ENSAYO CLÍNICO TESTS RÁPIDOS CORONA VIRUS

Clinical performance

Clinical Trial Results

[Clinical Trial Institutes]

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[Purposes]

Use Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit (Multiple Fluorescence PCR) (hereinafter referred to as "this kit") produced by Wuhan EasyDiagnosis Biomedicine Co., Ltd. for clinical evaluation, and verify its safety and effectiveness.

[Methods]

① Through a comparative study with clinically confirmed/excluded results, make a comparison by using the clinical sensitivity, clinical specificity and clinical accuracy for statistical analysis of the results, and evaluate the clinical performance of the evaluated reagent. ② Through comparison with similar products already on the market, make a comparison by using negative accordance rate, positive accordance rate and Kappa identity test for statistical analysis of the results, and verify whether the evaluated reagent is equivalent to the similar product to detect 2019-nCoV.

[Results]

① The comparative study of the evaluated reagents with clinically confirmed/excluded results for a total of 681 cases is completed, and 681 statistical cases are included, including 288 confirmed cases and 393 excluded cases. Comparison between evaluated reagent test results and clinically confirmed/excluded results meets the standards as follows: a) The clinical sensitivity is 95.14%, and the 95% confidence interval is 93.52%~96.75%; b) The clinical specificity is 95.93%, and the 95% confidence interval is 94.44%~97.41%; c) The clinical accuracy is 95.59%, and the 95% confidence interval is 94.05%~97.14%. ② The comparative study of the evaluated reagents with similar products on the market for a total of 756 cases is completed, 6 cases are excluded (specimens repeatedly included in the group), and 750 cases are finally included, including 295 positive cases accounting for 39.33% of the total specimens, as well as 455 negative cases accounting for 60.67% of the total specimens. There are 342 oropharyngeal swab specimens, including 149 positive cases and 193 negative cases; 249 nasopharyngeal swab specimens, including 73 positive cases and 176 negative cases; and 159 sputum specimens, including 73 positive cases and 86 negative cases. Adopt evaluated reagent negative and positive test results, and compare reagent negative and positive test results to meet the standards as follows: a) Negative accordance rate is 94.07%, and 95% confidence interval is 92.38%~95.76%; b) Positive accordance rate is 95.93%, and 95% confidence interval is 94.52%~97.35%; c) Total accordance rate is 94.80%, 95% confidence interval 93.21%~96.39%; d) Kappa identity test K value is 0.8920, and 95% confidence interval is 0.8590~0.9250.

[Conclusions]

① The comparison between the evaluated reagent test results and the clinically confirmed/excluded results shows high consistency, indicating that the evaluated reagents have good clinical applicability. ② The evaluated reagents have high consistency with the comparison reagents, indicating that the evaluated reagents meet the requirements for safety and effectiveness in clinical use and have good clinical applicability.

Data source: *General Clinical Trial Report on Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit (Multiple Fluorescence PCR)*