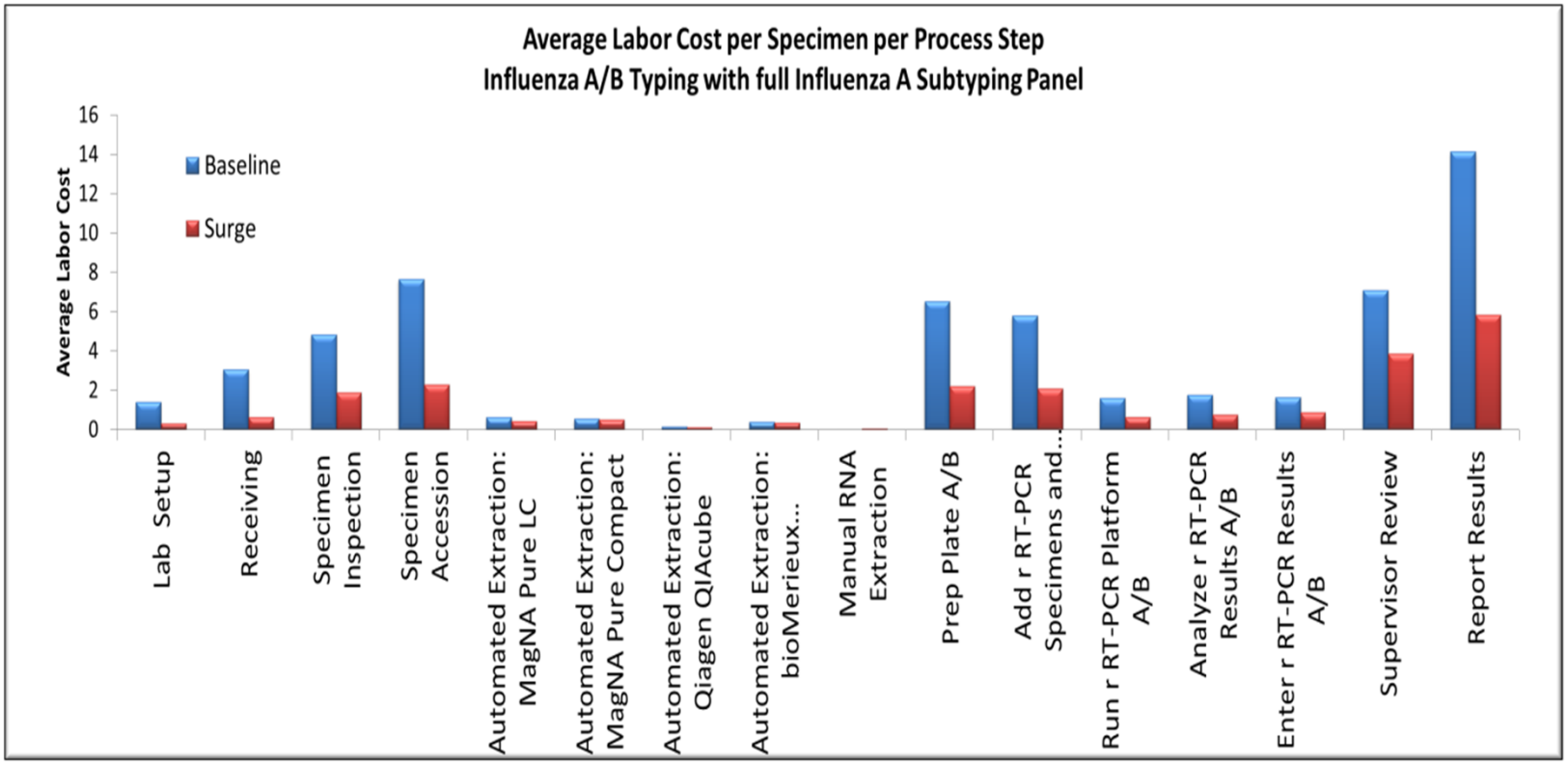
Capacity/Day and Cost/Specimen

Testing Algorithm	Average Capacity per Day	Range of Cost per Specimen Excluding IRR Materials	Range of Cost per Specimen Including IRR Materials
Full Subtyping Panel	52 specimens	$ 42 - 358	$ 81 - 398
Reflex Assay	65 specimens	$ 39 - 573	$ 83 - 620
AB Screen*	148 specimens	$ 34 - 137	$ 60 - 156

