Foot and Mouth Disease Virus
Antibody Test Kit

UBI® FMDV VP1 EIA (Ruminant)
DIRECTION INSERT

FOR IN VITRO DIAGNOSTIC USE ONLY
(For research use only)
(P/N 100053)

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U.S. Patent No. 6,107,021
Other Patents Worldwide
TRADE NAME & INTENDED USE

The UBI® FMDV VP1 EIA (RUMINANT) is a qualitative enzyme-linked immuno- sorbent assay (EIA) for in vitro detection of antibodies to Foot-and-Mouth Disease Virus (FMDV) in vaccinated or infected ruminants. It is a test for the serological surveillance of antibodies to FMDV in domestic ruminants that result from either vaccination or the presence of infectious FMDV. The UBI® FMDV VP1 EIA may be used to evaluate vaccinee status when used in combination with the UBI® FMDV NS EIA (CATTLE) to distinguish antibodies evoked by FMDV vaccination from antibodies elicited by current or previous FMDV infection or carrier status.

SUMMARY AND EXPLANATION OF THE TEST

Foot-and-Mouth Disease Virus (FMDV) is the causative agent of Foot-and-Mouth Disease (FMD) in cloven-hoofed animals. The virus is highly contagious and is controlled by vaccination, quarantine, and the slaughter of affected herds. Diagnosis is by clinical observation of lesions in the mouth and on the legs, with confirmation by virus isolation. However, rapid diagnosis by symptoms alone can be confounded because the symptoms of FMD can resemble those of other diseases such as vesicular stomatitis and swine vesicular disease, and may be mild or absent in sheep, goats, and wild species. Moreover, convalescent asymptomatic ruminant can serve as persistent carriers. Therefore, diagnosis and surveillance of FMDV infection is aided by serological tests.

FMDV occurs as seven antigenically distinct serotypes: A, O, C, Asia 1, and SAT 1, 2, 3 whose structural proteins frequently do not display extensive serologic cross-reactivity. The antigens of the UBI® FMDV VP1 EIA have been designed to detect antibodies with specificities for the VP1 structural proteins of diverse subtypes of FMDV serotype O.

The UBI® FMDV VP1 EIA (RUMINANT) is an enzyme-linked immunosorbent assay (EIA) which employs synthetic peptides as the solid-phase immunosorbent for detection of antibodies evoked by vaccination or infection. The peptide mixture that constitutes this sensitizing agent contains epitopes taken from immunoreactive domains of FMDV VP1 structural protein. These synthetic FMDV VP1 peptides impart the assay with excellent sensitivity and specificity for detection of anti-VP1 antibodies. Anti-VP1 antibodies are associated with FMDV vaccinee status or the presence of infectious FMDV (see ref. 7 in which VP1 is designated as VP3).

Synthetic FMDV VP1 peptides are site-specific antigens that possess serological reactivities to vaccinee and infected or convalescent serum samples. The use of site-specific synthetic peptides minimizes the incidence of nonspecific cross-reactivities in the specimen seen with longer virus-derived or recombinant polypeptide antigens. Also, non-specific reactivities to host cell antigens or expression vector antigens which are co-purified with complex virus-derived or recombinant antigens are avoided.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The purified, synthetic FMDV VP1 peptides are coated onto REACTION MICROPLATE wells as immunosorbent and used in an indirect solid-phase immunoassay. During the course of the assay, diluent, controls and diluted specimens are added to the REACTION MICROPLATE wells and incubated. Antibodies to FMDV vaccine or infectious FMDV, if present, bind with the solid-phase immunosorbent during incubation. Unbound materials will be removed during a thorough washing of the REACTION MICROPLATE wells. The bound ruminant antibodies are recognized by Protein A/G CONJUGATE during a second incubation. Bound enzyme is detected by the addition of a substrate solution containing hydrogen peroxide and 3,3',5,5'-tetramethyl- benzidine (TMB) to each well. A blue color develops in proportion to the amount of FMDV-specific antibodies present, if any, in the serum samples tested. This enzyme-substrate reaction is terminated by the addition of a solution of sulfuric acid to give a yellow color. The color changes that have occurred in each well are then measured spectrophotometrically at a wavelength of 450 nm.
# REAGENT COMPONENTS AND THEIR STORAGE CONDITIONS

