

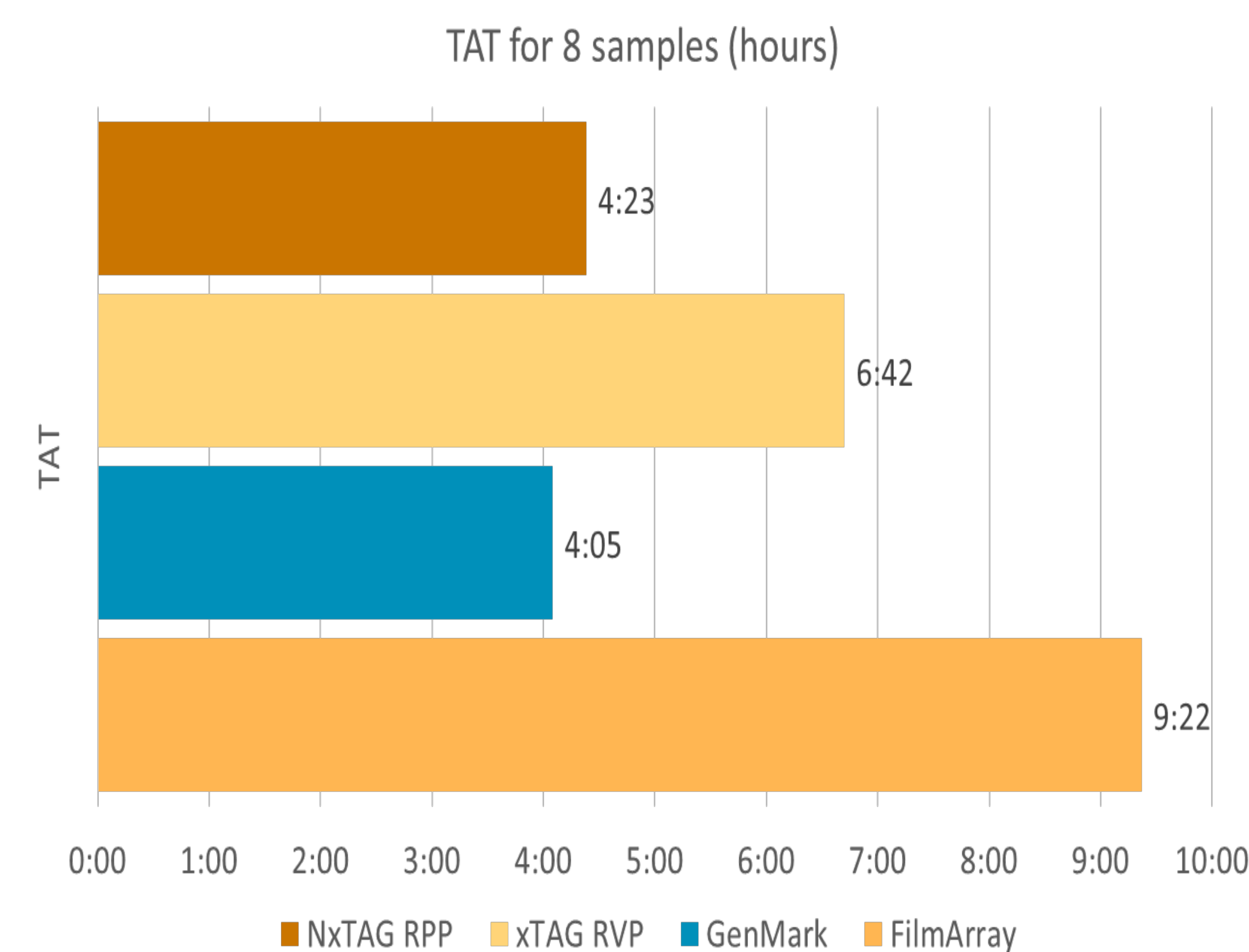
WORKFLOW STUDY AND COMPARISON FOR 4 COMMERCIALY AVAILABLE RESPIRATORY VIRUS PANEL ASSAYS