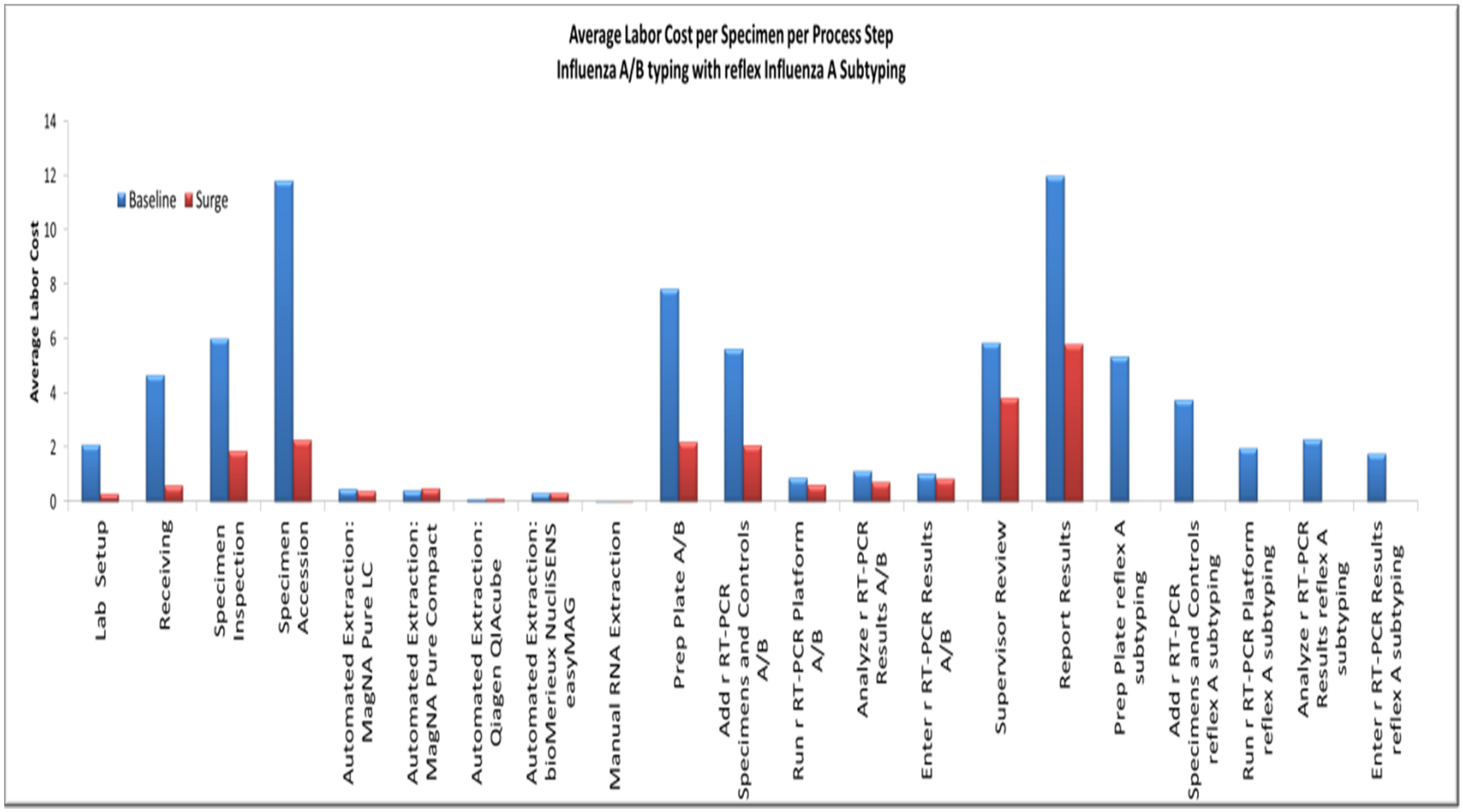
Cost of Extraction only



