Appendix 45

AN ADVANCED FIELD DEPLOYABLE "PEN SIDE" SAMPLE PREPARATION AND PCR SYSTEM

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INTRODUCTION

Exotic and Zoonotic diseases pose a threat to the world's wildlife, commercial livestock and the population in general. Efforts to control the spread of naturally occurring highly infectious pathogens, for example Highly Pathogenic Avian Influenza, have been complicated by the need to transport samples to the lab for ultimate identification. This is especially problematic in remote locations. This abstract describes a briefcase sized portable sample preparation and PCR system, which has been designed, from the outset, with the field veterinarians needs and mode of operation in mind, including the ability to sanitise the unit with disinfectant. The system automatically purifies nucleic acids from a wide range of sample types and carries out PCR analysis, reporting either a positive or negative result or a strain level identification where applicable. The system uses a number of novel technologies and approaches to provide a fully automated portable on-site identification capability in a wide range of weather conditions, by a person with no knowledge of PCR.

MATERIAL & METHODS

Operation of the device is extremely simple. A veterinarian suspecting the presence of disease takes a sample from the animal. The nature of the sample is dependant on the disease under suspicion and is not limited by the instrument. For example they may take blood samples or vesicular tissue as appropriate. The veterinarian then places that sample in to a single use sample preparation device and places the device on the instrument. At this point the assay to be performed is automatically selected and the automated sample preparation process begins. The purified nucleic acid is automatically mixed with PCR reagents and the PCR process begins. The instrument then performs the appropriate data analysis and reports the result as a positive and negative test result for the test carried out, and reports the strain level identification of the pathogen where applicable. This entire process is performed with no user intervention and is designed to be performed by a person with no knowledge of molecular biology techniques.

RESULTS

The overall performance of the system depends on the individual performance of the instrument, sample preparation and assays. Recent analysis of the performance of the PCR instrument has shown a good correlation with selected lab based PCR instruments, indicating a similar level of performance can be expected in the field. The sample preparation device was designed to take the lab based process into the field and automate it. Initial results indicate that the device performs as well as the original bench process.
There are currently 2 assays being developed and validated on this platform, one to detect all seven serotypes of Foot and Mouth Viruses in a single tube, and one to differentiate high and low pathogenic H5N1 Avian Influenza Virus. These assays are in development/validation using real samples in collaborating labs to determine their efficiency in a lab setting prior to their transfer to our field deployable platform (see abstracts in this volume). The platform uses a novel PCR chemistry called LATE-PCR which is able to identify many pathogens or strains of a pathogen in a single tube. The highly multiplexable nature of LATE-PCR means that a wide range of pathogens can be tested for simultaneously resulting in a simplified mode of operation. The system is currently being prepared for field based trials.

DISCUSSIONS AND CONCLUSIONS

"Pen side" detection systems offer the promise of rapid detection of disease allowing a more resilient response and more effective outbreak management. The challenge in deploying PCR based analysis systems in the field is the requirement for a simple, sample preparation system capable of producing good quality nucleic acid from a wide range of animal samples. Systems such as Smiths Detection's "Pen Side" testing system may provide the means to rapidly detection disease outbreaks.

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