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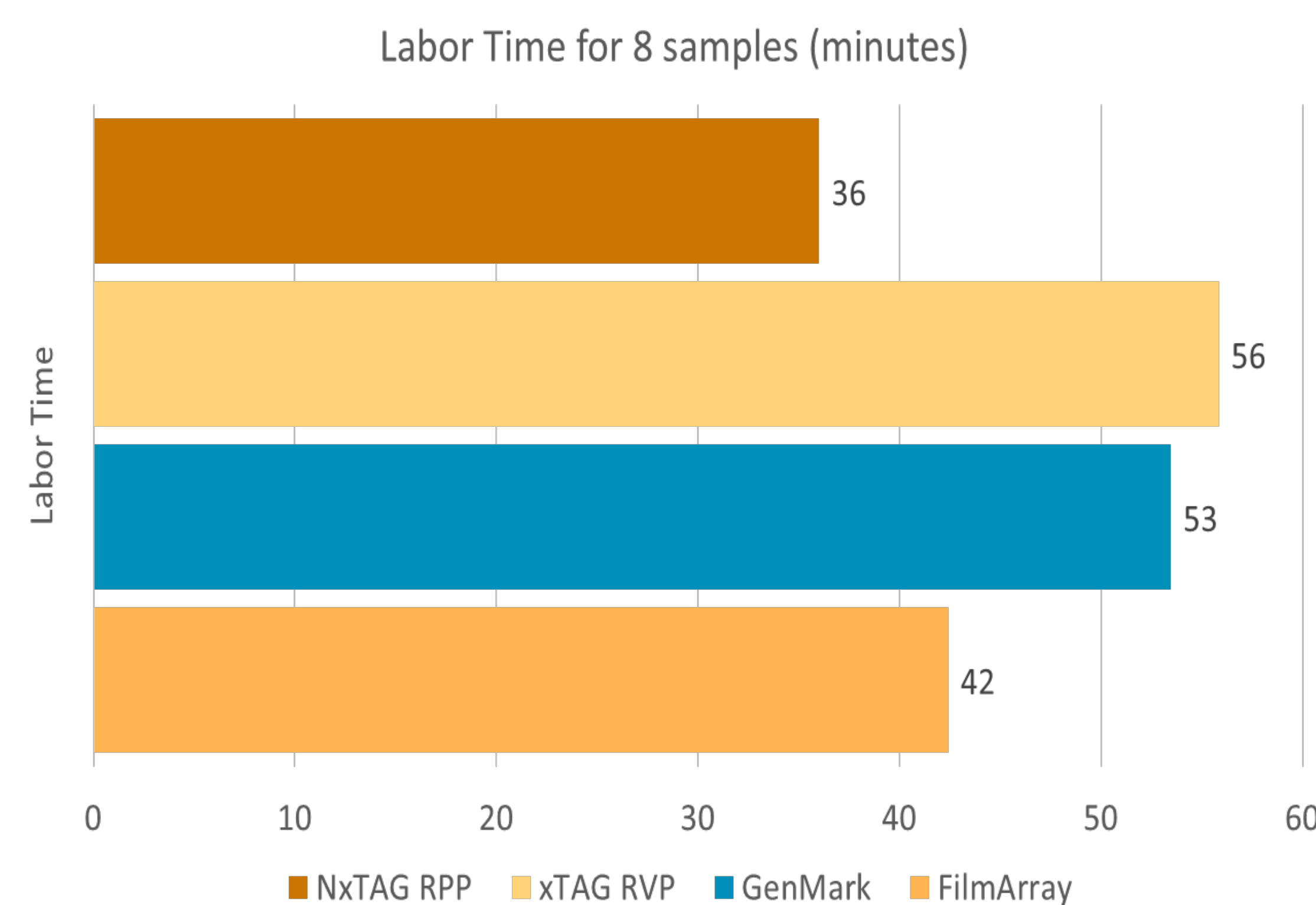
INTRODUCTION

Several commercially available, FDA approved assays are available for detection of respiratory virus pathogens within the molecular laboratory, each with different amounts of hands on time, batch sizes, and turn-around-times. Workflow studies can help a laboratory choose the most efficient and effective test option for their institution. In this study, a workflow comparison was performed between 4 commercially available respiratory virus panels. The study was specifically performed to evaluate the performance and impact the new NxTAG RPP assay would bring to the laboratory in terms of technologist hands on time and overall turnaround-time (TAT) for results. The end goal was to determine which assay would be best for testing samples during the 2015-2016 respiratory virus season.

