LABORATORY ALLIANCE of Central New York, LLC

Multiplex PCR Assay for SARS-CoV-2, Flu A, Flu B and RSV

Effective November 3, 2020, the Microbiology department of Laboratory Alliance of Central New York will be offering a new multiplexed, real-time, qualitative PCR test, called the QUAD PCR assay, for the simultaneous detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV). Suitable specimens for testing include a nasopharyngeal or nasal swab submitted to the laboratory in an appropriate viral transport medium. This new, rapid, multiplex gene amplification assay will be offered at the Rapid Response Labs at St. Joseph's Health and Crouse Health. The following patient populations only will qualify for this expedited testing:

- Hospitalized in-patients of Crouse and St. Joseph's Health
- ED direct admitted patients of Crouse and St. Joseph's Health

Clinical Significance

Respiratory disease caused by SARS-CoV-2, influenza A or B, and RSV may produce similar symptoms, requiring the use of appropriate laboratory tests to determine the etiology of a patient's infection. The significance of this laboratory testing has taken on an added dimension of importance with the recent emergence of SARS-CoV-2 as a cause of pandemic disease.

The Quad PCR assay targets the same gene sequences as the previously used SARS-CoV-2 and Flu A/Flu B/RSV assays. As such, the SARS-CoV-2, influenza A, influenza B and RSV assay will have comparable sensitivities and specificities of the previously used tests. Below are the comparative performance characteristics of the assays as provided by the manufacturer.

Performance Characteristics

The performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test was evaluated using archived clinical nasopharyngeal (NP) swab specimens in viral transport medium. Archived specimens were selected consecutively by date and previously known analyte result. A total of 240 NP swab specimens were tested with Xpert Xpress SARS-CoV-2/Flu/RSV side by side with a SARS-CoV-2 EUA RT-PCR test and the FDA-cleared Xpert Xpress Flu/RSV test in a randomized and blinded fashion.

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Xpress SARS-CoV-2/Flu/RSV test relative to the results of a SARS-CoV-2 EUA RT-PCR test for the SARS-CoV-2 target, and Xpert Xpress Flu/RSV for the Flu A, Flu B, and RSV targets, respectively.

Xpert Xpress SARS-CoV-2/Flu/RSV demonstrated a PPA and NPA of 97.9% and 100.0% for SARS-CoV-2, respectively; 100.0% and 100.0% for Flu A, respectively; 100.0% and 99.0% for Flu B, respectively; 100.0% and 100.0% for RSV, respectively.

Xpert Xpress SARS-CoV-2/Flu/RSV Performance Results

Target	Number of Specimens	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
SARS-CoV-2	240	46	0	193	1	97.9% (88.9% - 99.6%)	100.0% (98.1% - 100.0%)
Flu A	240	48	0	192	0	100.0% (92.6% - 100.0%)	100.0% (98.0% - 100.0%)
Flu B	240	46	2	192	0	100.0% (92.3% - 100.0%)	99.0% (96.3% - 99.7%)
RSV	240	47	0	193	0	100.0% (92.4% - 100.0%)	100.0% (98.1% - 100.0%)

TP: True Positive; FP: False Positive; TN: True Negative; FN: False Negative; CI: Confidence Interval

Test code	CFRPCR
Test name	COVID/FLU AB/RSV PCR
Method	Real time PCR
Specimen requirements	Nasopharyngeal or nasal swab collected on Dacron or flocked swabs Universal Transport Medium (UTM), Viral Transport Medium or Med Schenker (UTM)
Storage and Transport	Specimens placed in transport medium following collection can be stored for up to 24 hours at 15-30°C or up to seven days at 2-8°C prior to testing.
Stability	Ambient 24 hours at 15-30°C, refrigerated 7 days
Unacceptable Conditions	Any swabs other than Dacron on flocked swabs and any transport medium other than those indicated above.
Testing Schedule	Daily, 24 hours per day at SJH RRL and CH RRL
CPT Code	87637
Billing Code	3010462

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References:

1. Petric, M. et al. 2006. J. Infect. Dis. 194:S98-110.
2. Centers for Disease Control and Prevention. Seasonal influenza. http://www.cdc.gov. Accessed on March 14, 2013.
3. http://www.mayoclinic.com/health/respiratory-syncytial-virus. DS004514/DSECTION=prevention. Accessed on March 14, 2013.
4. Centers for Disease Control
5. Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV, Package Insert, Rev A, Oct 2020

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