## UBI® FMDV VP1 EIA (RUMINANT)

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FMDV VP1 Reaction Microplates</strong></td>
<td>2x96 wells</td>
<td>Store at 2-8°C sealed with desiccant.</td>
</tr>
<tr>
<td><strong>Non-Reactive Control</strong></td>
<td>1 mL</td>
<td>Normal goat serum is non-reactive for all FMDV antigens. Contains preservatives: 0.1% sodium azide and 0.02% gentamycin. Store at 2°-8°C.</td>
</tr>
<tr>
<td><strong>FMDV VP1 Reactive Control</strong></td>
<td>1 mL</td>
<td>Reactive serum is from an uninfected ruminant that was hyperimmunized with FMDV VP1 synthetic peptides. Contains preservatives: 0.1% sodium azide and 0.02% gentamycin. Store at 2°-8°C.</td>
</tr>
<tr>
<td><strong>Specimen Diluent (Buffer I)</strong></td>
<td>45 mL</td>
<td>Buffered salt solution containing carrier proteins and preservatives: 1% sodium azide (NaN₃) and 0.01% gentamycin. Store at 2°-8°C.</td>
</tr>
<tr>
<td><strong>Conjugate (HRP-rProtein A/G)</strong></td>
<td>0.4 mL</td>
<td>Horseradish peroxidase-conjugated recombinant Protein A/G containing 0.02% methylisothiazolone and 0.02% bromonitrodioxane as preservatives. Store at 2°-8°C.</td>
</tr>
<tr>
<td><strong>Conjugate Diluent (Buffer II)</strong></td>
<td>30 mL</td>
<td>Phosphate buffered saline solution containing carrier proteins with 0.02% gentamycin and 1% Antibiotic/antimycotic as preservatives. Store at 2°-8°C.</td>
</tr>
<tr>
<td><strong>TMB Substrate Solution</strong></td>
<td>25 mL</td>
<td>3,3',5,5'-tetramethyl benzidine (TMB) Solution. Store at 2°-8°C.</td>
</tr>
<tr>
<td><strong>Stop Solution</strong></td>
<td>25 mL</td>
<td>Diluted sulfuric acid solution (1.0M H₂SO₄). Store at 2°-30°C.</td>
</tr>
<tr>
<td><strong>Wash Buffer Concentrate</strong></td>
<td>150 mL</td>
<td>A 25X concentrate of phosphate buffered saline with surfactant. Store at 2°-30°C.</td>
</tr>
<tr>
<td><strong>Dilution Microplates</strong></td>
<td>192 wells</td>
<td>Blank, yellow microplates for predilution of specimens. Store at 2°-30°C.</td>
</tr>
<tr>
<td><strong>Plate Covers</strong></td>
<td>6 sheets</td>
<td>Clear, plastic adhesive sheets to be used to cover the Reaction Microplate wells during each incubation. Plastic sheets may be cut, before removing the paper backing, whenever less than a full plate of Reaction Microplate wells is being assayed. Alternatively, standard microplate lids may be used.</td>
</tr>
<tr>
<td><strong>Microwell Locator Label</strong></td>
<td>2 labels</td>
<td>(OPTIONAL, NOT REQUIRED)</td>
</tr>
</tbody>
</table>
MATERIALS REQUIRED - NOT SUPPLIED

1. 50 µL to 300 µL adjustable multichannel pipette with at least 5% accuracy, or equivalent reagent dispenser.

2. Adjustable single channel micropipette to deliver 10 µL to 200 µL with at least 5% accuracy, or equivalent pipettor diluter.

3. Incubator (37° ± 2°C).

4. Polypropylene tubes or containers (25 mL capacity) with screw top caps or equivalent.

5. Sodium hypochlorite solution, 5.25% (liquid household bleach), or an iodophor (e.g., Wescodyne®) as disinfectant.

6. The UBI® FMDV VP1 EIA test procedure requires a microplate reader capable of transmitting light at a wavelength of 450 nm.

