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Development of reference material to perform EU-wide proficiency tests for the diagnosis of highly pathogenic bacteria, including *Francisella tularensis*

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Aims: Within the framework of an EU project 21 participants in 18 different countries will have the opportunity to assess their quality of diagnostics of highly pathogenic bacteria, including *F. tularensis*. One major aim is to build up a permanent network.
Methods: Several work packages ensure the exchange of information, material and training among participants in order to establish different tools, for example network shared reference stocks for internal and external quality control. Furthermore, in support of diagnostic methods several external quality exercises with increasing degree of difficulty were and will be organized.
During the first exercise each laboratory received 15 different DNA samples for detection, including *F. tularensis ssp tularensis*, *F. tularensis* ssp*. holarctica* and *F. philomiragia*, as well as 15 samples of diverse species of inactivated bacteria, incl. *F. tularensis,* the latter of which were diluted in three matrices, PBS and water and mouse myeloma-cells as a clinical substitute specimen. To avoid any deviation of results deriving from the preparation of the test items, particular carefulness was attributed to planning, design, marking, packaging and transport. All samples were tested several times by molecular methods, immunological performance, sterility testing and microscopy to ensure high quality and homogeneity of the test items and to prevent cross contamination.
Results: The overall evaluation of the first exercise revealed the high quality of the provided reference material and various approaches in working procedures, equipment and preparedness of the participating laboratories. However, there is obvious need for further improvement of laboratory diagnostics because the differentiation of the subspecies as well as the contamination by *Francisella tularensis* and other coccobacilli during DNA extraction of inactivated samples produced false positive results of *F. tularensis.*
Conclusion: The best testing methods and working procedures according to quality management guidelines evaluated will be standardized after having proven practicable for all laboratories being involved.