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Advancing foot-and-mouth disease control: Integrating diagnostic validation, technology dissemination, and field evaluation of a cutting-edge diagnostic kit

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Abstract
Foot-and-Mouth Disease (FMD) remains a significant threat to global livestock health, necessitating rapid and accurate diagnostic tools for effective disease management. This study focuses on the diagnostic validation and technology dissemination of a novel diagnostic kit designed for the detection of FMD. The field evaluation phase assessed the diagnostic kit's performance under real-world conditions, considering challenges such as varying climates, diverse livestock populations, and different sample matrices. Data on the kit's performance were collected across multiple field sites, allowing for a robust understanding of its efficacy in diverse scenarios. this study presents a comprehensive approach to the development, validation, and dissemination of a diagnostic kit for FMD. The successful integration of laboratory validation and field evaluations underscores the practicality and reliability of the diagnostic tool, making it a valuable asset in global efforts to control and manage Foot-and-Mouth Disease.

Keywords: Technology, dissemination, cutting-edge, kit, livestock, FMD

1. Introduction
Foot-and-Mouth Disease (FMD) stands as a formidable challenge in the global livestock industry, causing substantial economic losses and posing a constant threat to food security. Timely and accurate detection of FMD is pivotal for effective disease management, preventing its rapid spread, and minimizing economic repercussions. Conventional diagnostic methods, while reliable, often face limitations in terms of accessibility, speed, and ease of use, especially in resource-limited field conditions (Reid *et al*., 2014) [3]. This research article delves into the implementation of a cutting-edge diagnostic tool designed to address these challenges, offering a promising solution for FMD detection in diverse and challenging field settings. The focal point of this study is the deployment and evaluation of a novel FMD diagnostic kit specifically engineered for reliable performance under real-world conditions. The demand for innovative diagnostic approaches has spurred the development of molecular and immunological techniques, aiming to enhance sensitivity, specificity, and operational feasibility (Knowles, Samuel, and Davies, 2001) [1]. The diagnostic kit under investigation leverages advances in molecular biology and immunology to provide a comprehensive and rapid detection solution for FMD. Its design incorporates elements that facilitate ease of use, portability, and robust performance, making it well-suited for deployment in field conditions with varying infrastructure (Nfon *et al*., 2013) [2]. This research builds upon existing literature addressing the need for improved FMD diagnostics. Previous studies have underscored the economic impact of FMD outbreaks (Knowles, Samuel, and Davies, 2001) [1], the challenges associated with traditional diagnostic methods (Nfon *et al*., 2013) [2], and the potential benefits of incorporating molecular techniques into FMD detection strategies (Reid *et al*., 2014) [3]. In light of these considerations, the current study aims to contribute valuable insights into the practical implementation of an advanced FMD diagnostic tool under field conditions. Through this research, we aspire to contribute to the ongoing global efforts to combat FMD and advance the field of veterinary diagnostics.

2. Materials and Methods

2.1 Development of diagnostic kit: The novel FMD diagnostic kit utilized in this study was based on breakthrough development. The kit employs antigen-antibody reaction allowing rapid and accurate detection of FMD virus in the field setting. Parallel testing was conducted using both the novel diagnostic kit and conventional laboratory methods (PCR, ELISA). Laboratory tests were performed following standard protocols (OIE, 2018) to validate the sensitivity and specificity of the novel kit.

2.2 Sample Collection: Field samples were collected from suspected FMD cases in various livestock populations. Samples included vesicular fluids, oral and nasal swabs, and serum from clinically affected animals. Collection followed established biosafety protocols (OIE, 2018).

2.3 Field Implementation: The field implementation phase involved trained personnel using the novel diagnostic kit in diverse geographic locations and environmental conditions. The kit's performance was evaluated in comparison to laboratory results. Data on kit performance, ease of use, and time to results were recorded.

2.4 Statistical Analysis: Statistical analysis was conducted to assess the diagnostic kit's sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) using standard formulas. Comparative statistical analysis was performed between the novel kit and conventional methods.

3. Results

A total of 120 samples were collected from 5 locations around Faculty of Veterinary Sciences and Animal Husbandry, Shuhama, Alusteng covering 7 different villages with varying environmental conditions. The diagnostic kit demonstrated a sensitivity of 87% and specificity of 88% with 95% confidence intervals. The overall accuracy of the diagnostic kit was 87%, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated as 79% and 81% respectively. In comparison to the gold standard reference method, the diagnostic kit showed 92% concordance. Discrepancies were observed in 8% of cases, and these were mainly attributed to presence of antibodies caused by vaccination. The diagnostic kit exhibited high analytical sensitivity, successfully detecting FMD virus in samples with concentrations as low as 2 pg. The specificity was maintained when challenged with non-FMD samples. The Receiver Operating Characteristic (ROC) Curve illustrated the trade-off between sensitivity and specificity, with an area under the curve (AUC) of 75%.

Challenges faced during field conditions included Vaccination, later phase of disease and temperature. Despite these challenges, the diagnostic kit demonstrated reliable performance. These factors may have influenced the overall results and should be considered in the interpretation.

4. Discussion

The validation of the diagnostic kit for the detection of Foot-and-Mouth Disease (FMD) in field conditions represents a critical step toward its practical implementation for disease surveillance and control. Our findings contribute valuable insights into the reliability and feasibility of deploying this technology in real-world scenarios. The diagnostic kit exhibited commendable sensitivity and specificity in field conditions, aligning with the objectives of rapid and accurate FMD detection (Al-Yousif *et al*., 2002) [4]. This performance is crucial for timely and targeted disease management interventions, especially in regions prone to FMD outbreaks. Our study's overall accuracy suggests the diagnostic kit's effectiveness in providing reliable results under diverse field conditions. The demonstrated positive predictive value (PPV) and negative predictive value (NPV) further emphasize its utility for confirming or ruling out FMD cases. Comparison with the gold standard reference method revealed a high level of concordance, affirming the diagnostic kit's reliability. The observed discrepancies were mainly attributed to factors such as emphasizing the importance of understanding and addressing potential challenges in field conditions (Ayers *et al*., 2001) [5].

The analytical sensitivity of the diagnostic kit, detecting FMD virus even at low concentrations (2 pg), underscores its potential for early detection and surveillance, aligning with recommendations for effective FMD control (Brüning *et al*., 1999) [6]. The maintained specificity against non-FMD samples highlights the kit's ability to discriminate between the target pathogen and related species (Callahan *et al*., 2002) [7]. Challenges encountered during the field validation underscore the importance of considering real-world constraints in diagnostic kit deployment. These challenges are consistent with previous studies and their acknowledgment is crucial for optimizing the kit's performance under diverse conditions.

The successful validation of the diagnostic kit in field conditions has significant implications for FMD control strategies. Its rapid and accurate performance could facilitate early detection, prompt response, and targeted interventions, ultimately contributing to the mitigation of FMD outbreaks

5. Conclusion

The validation of the diagnostic kit in field conditions establishes its efficacy and reliability for practical use in FMD detection. Addressing challenges identified during the study and considering its limitations will be crucial for optimizing its performance in diverse settings. This research lays the foundation for the widespread adoption of the diagnostic kit in the ongoing efforts to control and manage Foot-and-Mouth Disease.

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