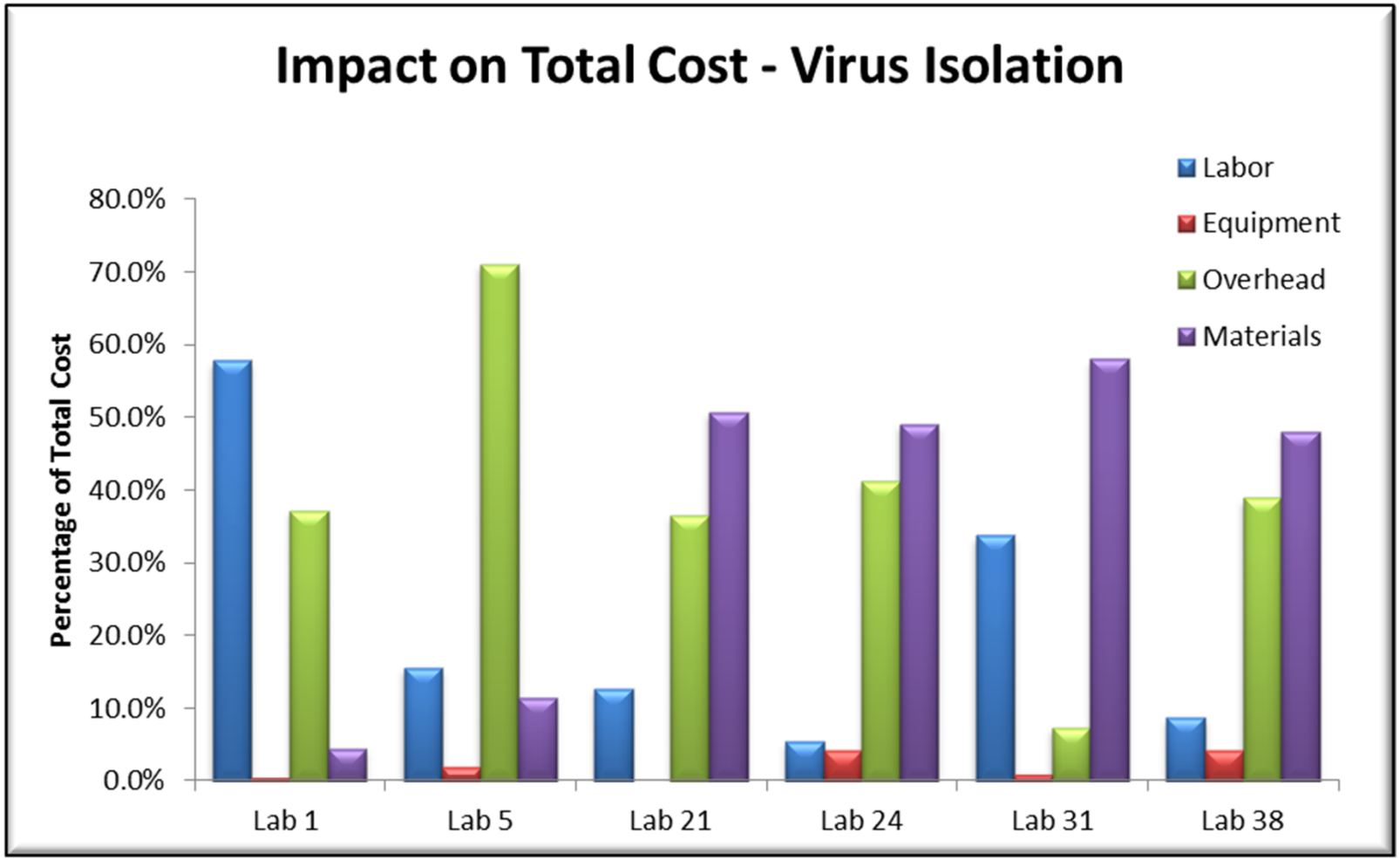
Greatest labor cost is report results step