7. Aspiration-wash system capable of dispensing and aspirating 250-350 µL.

8. Colored blank strips as fillers for REACTION MICROPLATE.

9. Pipettor troughs or boats.

10. Reagent grade (USP or equivalent) water.

11. Disposable gloves.

12. 10 mL serological pipettes.

13. Timer.

14. Absorbent tissue.

15. Biohazardous waste containers.

STORAGE OF REAGENTS

1. Opened undiluted reagents in their original containers are stable through the expiration dating indicated on their labels.

2. Store the UBI® FMDV VP1 EIA kit and its components at 2°-8°C when not in use and protect the components from excessive exposure to light.

3. STOP SOLUTION, WASH BUFFER CONCENTRATE, and DILUTION MICROPLATEs may be stored at room temperature (15°-30°C).

4. Opened, unused REACTION MICROPLATEs and MICROWELLs must be stored at 2°-8°C in the sealed foil pouch with the desiccant provided.

5. Materials should be used at room temperature (15°-30°C).
WARNINGS AND PRECAUTIONS

1. FOR VETERINARY DIAGNOSTIC USE ONLY.

2. HANDLE ASSAY SPECIMENS, REACTIVE AND NON-REACTIVE CONTROLS AS IF CAPABLE OF TRANSMITTING AN INFECTIOUS AGENT. Wear disposable gloves throughout the test procedure. Dispose of gloves as biohazardous waste. Wash hands thoroughly.

3. Kit components are matched for optimal performance and should not be used interchangeably between UBI® FMDV VP1 EIA kits of different lot numbers. Use only reagents supplied by UBI®.

4. Do not use kit components beyond the expiration date shown on kit label.

5. Two wells of NON-REACTIVE CONTROL, two wells of FMDV VP1 REACTIVE CONTROL should be assayed on each plate with each run of specimens. Controls must be placed in Column 1, Wells A1 and B1 for the NON-REACTIVE CONTROL and C1 and D1 for the FMDV VP1 REACTIVE CONTROL.

6. The NON-REACTIVE CONTROL, and FMDV VP1 REACTIVE CONTROL MUST BE DILUTED.

7. Use only reagent grade quality water to dilute WASH BUFFER CONCENTRATE.

8. Allow all kit reagents and materials to reach room temperature (15°-30°C) before use.

9. Do not remove REACTION MICROPLATEs from the foil storage pouch until immediately before use. Unused strips should be stored at 2°-8°C in the original foil pouch, with desiccant, and tightly sealed. Improper resealing of foil storage pouch may affect results.

10. If 25X WASH BUFFER CONCENTRATE is stored at a lower temperature (2°-15°C), crystals may form. Warm to room temperature (15°-30°C) and shake to dissolve crystals before use.

11. Do not expose TMB SUBSTRATE SOLUTION to strong light.

12. Avoid contact of STOP SOLUTION with skin, eyes, and mucous membranes. If there is contact, wash thoroughly with water.

13. Avoid contact of the SUBSTRATE SOLUTION and STOP SOLUTION with any oxidizing agent or metal.

14. Follow the installation, operation, calibration and maintenance instructions provided by the instrument manufacturers for both microplate reader, and automatic microplate washer.

15. Spills should be wiped up thoroughly using either an iodophor disinfectant or sodium hypochlorite (bleach) solution. Inactivation of acid-containing spills is not required.

   Iodophor Disinfectant: Should be used at a dilution providing at least 100 ppm available iodine.
   Wescodyne® may be used at a 1:100 to 1:150 final dilution in water. Wescodyne® is a registered trademark of West Chemical Products, Inc.
   Sodium Hypochlorite: Should be used as a 5.25% sodium hypochlorite solution (liquid household bleach).
   Acid-containing spills: Should be wiped dry. Spill areas should then be wiped with a 5.25% sodium hypochlorite solution.
   All materials used to contain and clean up spills should be considered biohazardous and disposed of accordingly.

16. This product contains sodium azide as a preservative. Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides may explode on percussion, such as hammering. To prevent formation of lead or copper azide, thoroughly flush drains with water after disposing of solutions.
containing sodium azide. To remove contamination from old drains suspected of azide accumulation, the National Institute for Occupational Safety and Health (USA) recommends the following:
(1) siphon liquid from drain trap using a rubber or plastic hose,
(2) fill with 10% sodium hydroxide solution,
(3) allow to stand for 16 hours, and
(4) flush well with water.

