2019 Health Technology Reassessment Report

Influenza A and B Antigen Test, Rapid Test

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Summary (English)

□ Background

The “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay]” is a test for verifying an infection caused by influenza A and B viruses. It was recognized as an innovative healthcare technology in 2013 and listed in the no-coverage list in 2014.

Recently, the Health Insurance Review & Assessment Service (HIRA) changed the coverage status of an item related to this technology to preliminary coverage for certain patient groups (ER, ICU). Therefore, various antigen test kits, all of which had been handled in a single no-coverage category, were differentiated according to the testing principles/methods and a dual system was created for the fees. As the test kits are no longer handled as if they belong to a single category and the fees are differentiated according to the classification of testing principles and methods, the need arose to clarify test the methods. To establish the appropriate fee, the Korea National Evidence-based Healthcare Collaborating Agency (NECA) was requested to perform a reassessment of equivalence (testing method, diagnostic accuracy, effectiveness, etc.) of the Influenza A and B Antigen Tests [Rapid Tests].

Accordingly, a subcommittee was assembled to assess the "Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay].”

□ Committee operation

The subcommittee, composed of 7 members (3 clinical pathologists, 1 infection specialist, 2 pediatricians, and 1 evidence-based medicine specialist), held 2 meetings between October 30 and December 27, 2019, to assess the said technology.

□ Methods

The effectiveness of the “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay]” was reassessed by confirming the testing method and reviewing relevant literature.

□ Results

A. Confirmation of the testing method

The subcommittee expressed that the “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay]” is a rapid antigen test for patients suspected of influenza A and B virus infection. They indicated that the testing method was immunochromatography using fluorescent immunoassay (ICA using FIA).

B. Effectiveness

Twenty-eight articles were included in the assessment of the effectiveness of the “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay].” Of those, 3 were systematic review articles, and 25 were cross-sectional studies in which diagnostic accuracy was reported (including 2 articles reviewed in the previous Innovative Health Technology Assessment).

The 3 systematic review articles reported diagnostic accuracy results of the “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay].” One article reported that the pooled sensitivity was 77.8% for influenza A and 73.5% for influenza B, and the pooled specificity was 98.5% for influenza A and 98% for influenza B. A second article, in which influenza A and B were not differentiated, reported a pooled sensitivity of 75.3% and a pooled specificity of 95.3%. In a third article, which presented sensitivity and specificity in ranges, the range of sensitivity was 71.4–95.8.% and 33.3–98.1% for influenza A and B, respectively, and the range of specificity for influenza A was 91.1-100%. The specificity for influenza B was not reported in the article.

Of the cross-sectional studies, 22 reported the diagnostic accuracy of the “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay]” for influenza A, and 19 reported it for influenza B. Five articles reported the overall diagnostic accuracy, instead of specifying for each influenza type.

For influenza A, the sensitivity was 41.5–100% and the specificity was 89–100%. For influenza B, the sensitivity was 33.3–98.1% and the specificity was 70.7–100%. For influenza A+B, the sensitivity and specificity were 59.3–83% and 61.2–99.7%, respectively. A meta-analysis was performed on the studies from which a 2×2 table could be created. The results were as follows. For influenza A (a total of 20 articles), the pooled sensitivity was 0.78 (95% CI 0.76-0.80, I2=61.2%) and the pooled

specificity was 0.98 (95% CI 0.98-0.99, I2=80.4%). For influenza B (a total of 18 articles), the pooled sensitivity was 0.81 (95% CI 0.79-0.84, I2=78.4%) and the pooled specificity was 0.97 (95% CI 0.96-0.97, I2=93.7%). For influenza A+B (a total of 4 articles), the pooled sensitivity was 0.72 (95% CI 0.67-0.76, I2=84.9%) and the pooled specificity was 0.86 (95% CI 0.85-0.88, I2=98.6%). Heterogeneity tended to be high.

Based on the review of effectiveness, the subcommittee expressed that the said testing method (fluorescent immunoassay) shows high sensitivity and is, therefore, effective for rapidly testing for influenza infection based on the diagnostic accuracy results for all the rapid antigen tests as well as the conventional rapid antigen tests (pooled sensitivity: 54.4–68.1% in influenza A, 53.2–71% in influenza B, and 61.1% in influenza A+B, pooled specificity: 99.2–99.4% in influenza A, 99.6–99.8% in influenza B, and 98.9% in influenza A+B).

▫ Conclusion

The “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay]” is a rapid antigen test performed in patients to confirm suspected influenza A and B virus infection. The testing method is ICA using FIA. Based on the review of articles that became available after the previous assessment, the was determined to have an excellent diagnostic accuracy for testing for the presence or absence of the influenza A and B viruses.

Based on the subcommittee's review, the Health Technology Reassessment Committee made the following assessment of the “Influenza A and B Antigen Test, Rapid Test [fluorescent immunoassay]” (January 10, 2020).

The Health Technology Reassessment Committee confirmed that the said technology is a rapid antigen test performed to confirm suspected influenza A and B virus infection, and the testing method is ICA using FIA. The committer also determined that the test shows high sensitivity and is effective for rapidly testing for influenza virus infection.