Reflex Assay greatest cost in Specimen Accession and Report Result steps



Data on virus isolation insufficient



Comparison of APHL cost model to an independent lab cost study

Categories	APHL Model Output	Lab Study Output	Difference Per Specimen
Materials per specimen	$ 11.56	$ 10.27	$1.29
Labor per specimen	$ 31.29	$ 14.92	$16.37
Depreciation	$ 2.38	$ 2.38	$0.00
Maintenance	$ 4.51	$ 4.51	$0.00
Indirect/Overhead costs	$ 18.38	$ 11.53	$6.85
Sum with overhead	**$ 68.12**	**$ 43.61**	**$24.51**

Analysis of Comparison

- Materials used were the same; however, cost differences were due to:
  - (1) variability in batch sizes
  - (2) differences in time periods for material cost estimation (e.g. one lab coat used per week vs. one lab coat used per two weeks).
- Labor cost differences were due to a rule in the APHL model to utilize any available employee who could perform that task and utilize their specific salary versus the lab study where the average employee salary was utilized. Also, waiting time was accounted for in the APHL model, further increasing labor costs (i.e. a staff member is utilized to begin a process but stands around idle until a machine becomes available for use).

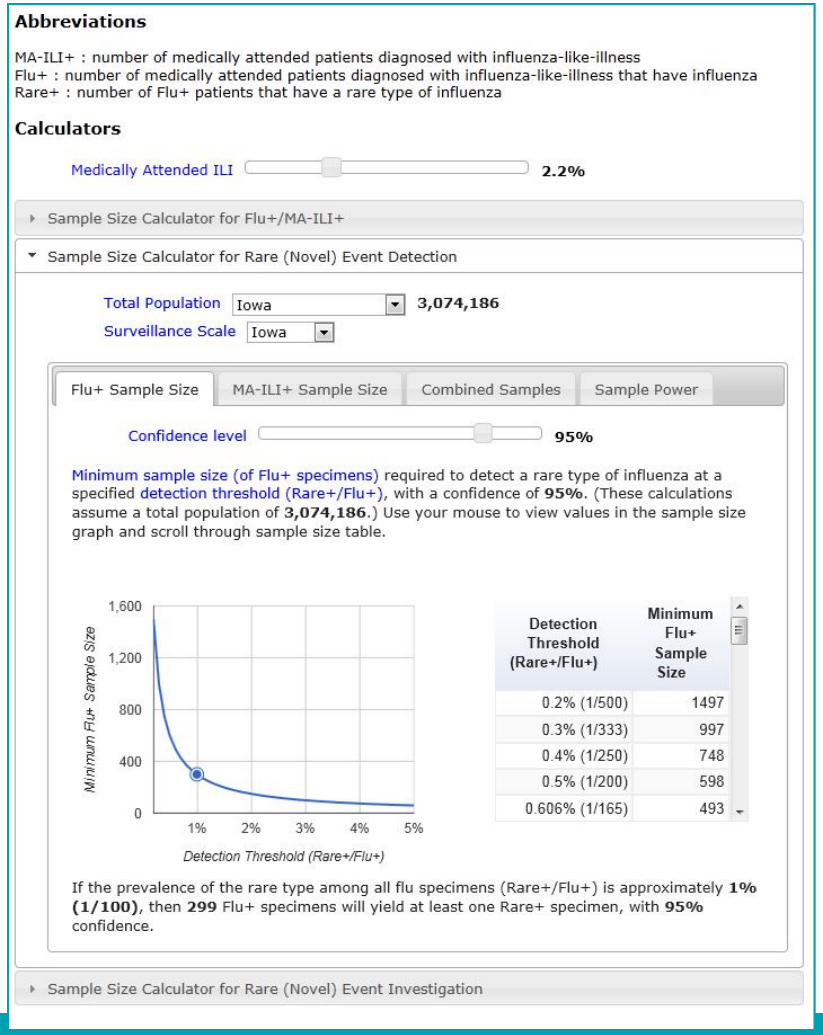
Analysis of Comparison cont.

- Overhead costs were accounted similarly for both models, adding a 38.8% cost to the direct costs already incurred; however, cost differences in the categorization (e.g. labor, materials) resulted in cost differences when this percentage was added to the costs per specimen.
- Maintenance costs were calculated the same (annual cost / annual throughput) in both models.
- Depreciation costs were calculated the same (annual cost / annual throughput) in both models.

