Internal validation report

ID Screen® FMD NSP Competition

Competitive ELISA (multi-species) kit for the detection of anti-FMDV non structural protein (NSP) antibodies in serum and plasma from bovine, ovine, caprine and porcine

- **High sensitivity and specificity**
- **Short and overnight incubations: deliver same-day FMD results** when using the short protocol
- **Efficiently detects all serotypes and carrier animals**
- **Applicable to multiple species (ruminants and swine)**
- **Easy-to-use:** no freeze-dried reagents and all dilution buffers are supplied coloured and ready-to-use

Introduction

Foot and mouth disease (FMD) is a highly contagious and economically devastating viral disease of cloven-hoofed animals. The causative agent belongs to the genus *Aphthovirus*, family Picornaviridae.

There are seven distinct serotypes of FMD virus (FMDV), namely, O, A, C, Asia 1, SAT 1, SAT 2 and SAT 3, and within each serotype there are numerous strains. Infection with one serotype does not confer immunity against another.

Circulation of FMDV in an animal population imposes severe restrictions on the movement of animal products and consequently on international trade.

The differentiation of herds which have been infected from those which have been vaccinated is a critically important follow-up activity to protective emergency vaccination. Both infection and vaccination elicit antibodies against structural antigens. Only assays that measure levels of antibodies against non-structural protein (NSP) can differentiate infected and vaccinated animals (DIVA).

NSP ELISAs are simple to perform and are suited to large scale application by a routine serological laboratory.

The **ID Screen® FMD NSP Competition** ELISA is designed to detect 3ABC non structural protein (NSP) antibodies. It can be used for bovine, ovine, caprine and porcine serum or plasma.

Test Principle

Wells are coated with 3ABC recombinant non-structural protein (NSP).

Samples to be tested and controls are added to the microwells. Anti-NSP antibodies, if present, form an antigen-antibody complex which masks the virus epitopes.

An anti-NSP horseradish peroxidase (HRP) conjugate is added to the wells. It fixes to the remaining free epitopes, forming an antigen-conjugate-HRP complex.

After washing in order to eliminate the excess conjugate, the substrate solution (TMB) is added.

The resulting coloration depends on the quantity of specific antibodies present in the sample to be tested. In the absence of antibodies, a blue solution appears which becomes yellow after addition of the stop solution. In the presence of antibodies, no coloration appears after addition of the stop solution

The microplate is read at 450 nm.

Result interpretation:

For each sample, the S/N percentage (S/N%) is calculated: [OD_{sample} / OD_{NC}] x 100.

Result	Status
S/N % ≤ 50%	POSITIVE
S/N %> 50%	NEGATIVE

Specificity

Results obtained with field samples from unvaccinated animals

The following 2009 sera from non-endemic and non-vaccinated areas (France) were tested using both the short and overnight protocols:

- 1091 bovine sera
- 538 swine sera
- 183 sheep sera
- 197 goat sera.

The results shown in Figure 1 were obtained with the short incubation, and are expressed as sample to negative control ratios (S/N%).

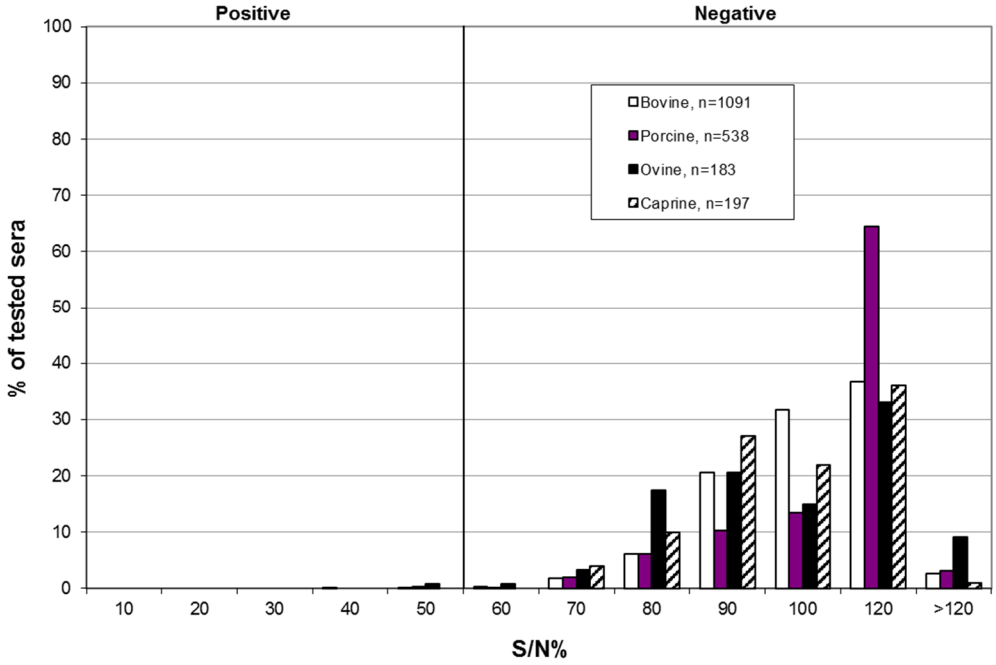

Figure 1: S/N% distribution for negative sera from non-endemic, non-vaccinated areas (short protocol).

