

Evaluation of a lateral flow device for the pen-side diagnosis of foot-and-mouth disease

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Conclusions

- The requirement for a specific, simple, cheap, disposable and rapid test to be made available to veterinarians to support clinical diagnosis of FMD has been met through the development and validation of the 1F10 lateral flow device

Diagnosis of FMD

- FMD-free areas
 - Early recognition of signs by farmer
 - Rapid reporting to veterinary authorities
 - VO to evaluate clinical signs
 - Submission of samples to laboratory

Diagnosis of FMD – Submission of samples to laboratory

- FMD-endemic areas
 - Time between identification and report of disease, collection and dispatch to lab can be protracted: leads to sample degradation
 - Long distances can delay the diagnostic result: can hinder effectiveness of local actions
 - Episodes of disease might go uninvestigated

Diagnosis of FMD

- Clinical diagnosis can be fraught
 - UK 2001 (over-reporting of disease by 23%?)
 - Cyprus 2007 (FMD outbreak in 2003?)

**FMD ?
(OMAGOD)**



Diagnosis of FMD

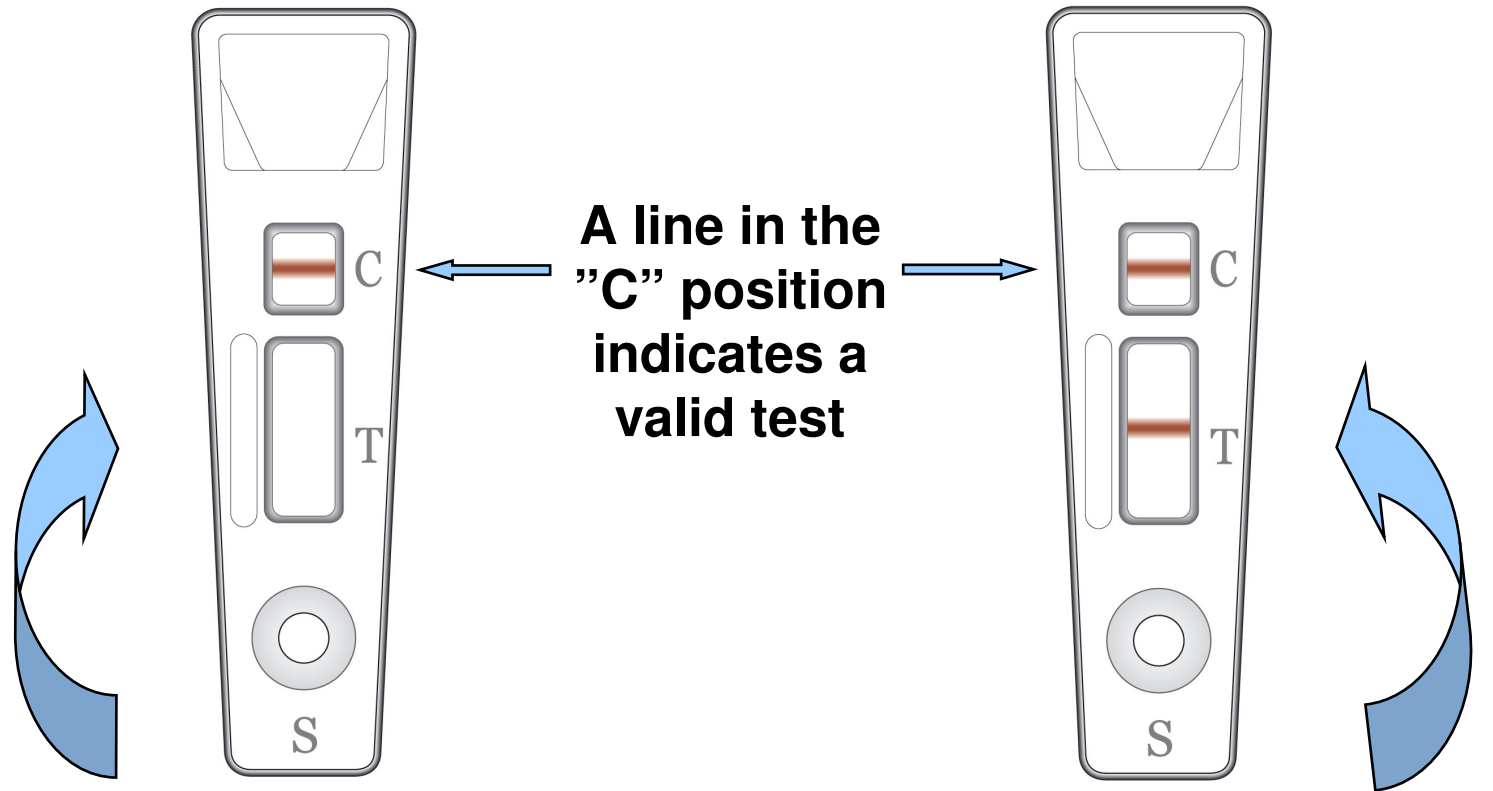
- Availability of 'Point of care' or 'Pen-side' diagnostic test would have the advantage of providing support to VO and could reduce time for test confirmation in secondary cases of disease
- Aid selection of appropriate material for lab submission
- Increase FMD awareness and improve epidemiological information

