GenMark ePlex RP 6 steps to completion

Luminex RVP 123 steps to completion

A Comparison of Multiplex Respiratory Panels: A Workflow Analysis

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Abstract

Background: The Lifespan microbiology laboratory currently performs approximately 8000 respiratory viral multiplex panel assays per year at Rhode Island Hospital (RIH) for a multi-hospital system. More than 80% of the time the multiplex assay is used for in-patient diagnosis of respiratory infections. While the current assay system provides excellent results and allows high capacity testing; high technical complexity, lengthy reporting time to result, large equipment footprint, and lack of key URI bacterial pathogens limit its overall efficiency in the lab and usefulness clinically for patient treatment, patient flow from the ER, and appropriate infection control. The objective of this study was a workflow study and a cost assessment of the GenMark Diagnostics ePlex® Respiratory Pathogen Panel* (Research Use Only) compared to our current protocol which includes a combination of the random access Cepheid Xpert Flu/RSV XC Assay at three separate hospitals with subsequent request on in-patients with negative Xpert for the Luminex xTAG Respiratory Viral Panel (RVP) performed at RIH.

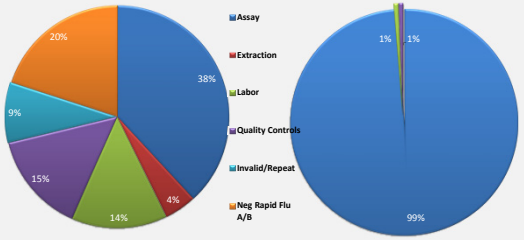
Methods: A time-motion operational workflow study (prior to influenza season) was done for a two day period in November 2016 evaluating all analytical steps from the time of specimen order to report in the electronic medical record for 39 specimens tested on a single day and then annualized for 8000 tests per year. RVP was performed four days per week. Overall metrics included the following: Operator hands-on-time, laboratory turnaround time, total time to result from physician order to posting, laboratory throughput and capacity, instrument footprint, and points of risk for operator error.

Conclusion: The current protocol of Cepheid Xpert Flu/RSV XC with reflex testing option to xTAG RVP for inpatients showed batch testing with a high complexity RVP limited both laboratory and clinical utility of the assay. While the implementation of the test is not laboratory cost-neutral, use of the ePlex RP allows for a single PCR test for inpatients, decentralization of testing to each acute care hospital for immediate random access 24/7, addition of bacterial pathogens critical to deescalating antibiotics, consistent reliable result reporting time to providers to optimize care plans and highly efficient use of laboratory space and technical labor.

*The ePlex Respiratory Pathogen Panel is not for sale in the US and the final product is subject to change.

Rapid Flu and xTag RVP

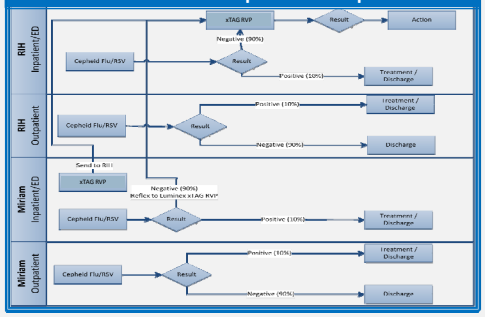
ePlex RP



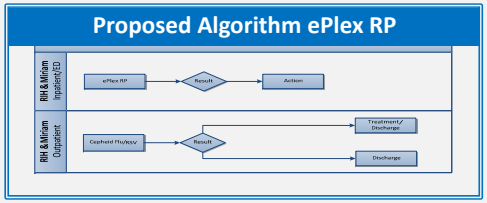
Percentage True Cost of xTAG RVP and GenMark ePlex RP