Conclusions

- Full subtyping panel is most cost efficient
- IRR is an invaluable resource to PHL
- Labor costs are a significant expense

Sample Size Calculator

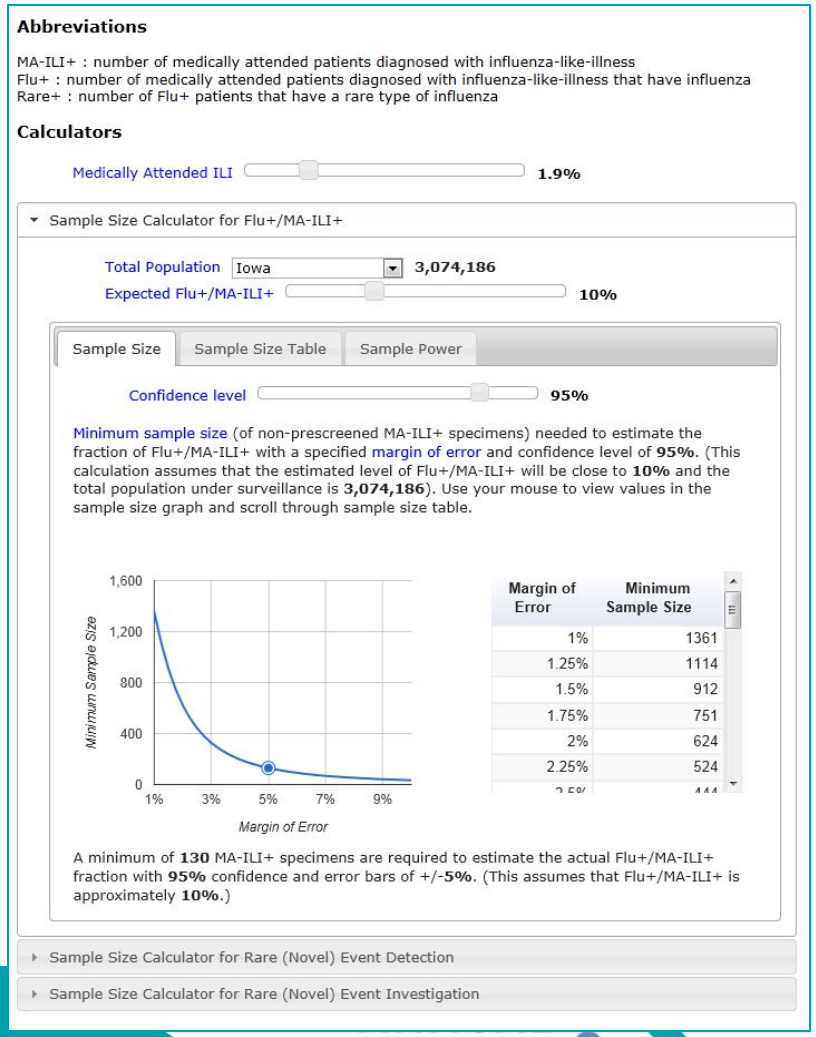


Detection of Rare (novel) event:

Using Iowa population data (3,074,186) to detect a novel strain circulating, and assuming a prevalence of 1% and a confidence level of 95%, SHL would need to test 299 Flu+ specimens to detect the novel strain. This type of calculation is very useful and would add to the discussion of the surveillance system for a novel influenza virus like H3N2v or H7N9.

Sample Size Calculator

Situational Awareness: Week 41 (10-13-2012) = second week when Flu+/ Flu+/MA-ILI+ rate was equal to or greater than 10%. SHL tested 49 specimens, which resulted in a 95% confidence level and an 8.32% margin of error that the true rate was 10%. To be at a 95% confidence level with a 5% margin of error, SHL would have needed to test 131 specimens, or 335 specimens to be at a 95% confidence level with a 3% margin of error.



Experience with capacity and cost models from Iowa's perspective

- More time, thought and discussion needs to be afforded influenza surveillance activities
- Importance of costing all tests
  - Costing compared favorably with current Iowa method

Conclusions

- The capacity and costing modeling should be extended to other public health testing
- Much can be gained be from discussions with epidemiologists
- This process can be extended to other projects such as the Lab Efficiencies Initiative and Shared Services models