

Foot and Mouth Disease Virus (FMDV) Vaccine Antibodies and ELISA Kits

FMD affects millions of farm animals (cow, buffalo, pigs, sheep, goat, etc) in the world that are of great economic concerns. ADI now offers the most comprehensive selection of individual FMD recombinant proteins (structural and non-structural), antibodies for research use.

Our ELISA kits offers the following **advantages**:

Convenience: ELISA kit contains all necessary reagents. Tests are conducted at room temp. for convenience.

Speed: Test results obtained in ~60-110 mins, fastest in industry.

Economy: Recombivirus ELISA platform employ highly purified recombinant proteins so there is no need to test sample in control viral extracts.

Safety: Recombivirus ELISAs do not contain any live or dead virus or viral derived proteins. No safety issues.

Easy testing options: ELISA kits are available for individual serotypes (O, A, A1, SAT 1-3) or Combo (O+A+A1) or SAT1-3.

Advanced Testing: New **DIVA tests** based upon 3ABC, 3D, 2ABC will offer better DIVA options for all serotypes.

FMDV Mouse ELISA: ADI has developed mouse FMDV ELISA for testing FMDV vaccine antigenicity testing.

List of FMDV ELISA Kits available from ADI.

Product details, data sheets, and pricing available (http://4adi.com/commerce/catalog/spcategory.jsp?category_id=2786)

Items Description	Kit Type	Species	ELISA Cat#
RecombiVirus FMDO VP-1 IgG ELISA Kit, Quantitative	Antibody (O+A+A1, VP1) Combo	Mouse	RV-400750-1
RecombiVirus FMDO VP-1 IgG ELISA Kit, Quantitative	Antibody (SAT1-3, VP1)	Mouse	RV-400760-1
RecombiVirus FMD 3ABC IgG ELISA Kit, All FMD Serotype, Quantitative	Antibody (3ABC/DIVA)	Mouse	RV-400770-1

Catalog#	Product Description	Product Type
RV-400751-CP5	Recombinant FMDV-VP1 (Serotypes O+A+A1, Combo) antigen coated plates for ELISA (5x96)	Antigen Plates
RV-400761-CP5	Recombinant FMDV-VP1 (Serotypes SAT1+2+3, Combo) antigen coated plates for ELISA (5x96)	Antigen Plates
RV-400771-CP5	Recombinant FMDV-3ABC (all serotypes) antigen coated plates for ELISA (5x96)	Antigen Plates
RV-400600-01N	Bovine/Cow Anti-FMDV-VP1, Serotypes O+A+A1 IgG negative serum	Disease sera, animals
RV-400600-02P	Bovine/Cow Anti-FMDV-VP1, Serotypes O+A+A1 IgG positive serum	Disease sera, animals
RV-400610-03N	Bovine/Cow Anti-FMDV-VP1, Serotypes SAT1+2+3 IgG negative serum	Disease sera, animals
RV-400610-04P	Bovine/Cow Anti-FMDV-VP1, Serotypes SAT1+2+3 IgG positive serum	Disease sera, animals
RV-400620-05N	Bovine/Cow Anti-FMDV-3ABC, all serotypes IgG negative serum	Disease sera, animals
RV-400620-06P	Bovine/Cow Anti-FMDV-3ABC, all serotypes IgG positive serum	Disease sera, animals

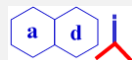
List of FMDV Antibodies and other reagents available from ADI.

Complete product listing. Product details, data sheets, and pricing available at (http://4adi.com/commerce/catalog/spcategory.jsp?category_id=2786)