WASTE DISPOSAL

Dispose of all specimens and materials used to perform the test as if they contain infectious agents. Dispose of all waste in accordance with all local, state and federal regulations. The preferred method of disposal is autoclaving for a minimum of one half hour at 121°C with 15 lbs pressure. Disposable materials may be incinerated. Liquid wastes not containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 0.5% sodium hypochlorite. Allow 30 minutes for decontamination to be completed. Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.

SPECIMEN COLLECTION AND PREPARATION

1. The UBI® FMDV VP1 EIA is performed on ruminant serum.
2. Specimens containing precipitates or particulate matter may give inconsistent test results. If necessary, specimens should be clarified by centrifugation prior to testing.
3. If specimens are to be stored, they should be refrigerated at 2°-8°C or frozen. Multiple freeze-thaw cycles should be avoided.
4. If specimens are shipped, they should be packaged in compliance with Federal regulations covering the transportation of etiologic agents.

PREPARATION OF REAGENTS

1. Prepare the WORKING CONJUGATE SOLUTION as follows:
   A. Using polypropylene containers, dilute the CONJUGATE 1:101 with CONJUGATE DILUENT, prior to use according to the chart below. Mix well. This is the WORKING CONJUGATE SOLUTION.
B. Once diluted, WORKING CONJUGATE SOLUTION must be used within eight hours.

WORKING CONJUGATE PREPARATION CHART

<table>
<thead>
<tr>
<th>No. of Tests</th>
<th>Conjugate (µL)</th>
<th>Diluent (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>20</td>
<td>2.0</td>
</tr>
<tr>
<td>24</td>
<td>30</td>
<td>3.0</td>
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<td>32</td>
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<td>80</td>
<td>100</td>
<td>10.0</td>
</tr>
<tr>
<td>88</td>
<td>110</td>
<td>11.0</td>
</tr>
<tr>
<td>96</td>
<td>120</td>
<td>12.0</td>
</tr>
</tbody>
</table>

2. Prepare the DILUTED WASH BUFFER as follows:

A. Dilute one (1) volume of WASH BUFFER CONCENTRATE with 24 volumes of reagent grade water. Mix well.

B. DILUTED WASH BUFFER is stable for 3 months. Store at 2°-30°C. Do not use DILUTED WASH BUFFER until it has reached room temperature (15°-30°C), and has been mixed by shaking.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

1. Changes in the physical appearance of the reagents supplied may indicate deterioration of these materials. Do not use reagents which are visibly turbid.

2. The TMB SUBSTRATE SOLUTION should be colorless to pale yellow for proper performance of the assay. Any other color and/or formation of crystals may indicate deterioration of the TMB SUBSTRATE SOLUTION.

INSTRUMENTS

Any spectrophotometer capable of transmitting a light source of 450 nm through a microtiter well may be used. If a dual filter instrument is used, the reference wavelength should be within the range of 620 and 690 nm. The manuals provided by the instrument manufacturer should be reviewed for additional information pertaining to the following:

1. Installation and special requirements.
2. Operational principles, instructions, precautions and hazards.
3. Manufacturer's specifications and performance capabilities.
4. Service and maintenance information.

ASSAY PROCEDURE

Allow pouchged REACTION MICROPLATE wells and reagents to reach room temperature (15°-30°C) for at least 30 minutes, but do not expose to direct sunlight or elevated temperatures (>30 °C).

Caution: Verify that dispensing equipment delivers specified sample and/or reagent volumes and does not introduce cross-contamination.
1. Separate DILUTION MICROPLATEs are provided for specimen dilution.
   A. Use two wells (A1 and B1) for NON-REACTIVE CONTROL.
   B. Use two wells (C1 and D1) for FMDV VP1 REACTIVE CONTROL.
   C. Use one well for each specimen.
   D. Place the DILUTION MICROPLATE over the MICROWELL LOCATOR LABEL (optional).
   E. Dilute the CONTROLS and SPECIMENS as follows (1:21):
      a. Add 200 \( \mu \text{L} \) of SPECIMEN DILUENT into each CONTROL or SPECIMEN well of the DILUTION MICROPLATE;
      b. Dispense 10 \( \mu \text{L} \) of CONTROLS or SPECIMENS into the assigned wells of the DILUTION MICROPLATE. Mix thoroughly by pipetting up and down 3 times. Use a separate pipette tip for each diluted CONTROL or SPECIMEN.