Development of pen-side test

- Requirement for development of a rapid chromatographic strip test or lateral flow device (LFD) for pen-side diagnosis based on a mab that reacts against FMDV of all seven serotypes

Test Procedure

Reading results after 10-30 minutes



No line in the "T" position indicates a

NEGATIVE test result

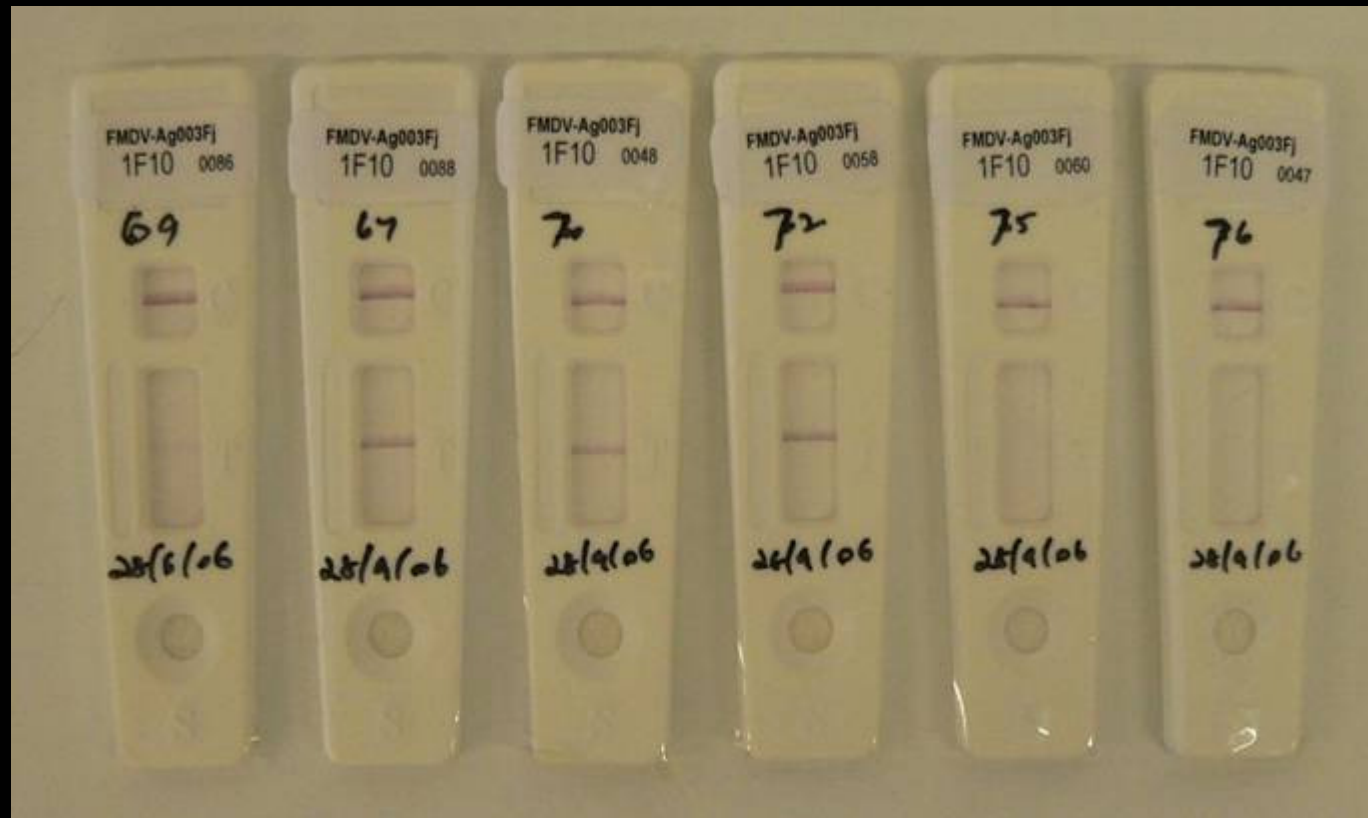
A line in the "T" position indicates a

POSITIVE test result

Selection of mab for LFD development

- Approximately 20 mabs selected and evaluated
- Brescia 1F10 mab – pan-reactive to FMDV, disease-specific – selected for development and test validation
- Gold particles used in LFD instead of latex beads: enhanced sensitivity