FMD Serotype	Product Type	Catalog#	Product Description
A1 (Asia-1)	Antiserum	FMDA16-S	Anti-FMDV, serotype A1, viral protein 1 (FMDA1-VP1) protein antiserum
	Rec. Protein	FMDA16-R-10	Recombinant (E-coli) FMDV, Asia1, viral protein 1 (FMDA1-VP1) purified
A	Antiserum	FMDA11-S	Anti-FMD, serotype A, viral protein 1 (FMDA-VP1) protein antiserum
	Rec. Protein	FMDA15-R-10	Recombinant (E-coli) FMDV, serotype A viral protein 1 (FMDA-VP1) purified
C	Pure peptide	FMDC11-P	FMDV, serotype C, VP1 (FMDC-VP1) GH loop Control/blocking peptide
	Antiserum	FMDC11-S	Anti-FMDV, serotype C, VP1 (FMDC-VP1) GH loop peptide antiserum
O	Antibodies	FMDO2A11-A	Anti-FMDV, serotype O, 2A (FMDO-2A) peptide IgG, aff pure
	Antigen Peptide	FMDO2A11-P	FMDV, serotype O, 2A (FMDO-2A) Control/blocking peptide
	Antiserum	FMDO2A11-S	Anti-FMDV, serotype O, 2A (FMDO-2A) peptide antiserum
	Antiserum	FMDO2B11-S	Anti-FMDV, serotype O, 2B (FMDO-2B) protein antiserum
	Rec. Protein	FMDO2B15-R-10	Recombinant (E. coli) FMDV, serotype O, 2B (FMDO-2B) purified
	Antiserum	FMDO2C11-S	Anti-FMDV, serotype O, 2C (FMDO-2C) protein antiserum
	Rec. Protein	FMDO2C15-R-10	Recombinant (E. coli) FMDV, serotype O 2C (FMDO-2C) purified
	Antiserum	FMDO3AB11-S	Anti-FMDV, serotype O, 3AB (FMDO-3AB) protein antiserum
	Rec. Protein	FMDO3AB15-R-10	Recombinant (E. coli) FMDV, serotype O, 3AB (FMDO-3AB) purified
	Antiserum	FMDO3C11-S	Anti-FMDV, serotype O, 3C (FMDO-3C) protein antiserum
	Rec. Protein	FMDO3C15-R-10	Recombinant (E. coli) FMDV, serotype O, 3C (FMDO-3C) purified
	Antiserum	FMDO3D11-S	Anti-FMDV, serotype O, 3D (FMDO-3D) protein antiserum
	Rec. Protein	FMDO3D15-R-10	Recombinant (E. coli) FMDV, serotype O, 3D (FMDO-3D) purified
SATs	Antiserum	FMDOVP11-S	Anti-FMDV, serotype O, viral protein 1 (FMDO-VP1) protein antiserum
	Rec. Protein	FMDOVP15-R-10	Recombinant (E. coli) FMDV, serotype O viral protein 1 (FMDO-VP1) purified
	Antiserum	FMDS11-S	Rabbit Anti-FMDV serotype SAT-1, viral protein 1 (FMDS1-VP1) antiserum
	Rec. Protein	FMDS15-R-10	Recombinant (E-coli) FMDV serotype SAT-1 viral protein 1 purified
	Antiserum	FMDS21-S	Rabbit Anti-FMD serotype SAT-2, viral protein 1 (FMDS2-VP1) antiserum
	Rec. Protein	FMDS25-R-10	Recombinant (E-coli) FMD serotype SAT-2 viral protein 1 purified

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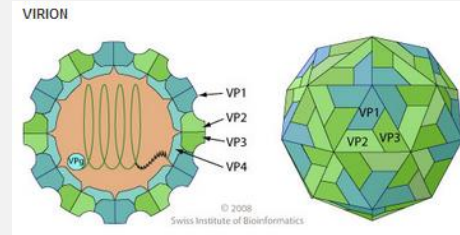
Foot and Mouth Disease Virus (FMDV) -General Information

FMD disease is a viral disease that affects cloven-hoofed animals, including domestic and wild bovids. The causative agent is **FMDV**, apicomavirus. The virus causes a high fever followed by blisters inside the mouth and on the feet that may rupture and cause lameness. FMD has severe implications for animal farming, since it is highly infectious and can be spread by infected animals. Its containment demands considerable efforts in vaccination, strict animal monitoring (diagnosis), trade restrictions, quarantines, and occasionally the killing of animals.

Global impact of FMD outbreak has been estimated tens of billions \$. Swine industry has an estimated economic impact \$128 billions over 10-years. For a potential outbreak in California alone may incur loss of \$3 to \$69 billions. Ten States in the US have populations in excess of 5 millions and 4 States have more than 10 million animals.

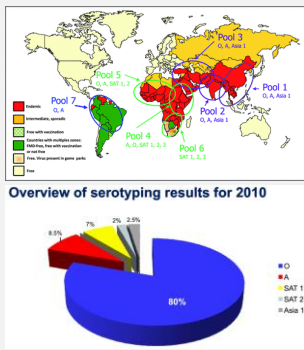
FMD susceptible animals include cattle, water buffalo, sheep, goats, pigs, antelope, deer, and bison. In laboratory experiments, mice, rats, and chickens have been successfully infected by artificial means, but they are not believed to contract the disease under natural conditions. Humans are very rarely infected because FMD is sensitive to stomach acid, it cannot spread to humans via consumption of infected meat. **Effective vaccines** and stringent control measures have enabled FMD eradication in most developed countries, which maintain unvaccinated, seronegative herds in compliance with strict international trade policies. However, the **disease remains enzootic in many regions of the world**, posing a serious problem for commercial trade with FMD-free countries. **Endemic areas** include parts of Asia, Africa, Middle east and South America.

