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Laboratory News

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FILMARRAY® RESPIRATORY PANEL (RP) 20-PLEX NUCLEIC ACID TEST

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SUMMARY

Effective July 1, 2013, the FilmArray® Respiratory Panel 20-plex nucleic acid test will be available to the following clinical areas:

- Ministry Saint Joseph's Hospital ICU units
- Ministry Saint Joseph's Hospital Emergency Department
- Marshfield Clinic - Marshfield Center Urgent Care Department
- All other areas only upon consultation with a pathologist or PhD microbiologist.

With an analytical time of approximately one hour, the FilmArray® Respiratory Panel can accurately and rapidly detect the following respiratory pathogens:

Viruses

Adenovirus	Coronavirus 229E
Coronavirus HKU1	Coronavirus NL63
Coronavirus OC43	Enterovirus/Rhinovirus
Human Metapneumovirus	Influenza A H1
Influenza A H1-2009	Influenza A H3
Influenza B	Parainfluenza 1
Parainfluenza 2	Parainfluenza 3
Parainfluenza 4	Respiratory Syncytial Virus

Bacteria

Bordetella pertussis	*Mycoplasma pneumoniae*
Chlamydophilia pneumoniae	

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The FilmArray® Respiratory Panel is intended to provide a broad-spectrum diagnosis of respiratory viral and atypical bacterial pathogens in those severely ill patients requiring a comprehensive diagnosis. It is not meant to replace the Influenza A/B, RSV, and *Bordetella* nucleic acid tests currently performed at Marshfield Labs. Importantly, while many of the viruses detected by the FilmArray® Respiratory Panel currently have no FDA-approved antiviral therapies, knowledge of the infectious etiology may be of value in guiding therapy. Additionally, the FilmArray® Respiratory Panel detects *C. pneumoniae* and *M. pneumoniae*, the causes of atypical bacterial pneumonia, which are not recoverable with routine culture methods.

BACKGROUND

Respiratory viruses (RVs) have historically been detected by culture on cultivated cell lines, with fluorescent antibody (FA) stains, or through RV antigen detection by rapid immunoassay. Viral culture can detect several important RVs including influenza and RSV with relatively good sensitivity, but typically takes several weeks to complete and requires specialized culture and detection techniques. While several improvements in RV culture such as the use of centrifuged shell vials and mixed-cell monolayers have reduced the turnaround time from weeks to days, technical limitations still exist. Furthermore, culture alone cannot practically detect those RVs beyond influenza and RSV that are now known to cause respiratory disease, sometimes severe in nature. FA, while highly specific has variable sensitivity, particularly when specimen collection is sub-optimal. It is also complex, requiring special techniques and equipment. Rapid antigen detection tests are restricted to influenza and RSV, and are hampered by unacceptably low levels of sensitivity.

Within the last 10-15 years, clinical virology has experienced a renaissance as the virus nucleic acid tests (NATs) of research labs, based upon PCR and other amplification techniques, moved into the clinical sphere. Clinical laboratories now regularly use nucleic acid tests to rapidly and accurately detect RVs in respiratory secretions. In fact, many academic medical centers now rely entirely upon NATs.

However, until recently the FDA-cleared commercial assays used in all but the most sophisticated medical centers could only detect one or several viruses at a time, limited to Influenza A, Influenza B, and/or RSV. While the detection of these three has the broadest diagnostic value in most patient populations, the need for commercially available NATs that detect the full spectrum of RVs was nevertheless recognized. Several such assays have now been cleared for *in vitro* diagnostic use by clinical virology laboratories, one of which is the FilmArray® Respiratory Panel. It was chosen by our laboratory for its accuracy, rapidity and ease of operation, making it truly available '24/7'.

ORDERING INFORMATION

Test	Keywords	Lab Test Code	Clinic (Com)	Hospital (Centricity)
Respiratory Viral Panel	Respiratory Virus, Virus Culture, Flu, RSV, Adeno, Entero, Rhino, Virus	FARP	Respiratory Viral Panel by PCR (Restricted to MFLD Main Campus Urgent Care)	Respiratory Viral Panel by PCR (Restricted to ER/ICU use)

DOWNTIME

Write-In (Form 1).

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CONTACTS

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or
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SELECTED REFERENCES

1. Rand, K. H., H. Rampersaud, and J. J. Houck. *Comparison of two multiplex methods for detection of respiratory viruses: FilmArray RP and xTAG RVP*. J. Clin. Microbiol. 2011. 49:249.
2. Pavia, A. T. *Viral infections of the lower respiratory tract: old viruses, new viruses, and the role of diagnosis*. Clin. Infect. Dis. 2011. 52(Suppl 4): S284.
3. Renois, F., D. Talmud, A. Huguenin, et al. *Rapid detection of respiratory tract viral infections and coinfections in patients with influenza-like illnesses by use of reverse transcription-PCR DNA microarray systems*. J. Clin. Microbiol. 2010. 48:3836.

LABORATORY UPDATE: *HELICOBACTER PYLORI* ANTIBODY (HEPY)

EFFECTIVE JULY 18, 2013

In order to provide better service, Marshfield Labs will move the *H. pylori* antibody test to a new platform, the Siemens Immulite 2000 analyzer.

WHAT REMAINS UNCHANGED

Test name:	Helicobacter pylori Abs
Test code:	HEPY
CPT code:	86677
Performance:	Daily, M – F

WHAT WILL CHANGE

- Blood collection in the Serum Separator Tube (SST) is now acceptable, in addition to the Red Top Tube (RTT).
- The recommended sample volume has been reduced to 0.5 mL.
- The minimum sample volume has been reduced to 0.2 mL.
- Hemolyzed and/or lipemic specimens are now acceptable.

CONTACTS

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