Results

Current Algorithm
xTAG RVP and Cepheid GeneXpert



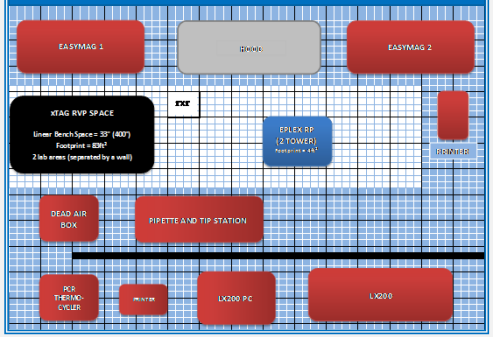
Proposed Algorithm ePlex RP



Comparison of Multiplex Respiratory Assay Systems
(N = 39 samples)

	Luminex® xTAG	GenMarkDx ePlex® RP	Benefit with ePlex® RP
Daily hands-on time	369 min	62.4 min	83% reduction of hands on time
CLIA Complexity, technological expertise and total steps for assay	CLIA High Complexity, Specialized techs, 123 steps	Complexity TBD, Generalist tech, 6 steps	Decreased complexity Increased flexibility of workforce
Risk for Operator Error	High	Low	Higher confidence of successful patient result reporting
Sample tracking and Interface	None	Positive Sample Identification and bi-directional LIS interface	Decrease in sample mismatch & transcription error rate with autofile resulting
Time of order to reportable result	42:28:02 (includes Xpert® Flu/RSV XC and xTAG RVP add-on)	3:30:11	Time to clinically actionable results decreased by 38 hours (91%) CONSISTENCY in time to reportable; performed 24/7
Bacterial Targets Pertussis, Mycoplasma	No	Yes	Differentiation of viral vs. bacterial aids in anti-microbial stewardship and infection control efforts
Required lab bench space	83 sq. ft.	4 sq. ft. 2 towers - 6 bays each	95% gain of vital laboratory space
Test Cost (80% xTAG RVP in-patients)	Multiple components contribute to costs	Assay cartridge major cost	Implementation of ePlex RP is not cost-neutral

Instrument Footprint Comparison

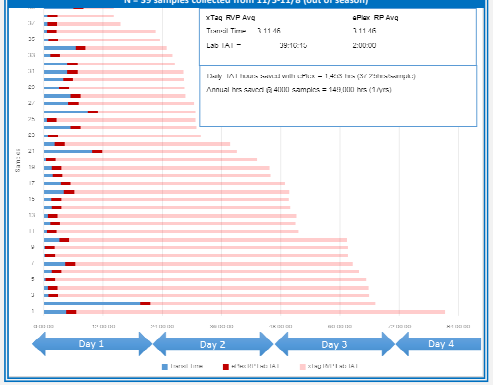


How valuable is your lab space?

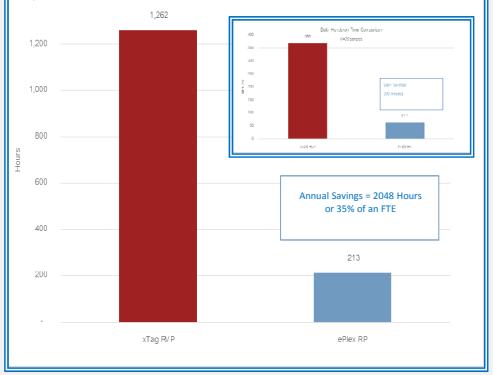
xTag RVP

ePlex RP

RIH RVP Turnaround Time Comparison
N = 39 samples collected from 11/5-11/8 (out of season)



Annual Hands-on Time Assessment (8000 specimens)
INSET: Daily Hands on Time



Conclusions

- Batch testing with a high complexity xTAG RVP limits both laboratory and clinical utility of the assay
- Cost of ePlex RP is not cost neutral
- Use of ePlex RP allows decentralization of testing in a multisite hospital with 24/7 random access
- Additional targets including bacteria on the ePlex RP critical to deescalating antibiotic use
- ePlex RP allows for highly efficient use of laboratory space and technical labor