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Talk

Results of the 1st external quality assurance for SARS new coronavirus diagnostic PCR and serology

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Background

The detection of the new Coranavirus (CoV) causing agent of the severe acute respiratory syndrome (SARS) for diagnostic purposes is still a critical step in prevention of secondary hospital infections. In this respect the PCR for SARS diagnostic is the fastest and most sensitive method and was published very early after the description of the new pathogen by different groups. To evaluate the quality and sensitivity of the SARS PCR performed in diagnostic laboratories all over the world an external quality assurance (EQA) for SARS PCR was initiated by the WHO, the European Network for Diagnostics of "Imported" Viral Diseases (ENIVD) and the Robert Koch-Institut.

Methods

Therefore 10 samples of

inactivated SARS CoV strains isolated in Frankfurt and Hong Kong in different dilutions and negative controls were prepared. The freeze dried samples were send by mail to 62 different laboratories, in 37 countries in Europe and Israel (35), Asia (11), The Americas (11), Australia and New Zealand (4) and Africa (1). The results were returned by email or fax 1 week (13), 2 weeks (14), 3 weeks (6) and later (29) after receiving the material which does not mimic at all the possible speed of this fast method. But this was not considered in the evaluation of these first SARS EQA.

Results

44 laboratories showed good or excellent results (26 = 100%, 18 = 90%) and even the 14 laboratories which archived only 80% (10) or 70% (4) correct results are mostly lacking sensitivity. The results of the other 4 laboratories show basic problems in regard to sensitivity, specificity and consistency of results and must be overcome as soon as possible.

4 laboratories seem to have problems with the specificity finding a positive signal in negative samples. The different methods used for preparation of the SARS CoV genome and diagnostic PCR test procedure used by the participating laboratories will be discussed in more detail in the presentation.

Conclusion

However, in contrast to previous EQAs for Ebola, Lassa and Orthopoxviruses the quality of PCR results was rather good which might be caused by the early publication and distribution of well developed PCR methods.

An EQA for evaluation of SARS specific serology is still ongoing, first results will be available beginning of April 2004.