

Performance and Cost-Effectiveness of Verigene RP Flex

Silva A, LaCount R, Ballard L, Milham B

St. Mary's Hospital and Regional Medical Center, Grand Junction, CO, USA



Introduction

Until recently, none of the multiplex respiratory pathogen tests alone could provide the flexibility to satisfy the clinician's desire for both targeted respiratory pathogen testing, as well as broad respiratory pathogen testing in a cost-effective manner for both the lab and patient. Verigene RP Flex allows the user to choose any combination of the 13 viral and 3 bacterial targets for an individual sample at the time of test ordering based on the clinician and patient's needs and pay just for the targets reported. In this study, we determined the analytical performance of RP Flex using NP washes and NP eswabs and analyzed the cost-effectiveness of flexible testing with RP Flex relative to St. Mary's previous respiratory algorithm and use of broad respiratory viral panel (RVP) only.

Methods

Method Comparison

A combination of clinical (n=22), contrived (n=28) and characterized control (n=6) specimens were tested with RP Flex. The clinical NP eswabs and NP wash specimens were prospectively collected between December 2014 and May 2015 and were frozen at -80°C. Contrived specimens were made by spiking UTM, eswab and NP washes with known positive specimens provided by Zeptomatrix. The characterized controls were provided by Zeptomatrix.

Financial/Resource Analysis

The financial analysis was performed using testing volumes and pricing from 2013 and list pricing for RP Flex and a comparable RVP.

Testing algorithms that were analyzed into included:

- Send-out of all Respiratory tests to a reference lab.
- Rapid antigen test, flu and RSV tests (EIA) in-house and send-out of remaining tests.
- Molecular flu and RSV in-house and send-out all other tests.
- Molecular broad respiratory panel for all patients in-house.
- Molecular flu, RSV and Molecular Broad Respiratory Panel with flex in-house.

Results

Method Comparison

Results of the method comparison are presented in Table 1. RP Flex positive and negative agreement was 100% across all sample types.

Financial/Resource Analysis

In 2013, a total of 1,234 flu EIA, 76 flu serotyping's, 232 RSV EIA, 2 flu/RSV PCR, 1 adv PCR, 37 EV PCR, 135 pertussis PCR, and 77 respiratory viral panel tests were sent to a reference lab for testing in 2013, totaling \$191,532 in charges. Use of a broad RVP in-house at \$130 per test for this testing would have cost \$226,690. Use of RP Flex with flexible pricing would have cost only \$94,860.

Method Comparison

Table 1: Performance of RP Flex compared to reference methods using eswab and NP washes

RP Flex Target	TP	TN	FP	FN	PPA	NPA
Adenovirus	17	39	0	0	100%	100%
hMPV	17	39	0	0	100%	100%
Flu A	17	39	0	0	100%	100%
Flu A/H1	13	43	0	0	100%	100%
Flu A/H3	17	39	0	0	100%	100%
Flu B	23	33	0	0	100%	100%
Para 1	17	39	0	0	100%	100%
Para 2	17	39	0	0	100%	100%
Para 3	13	43	0	0	100%	100%
Para 4	8	48	0	0	100%	100%
Rhinovirus	16	40	0	0	100%	100%
RSV A	20	36	0	0	100%	100%
RSV B	30	16	0	0	100%	100%
B. pertussis	13	43	0	0	100%	100%
B. parapertussis/ brochiseptica	6	50	0	0	100%	100%
B. holmesii	14	42	0	0	100%	100%

Financial/Resource Analysis

Table 2: Cost analysis of a RP Flex versus existing respiratory algorithm and a broad RVP

Test Algorithm Considered	Flu PCR	RSV PCR	Flu/RSV PCR	Adv PCR	EV PCR	Pertussis PCR	Broad RVP	Total
# of Tests/Year	1,244	232	2	135	37	2	77	1,729
Flu/RSV PCR In-House + Send-Out	\$65			\$230	\$174	\$72	\$555	\$176,437
Broad RVP Only In-House	\$130							\$224,770
Verigene RP Flex In-House	\$50	\$50	\$70	\$50	\$50	\$50	\$140	\$93,420

Financial/Resource Analysis (cont.)

Table 3: Summary of the pros and cons associated with respiratory testing algorithms

Testing Algorithm	Pros	Cons
Send-out all respiratory tests to reference lab	<ul style="list-style-type: none"> • Labs with very limited resources can execute this algorithm 	<ul style="list-style-type: none"> • Turnaround time (2-3 days) not clinically meaningful • Expensive for the clinical value provided
Rapid flu & RSV in-house, send-out remaining tests to reference lab	<ul style="list-style-type: none"> • Reduced turnaround time (TAT) for flu & RSV testing • Satisfy Emergency Department's (ED) desire for < 60 minute TAT • Provide some testing closer to patient to impact clinical management decisions 	<ul style="list-style-type: none"> • Turnaround time (2-3 days) not clinically meaningful • Expensive for the clinical value provided • Sensitivity of rapid tests not ideal for optimal patient management
Molecular flu +/- RSV in-house, send out remaining tests to reference lab	<ul style="list-style-type: none"> • Reduced TAT for flu & RSV testing • Highly sensitive molecular testing for flu +/- RSV • Provide flu +/- RSV testing with strong sensitivity closer to the patient 	<ul style="list-style-type: none"> • Turnaround time (2-3 days) not clinically meaningful for send-out tests • Expensive for the clinical value provided
Molecular broad respiratory panel for all patients	<ul style="list-style-type: none"> • Reduced TAT for all respiratory pathogen testing • Highly sensitive molecular testing for flu +/- RSV 	<ul style="list-style-type: none"> • Expensive cost of testing to lab and patient • Testing is often times too broad for a patient
Molecular flu +/- RSV and Molecular Broad Respiratory Panel	<ul style="list-style-type: none"> • Reduced TAT for all respiratory pathogen testing • Highly sensitive molecular testing for all pathogens • Minimizes unnecessary testing cost to patient 	<ul style="list-style-type: none"> • Expensive to acquire multiple molecular platforms • Extra quality control testing, proficiency testing, lab technician training, and inventory management of reagents

Conclusions

With RP Flex, labs of all sizes can offer a respiratory pathogen testing algorithm that fully addresses clinician and patient needs in a format that minimizes the financial and resource burden on the laboratory. The ability to use collection devices, eswabs, that are commonly used in clinician offices, as well as being able to use NP washes that are collected as part of a treatment technique for pediatric patients allows clinicians to expand their testing options. Simplifying the collection technique and offering a broad range of testing in-house without placing the cost burden on the patient or laboratory results in better community health care.