INgezim® FVR Compac

R.13.FVR.K.3

Blocking ELISA kit for detection of antibodies specific of Rift Valley Fever Virus N protein.
Multispecies assay for serum and plasma samples

TECHNICAL INFORMATION

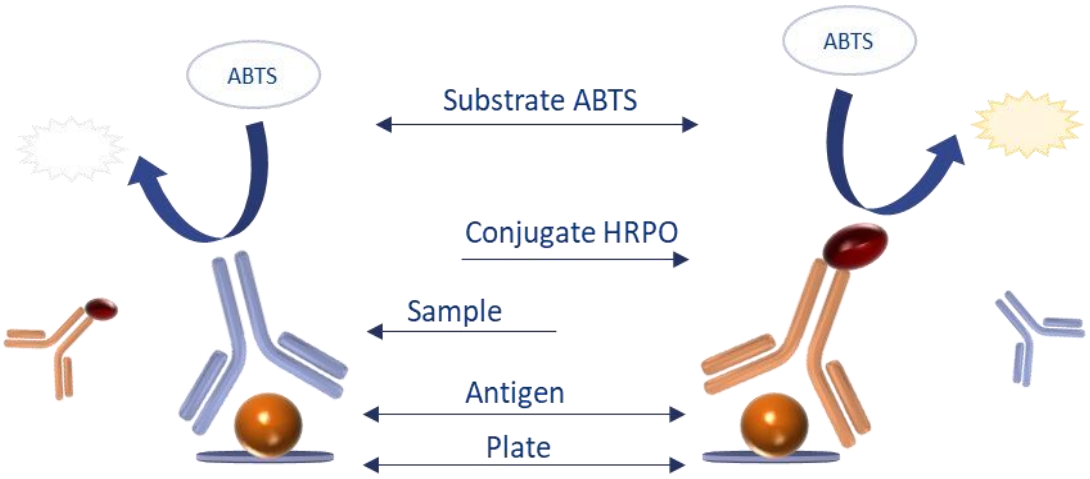
LAST REVISION: 19/06/23

INDEX OF CONTENTS

1 PRODUCT APPLICATION:

INgezim® FVR COMPAC has been designed for the detection antibodies specific of RVFV N protein in serum and plasma samples. The assay is valid for all species affected by this disease.

2 TECHNICAL BASIS OF THE PRODUCT:



1. Plates are supplied coated with RVFV recombinant N protein.
2. On these wells, samples are added and incubated.
3. If serum samples contain specific antibodies to N protein, they will bind the antigen.
4. At this point a washing step is needed to remove all non-specifically fixed materials
5. Monoclonal Antibody specific of RVFV N protein conjugated with HRPO is added. This conjugate will bind to the N protein coated to the plate if there are not antibodies specific in the sample (negative). In case there were antibodies specific in the sample (positive), these Abs will block the specific sites in the N protein avoiding the union of the conjugate.
6. Again a washing step is required to remove all non specifically fixed conjugate
7. If a substrate for peroxidase is added, a colorimetric reaction will appear for negative samples.

3 KEY REAGENTS USED

The optimum performance of the test is partially due to the high quality of the key reagents used in its formulation, which are:

- **Antigen**: RVFV recombinant N protein.
- **Conjugate:** Monoclonal Antibody specific to RFVF N protein conjugated with HRPO (horseradish peroxidase).

4 VALIDATION

4.1 DIAGNOSTIC SPECIFICITY

In order to determine the diagnostic specificity, sera from different RVFV free sources were analyzed:

- 1626 Spanish sheep, goats and cattle.
- 1014 Spanish wild animals (fallow deer, goats, alpaca, deer)

The obtained results showed 99.9 specificity since only one sheep serum gave doubtful result. This sample was positive by ID Screen® Rift Valley Fever Competition and negative by SN.

4.2 DIAGNOSTIC SENSITIVITY

To determine the ability of the assay detecting positive samples, 31 sera of sheep were analyzed:

- 23 experimentally infected and bled at days 18 and 24 p.i. (2013)
- 8 sera of sheep naturally infected before 2013.

From the obtained results, the assay shows 96.87% sensitivity since only one serum gave negative results.