METRIC COMPARISON-TURN AROUND TIME



METRIC COMPARISON-LABOR TIME



| Instrument | Instrument Capacity | Number of Instruments | Total TAT (h:mm:ss) for batch size (arrival to result) | | | | |
|-------------------|---------------------|-----------------------|--|---------|----------|----------|-----------|
| | | | 1 | 8 | 15 | 24 | 96 |
| BioFire FilmArray | 1 | 1 | 1:37:15 | 9:22:17 | 17:07:19 | 27:05:13 | 106:48:25 |
| BioFire FilmArray | 1 | 6 | 1:37:15 | 2:46:41 | 3:56:07 | 5:06:33 | 18:53:45 |
| GenMark DX | 8 | 1 | 3:38:21 | 4:04:49 | 7:40:20 | 11:23:25 | 44:17:07 |
| NxTAG RPP | 96 | 1 | 4:01:04 | 4:22:52 | 4:44:40 | 5:12:41 | 8:56:50 |
| xTAG RVP v1 | 96 | 1 | 6:19:27 | 6:41:36 | 7:03:45 | 7:32:13 | 11:20:00 |



xTAG RVP v1



GenMark DX



BioFire FilmArray



NxTAG RPP

RESULTS

Results are shown for batch sizes of 8 samples to best reflect the current workflow requirements. The Luminex xTAG Respiratory Viral Panel had a hands on time of 56 minutes with a complete TAT of 6 hours and 42 minutes. The GenMark eSensor Respiratory Viral Panel had a hands on time of 53 minutes and a complete TAT of 4 hours and 5 minutes. The BioFire FilmArray Respiratory Panel had a hands on time of 42 minutes and a complete TAT of 9 hours and 22 minutes. The Luminex NxTAG Respiratory Pathogen Panel had a hands on time of 36 minutes and a complete TAT of 4 hours and 23 minutes.

CONCLUSION

The FilmArray 1 instrument configuration is unfeasible for more than 6 to 8 samples per shift; while the FilmArray 6 instrument configuration should be feasible for up to 24 samples in a single shift. At lower volumes, the GenMark assay and Luminex NxTAG RPP are the best options for the fastest TAT. At high volumes (>24 samples), the FilmArray 6 instrument configuration, Luminex NxTAG RPP and Luminex xTAG RVP are the only options providing same-day results. Additionally as volumes increase, the Luminex NxTAG RPP changes only incrementally for labor time and turnaround time up to 96 samples. Ultimately, this study showed that with volumes ranging close to 60 specimens per day the Luminex NxTAG RPP was the best option for our laboratory during the 2015-2016 respiratory virus season. This allowed for the fastest TAT with the least amount of hands on time in our laboratory. In conclusion, when hands on time, TAT, performance and cost are considered NxTAG RPP was the best solution for our laboratory.