2. Cut open the foil pouch and remove the REACTION MICROPLATE.
   If necessary, remove any excess antigen-coated strips from the frame and return them to the foil pouch. Seal the extra strips securely inside the foil pouch making sure to include the desiccant provided. Return to storage at 2°-8°C immediately. It may be necessary to replace these strips with blank strips (not provided in the kit), depending on the washing system used.

3. Transfer 100 \( \mu \text{L} \) of the diluted CONTROLS and SPECIMENS from each well of the DILUTION MICROPLATE to its corresponding well in the REACTION MICROPLATE. Dispose of the DILUTION MICROPLATE and unused liquid as biohazardous waste.

4. Within 30 minutes of SPECIMEN/CONTROL addition, cover with the enclosed lid or equivalent and incubate for 60 ± 5 minutes at 37° ± 2°C.

5. Prepare WORKING CONJUGATE SOLUTION, as described in the PREPARATION OF REAGENTS section prior to washing the microplates.

6. Uncover the REACTION MICROPLATE and wash with DILUTED WASH BUFFER.
   A. Automatic Microplate Washer - Use six (6) washes with at least 300 \( \mu \text{L/well/wash} \). It is recommended that the plate be reoriented in the washer following the first three (3) wash cycles, by turning 180 degrees to assure uniform treatment.
   B. Manual Microplate Washer - Wash six (6) times, using at least 300 \( \mu \text{L/well/wash} \). Fill the entire plate, then aspirate in the same order.
   C. Handheld Multichannel (8 or 12) Pipettor - Wash six (6) times using at least 300 \( \mu \text{L/well/wash} \). Discard liquid.

7. After washing is complete, excess liquid may be removed from the REACTION MICROPLATE by inverting and tapping on absorbent paper until no further moisture appears on the paper. Dispose of the absorbent paper as biohazardous waste.

8. Add 100 \( \mu \text{L} \) of the WORKING CONJUGATE solution (1:101) to all wells of the REACTION MICROPLATE.

9. Cover and incubate for 30 ± 2 minutes at 37° ± 2°C.

10. Uncover and repeat the wash procedure as in step 6 and step 7.

11. Add 100 \( \mu \text{L} \) of SUBSTRATE SOLUTION to each well of the REACTION MICROPLATE.

12. Cover and incubate in the dark for 15 ± 1 minute at 37° ± 2°C.

13. Uncover and add 100 \( \mu \text{L} \) of STOP SOLUTION to each well of the REACTION MICROPLATE. Mix by gently tapping the side of the REACTION MICROPLATE.
14. Read the absorbance of each well at 450 nm. Blank on air.
   **NOTE:** Absorbance should be read within 15 minutes of the addition of the STOP SOLUTION to the REACTION MICROPLATE.

15. Review absorbance values for the CONTROLs. Refer to CALCULATION OF RESULTS for control validation parameters and calculation procedures.

**CALCULATION OF RESULTS**

1. Criteria for Valid Assay Run

   A. Ensure that the mean absorbance value of the NON-REACTIVE CONTROLs (NRC) is ≤ 0.2. If the mean of the NRC is not within this range, the assay is invalid and must be repeated.

   B. Ensure that the FMDV VP1 REACTIVE CONTROL values (RC) are ≥ 0.500, and within the linear response range of the microplate reader. If individual RC values are not within this range, the assay is invalid. The instrument may need to be recalibrated and the tests must be repeated.

