

EXTERNAL QUALITY ASSESSMENT OF MOLECULAR DIAGNOSTICS FOR ZIKA VIRUS AND MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS IN KOREA

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Abstract. In Korea since August 2016, molecular tests for Zika virus and Middle East respiratory syndrome coronavirus (MERS-CoV) have been extended for use in non-governmental medical institutions to prepare for potential emergence of these viruses. The study evaluated reliability of Zika virus and MERS-CoV molecular tests performed by non-governmental medical laboratories. In December 2016, information on participation in a Zika virus and MERS-CoV external quality assessment (EQA) was sent to 36 laboratories performing molecular tests for these viruses. Sensitivity and specificity were tested using five samples of Zika virus and 12 samples of MERS-CoV, each containing a different viral load. Thirty-three laboratories returned their EQA results for Zika virus and 25 for MERS-CoV. For Zika virus assay, 73% of participating laboratories tested both serum and urine samples, and for MERS-CoV, 92% tested lower, or both upper and lower, respiratory tract specimens. There was one false-positive result from Zika virus tests. MERS-CoV EQA results were 96% correct except for one outlier. EQA samples for Zika virus and MERS-CoV tests showed good homogeneity and stability for up to 72 hours at 4°C and eight weeks at -70°C. Although there is still room for improvement with respect to outliers and false-positive results, EQA of Zika virus and MERS-CoV molecular tests in Korea revealed good assay performance. The EQA method used in the study will help laboratories cope with assays of other new pathogens.

Keywords: external quality assessment, Middle East respiratory syndrome coronavirus, quality control, Zika virus, Korea

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