proteins. P1 of the genome encodes for the capsid proteins (VP1-4) while P2 encodes non-structural proteins (NSP2A/2B/2C) and P3 region (NSP3A/Vpg/3Cpro, and 3D pol). VP1-3 are on the surface, and VP4 is internal. **VP1 is the major antigen** of FMDV capsid protein that contains the major B-cell epitope, which is the major immunodominant epitope eliciting protective humoral immunity. Upon virus entry into a cell, the viral genome is rapidly translated into a polyprotein which produces 12 mature proteins.



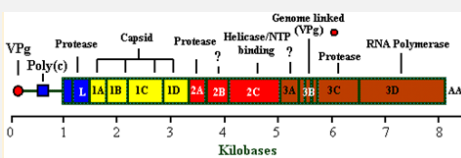
Diagnosis of FMDV is based upon virus isolation, presences of FMD antigens or nucleic acid but the presence of serotype specific

antibodies in the serum remains the method of choice due to its speed, efficiency and economy. Antibodies to FMD-VP1 may arise due to vaccination or infections. VP1 proteins are highly variable among different serotypes so it is necessary to have serotype specific VP1 antibody ELISA. Antibodies to NSPs, are induced mostly due to natural infection. However, some vaccines may contain residual NSPs and repeated immunization may make it difficult to distinguish infected from vaccinated animals (DIVA test). Therefore, it is necessary to have NSP tests based upon multiple NSPs (3ABC, 3D, 2ABC etc). NSPs are highly conserved (95-100%) in various serotypes making it possible to detect all serotypes NSP antibodies using a single kit.



Of the **seven FMD serotypes** of this virus, A, C, O, Asia 1 and SAT3 appear to be distinct lineages; SAT 1 and SAT 2 are unresolved clades. **FMD serotypes are not uniformly distributed in the regions of the world** where the disease still occurs. For example, the cumulative incidence of FMD serotypes show that six of the seven serotypes of FMD (O, A, C, SAT-1, SAT-2, SAT-3) have

occurred in Africa, while Asia contends with four sero-types (O, A, C, Asia-1), and South America with only three (O, A, C). Periodically there have been incursions of SAT-1 and SAT-2 from Africa into the Middle East. **FMD serotype O is the most common.** In India, FMD serotypes O accounts for 50-60%, Asia 1 (15-20%) and A (10-15%) outbreaks. A recent FMD world survey of 38 countries in 2010 reported 80% samples of serotype O, A (8.5%), SAT-1 (7%), SAT-2 (2%), and Asia-1 (2.5%, only in India), Serotypes C and SAT-3 are very rare.



The **FMDV genome** is ~8.2Kb. It is a small nonenveloped virus with a pseudo T=3 icosahedral capsid made up of 60 copies of four structural (SP)

All currently approved **FMD Vaccines** employ **killed FMD viruses** (Monovalent or a combination of various serotypes); FMD virus grown in BHK-21 (baby hamster kidney cells (BHK) or epithelial cell culture and then killed using chemicals (binary ethylamine or BEI). Most vaccines contain Alum or oil adjuvants. **Worldwide, tens of billion doses of FMD vaccine** are administered every year. Endemic countries like India manufacture mono, bi and trivalent vaccines **BioFMD-Oil™** (Biovet), **FUTVAC™** (Brilliant Biopharma). **Raksha** (Indian Immunological) against strains O,A, Asia 1. Other manufacturers of FMDV vaccine are Bayer, Merial, and Intervet.

Drawbacks of current FMD Vaccines: Most inactivated (killed) vaccines may still contain residual live virus; and it creates great danger in releasing the highly infectious virus into non-infected animals. Current vaccines have short shelf life and require cold chain for storage and distribution, a great problem in developmign countries. They also also contain small but significant concentrations of NSP (2-3ABC etc) that is sufficient to make antibodies in vaccinated animals. **New generation of subunit vaccines:** ADI is developing and testing several **recombinant FMD antigenic proteins** that will provide better protection than current killed FMD vaccines. Ideally, there is a need for **an universal FMD vaccine**, based upon single or a combination of FMD proteins from 3-7 FMD serotypes with unique DIVA tests.

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