FMD 1F10 'gold particle' LFD examples

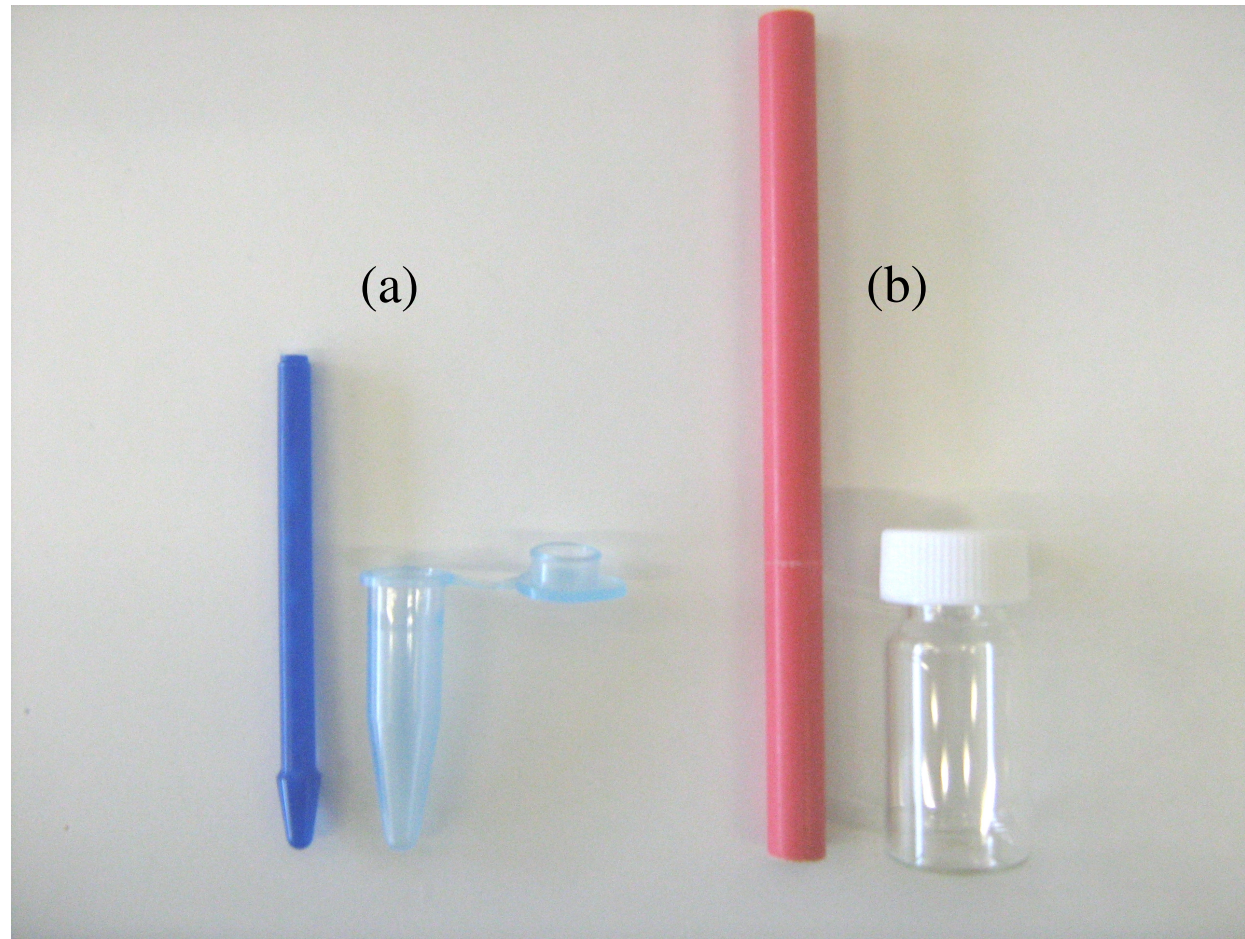


Sensitivity of 1F10 LFD

FMDV type	1F10 LFD			ELISA		
	No. tested	No. positive	% Sensitivity	No. tested	No. positive	% Sensitivity
O	131	121	92.4	128	122	95.3
A	41	36	87.8	41	32	78.0
C	24	15	62.5	24	14	58.3
SAT 1	24	16	66.7	24	13	54.2
SAT 2	34	20	58.8	34	30	88.2
SAT 3	10	7	70.0	10	9	90.0
Asia 1	40	39	97.5	40	36	90.0
Total	304	254	83.6	301	256	85.0

Specificity of 1F10 LFD

Sample	1F10 LFD			ELISA		
	No. tested	No. positive	% Specificity	No. tested	No. positive	% Specificity
SVDV	5	0	100	5	0	100
VSV	5	0	100	5	0	100
Negative	7	0	100	7	0	100
NVD (VI/E)	735	1	99.9	725	1	99.9
NVD (VI/E/PCR)	251	4	98.4	251	0	100
Total	1003	5	99.5	993	1	99.9



Two alternative sample homogenizers for preparing epithelial suspensions under field conditions: (a) a disposable pellet pestle with microtube (Anachem) and (b) a plastic rod (The BMC Research Workshop, Uppsala University, Uppsala, Sweden) in combination with a disposable glass bottle.

Recovery of FMDV from LFD

- 'T' line cut from LFDs left on bench for 1 year – weak positive PCR but negative VI and sequencing results
- 'T' line and sample pad cut from LFD at day 2 – positive PCR but negative VI results
- Other approaches for virus recovery to be attempted – freon treatment to dissociate ag/ab complexes, transfection of RNA into susceptible cells

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