2. Calculation of Results

   A. Determine the Mean of the NON-REACTIVE CONTROLs (NRC).

       Example: Sample No.       Absorbance
       A1                    0.102
       B1                    0.113
       Total                0.215
       AVG 0.215/2 = 0.108 (NRC)

   B. Determine the Mean of the FMDV VP1 REACTIVE CONTROLs (RC).

       Example: Sample No.       Absorbance
       C1                    1.245
       D1                    1.191
       Total                2.436
       AVG 2.436/2 = 1.218 (RC)

   C. Calculation of the CUTOFF VALUE

       CUTOFF VALUE = (0.23) x (RC)

       Example: RC = 1.218

       CUTOFF VALUE = (0.23) x (1.218)
       = 0.280

   D. Compare SPECIMEN absorbance values to the CUTOFF VALUE as indicated in the INTERPRETATION OF RESULTS section.
INTERPRETATION OF RESULTS

1. Specimens with absorbance values less than the CUTOFF VALUE are considered non-reactive by the criteria of the UBI® FMDV VP1 EIA (RUMINANT) and may be considered negative for antibodies to FMDV VP1.

2. Specimens with absorbance values greater than or equal to the CUTOFF VALUE are considered initially reactive. This VP1 reactivity may result from FMDV infection or vaccination. If the reactive specimens are from a vaccinated herd, the reactivity is most likely a result of effective vaccination.

3. Initially reactive specimens, if coming from a ruminant herd that has not been vaccinated with FMDV vaccines, should be retested in duplicate (using the original specimen) before final confirmation of the result.

4. Initially reactive specimens, which are reactive in either of the repeat tests, are considered repeatably reactive for antibodies to FMDV vaccine or infectious FMDV. These specimen should be tested with the UBI® FMDV NS EIA (RUMINANT) for differentiation between infected or vaccinated status.

5. When specimens are tested by both the UBI® FMDV VP1 EIA (RUMINANT) and the UBI® FMDV NS EIA (CATTLE), the results can be interpreted using the following algorithm:

<table>
<thead>
<tr>
<th>FMDV VP1 EIA</th>
<th>FMDV NS EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

6. Specimens that test positive in the VP1 EIA but negative in the NS EIA are likely to be from vaccinated animals.

7. For any specimen that is reactive in both the VP1 EIA and the NS EIA tests, the signal (OD450 nm)/cut-off ratios of the tests should be compared. If the VP1 EIA signal/cut-off value is at least 1.7 times higher than the NS EIA signal/cut-off value, the specimen is more likely to be from a vaccinated animal rather than from an infected one.

8. All other VP1 and NS double reactive specimens are most likely from animals that were infected by the Foot-and-Mouth Disease Virus.

LIMITATIONS OF THE PROCEDURE

1. The UBI® FMDV VP1 EIA (RUMINANT) is not recommended for indications using serum diluted beyond the 1:21 dilution required for optimal assay performance, or for indications using plasma or other bodily fluids. Likewise, pooled and diluted specimens are not recommended for use in this assay.

2. The UBI® FMDV VP1 EIA (RUMINANT) has been formulated specifically for use with domesticated RUMINANTS. The assay is not valid for swine.

3. The UBI® FMDV VP1 EIA (RUMINANT) is formulated for detection of anti-VP1 antibodies associated with subtypes of FMDV serotype O. Use of this test is not recommended if the presence of FMDV of other serotypes is suspected or if animals have been immunized only with FMDV vaccines of other serotypes.
4. The UBI® FMDV VP1 EIA PROCEDURE and the INTERPRETATION OF RESULTS sections must be closely adhered to when testing for the presence of antibodies to FMDV vaccine or infectious FMDV in serum from individual animals.

5. Diagnosis of FMD can only be established clinically or by virus isolation. UBI® FMDV VP1 EIA (RUMINANT) testing alone cannot be used for diagnosis, even if the recommended investigation of reactive specimens suggest a high probability that antibody to infectious FMDV is present. A negative test result at any point in the investigation in individual animals does not preclude the possibility of exposure to or active infection with FMDV.

6. The UBI® FMDV VP1 EIA (RUMINANT) does not distinguish between antibodies evoked by vaccination or infection.
BIBLIOGRAPHY


UBI® is a registered trademark of United Biomedical, Inc.
Manufactured for:
United Biomedical, Inc.
25 Davids Drive
Hauppauge, NY 11788
U.S.A.

US Patent 6,107,021
Worldwide patents pending

Version 3 (DI091201)