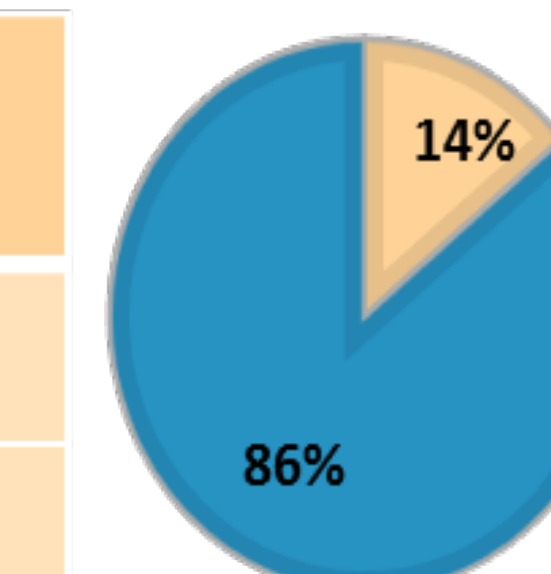
MATERIALS & METHODS

The 4 assays that were compared in this workflow study were as follows: Luminex xTAG Respiratory Viral Panel (RVP, version 1), GenMark eSensor Respiratory Viral Panel, BioFire FilmArray Respiratory Panel, and the Luminex NxTAG Respiratory Pathogen Panel (RPP). All assays were performed as listed in the package inserts and all testing was performed by the same technologist. Each instrument was observed for several runs to include a small batch size and large batch size. Process analysis and time studies were used to quantify the labor time, automation time and other aspects of the instrument process run. Each instrument studied has a number of steps that can be categorized as fixed or variable components allowing each instrument to be simulated to understand the operating time for various batch sizes and configurations.

Comparison of Manual Labor to Automation
 (*) Manual plus Automation time may not equal the overall Turnaround Time if some tasks are performed simultaneously

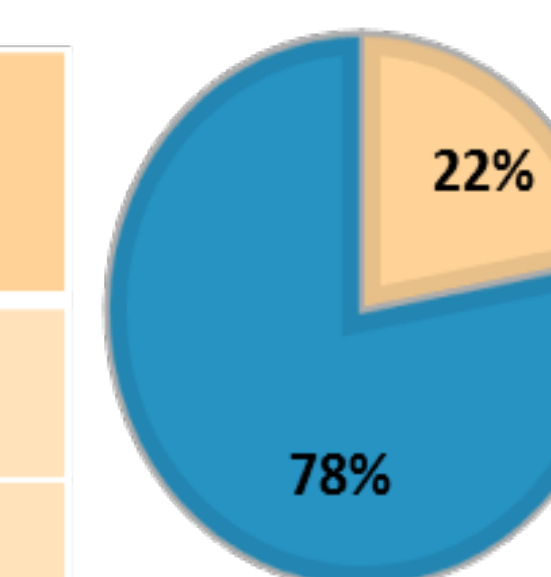
xTAG RVP Manual and Automation Time Run of 8 samples (h:mm:ss)

| | |
|--------------------|---------|
| Manual Labor | 0:55:50 |
| Automation / Other | 5:42:12 |



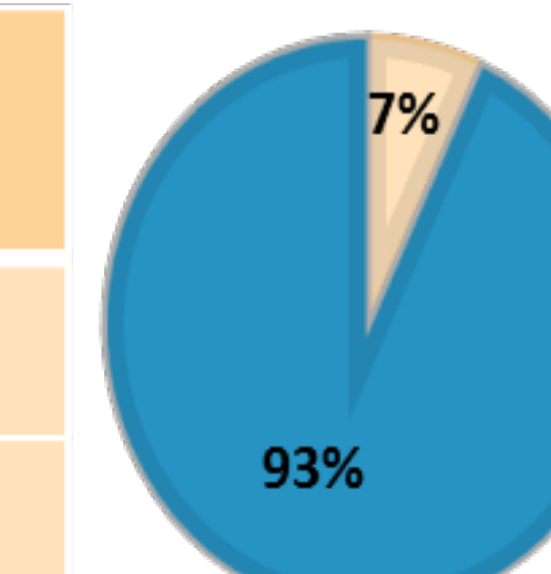
GenMark DX Manual and Automation Time Run of 8 samples (h:mm:ss)

| | |
|--------------------|---------|
| Manual Labor | 0:53:27 |
| Automation / Other | 3:09:19 |



BioFire Film Array Manual and Automation Time Run of 8 samples (h:mm:ss)

| | |
|--------------------|---------|
| Manual Labor | 0:42:24 |
| Automation / Other | 8:47:28 |



RPP Manual and Automation Time Run of 8 samples (h:mm:ss)

| | |
|--------------------|---------|
| Manual Labor | 0:35:54 |
| Automation / Other | 3:59:03 |