Table 1 below summarizes the measured specificity for each species tested.

Species	**Specificity** (%) (number of samples)	$CI_{95\%}$
Bovine	**99.7** (1088 / 1091)	99.2 % - 99.9 %
Swine	**99.6** (536 / 538)	98.7 % - 100 %
Ovine	**99.5** (182 / 183)	97.0 % - 100 %
Caprine	**100** (197 / 197)	98.1 % - 100 %
TOTAL	**99.7** (2003 / 2009)	**99,4 % - 99.9 %**

Table 1: Measured specificity for sera from non-endemic and non-vaccinated areas.

Measured specificity was high, regardless of the species tested.

Results obtained with samples from experimentally vaccinated or multi-vaccinated cattle

The ability of the ID Screen® FMD NSP Competition to be a DIVA test (Differentiating Infected from Vaccinated Animals) was evaluated by testing animals vaccinated with O monovalent highly purified vaccine, a commercially available purified vaccine without any FMDV non-structural proteins, at 0 day post vaccination (dpv) and 50 dpv.

The presence of antibodies against the structural proteins and the non-structural proteins was evaluated using the ID Screen® FMD Type O Competition and the ID Screen® FMD NSP Competition ELISA kits, respectively.

The results obtained are shown in the following table:

	ID Screen® FMD Type O cELISA Cut-off : 35 % < S/N % ≤ 45% DOUBTFUL				**ID Screen® FMD NSP cELISA** *(Short Protocol)* Cut-off : S/N% ≤ 50% POS			
	0 dpv		**50 dpv**		**0 dpv**		**50 dpv**	
Animal ID	S/N%	Result	S/N%	Result	S/N%	Result	S/N%	Result
201	102	(-)	7	(+)	108	(-)	97	(-)
202	101	(-)	13	(+)	111	(-)	96	(-)
203	99	(-)	2	(+)	107	(-)	98	(-)
204	95	(-)	12	(+)	107	(-)	81	(-)
205	101	(-)	19	(+)	104	(-)	102	(-)
206	104	(-)	7	(+)	107	(-)	109	(-)
207	102	(-)	5	(+)	104	(-)	106	(-)
208	98	(-)	28	(+)	103	(-)	91	(-)
209	91	(-)	15	(+)	102	(-)	85	(-)
210	97	(-)	11	(+)	109	(-)	98	(-)
211	95	(-)	4	(+)	106	(-)	96	(-)
212	94	(-)	14	(+)	91	(-)	98	(-)
213	98	(-)	9	(+)	85	(-)	97	(-)
214	102	(-)	4	(+)	98	(-)	107	(-)
215	101	(-)	16	(+)	96	(-)	107	(-)
216	103	(-)	9	(+)	98	(-)	101	(-)
217	99	(-)	8	(+)	97	(-)	97	(-)
218	95	(-)	14	(+)	96	(-)	88	(-)
219	104	(-)	10	(+)	98	(-)	106	(-)
220	92	(-)	28	(+)	81	(-)	88	(-)
221	104	(-)	37	(+/-)	97	(-)	108	(-)
222	103	(-)	16	(+)	107	(-)	111	(-)
223	98	(-)	28	(+)	107	(-)	107	(-)
224	102	(-)	23	(+)	101	(-)	107	(-)
225	94	(-)	21	(+)	97	(-)	104	(-)
226	102	(-)	11	(+)	88	(-)	107	(-)
227	101	(-)	20	(+)	106	(-)	104	(-)
228	91	(-)	26	(+)	92	(-)	103	(-)

Table 2: Results obtained with the ID Screen® cELISAs on samples from vaccinated animals (n=28)

- At 50dpv, seroconversion was detected in all the animals vaccinated with this O monovalent highly purified vaccine with the ID Screen® FMD Type O cELISA while these vaccinated animals were found negative with the ID Screen® FMD NSP cELISA.
- The ID Screen® FMD NSP cELISA allows the differentiation between vaccinated and infected samples.

Agreement between the short and overnight protocols

The ID Screen® FMD NSP cELISA includes both short and overnight protocols, thereby offering laboratories flexibility in their testing programs.

In order to verify that these protocols generate similar results, 960 sera among the 2009 sera described in the previous chapter were tested in parallel using the short and overnight protocols.

- Agreement between the two protocols was high (99.69%). Laboratories may therefore use either the short or overnight incubation.
- The short incubation offers the possibility of providing **same-day results to customers**.

Comparison with another ELISA

Sera from non-endemic and non-vaccinated areas (France) were tested using the ID Screen® FMD NSP cELISA and another commercially available NSP Competitive ELISA (Kit A).

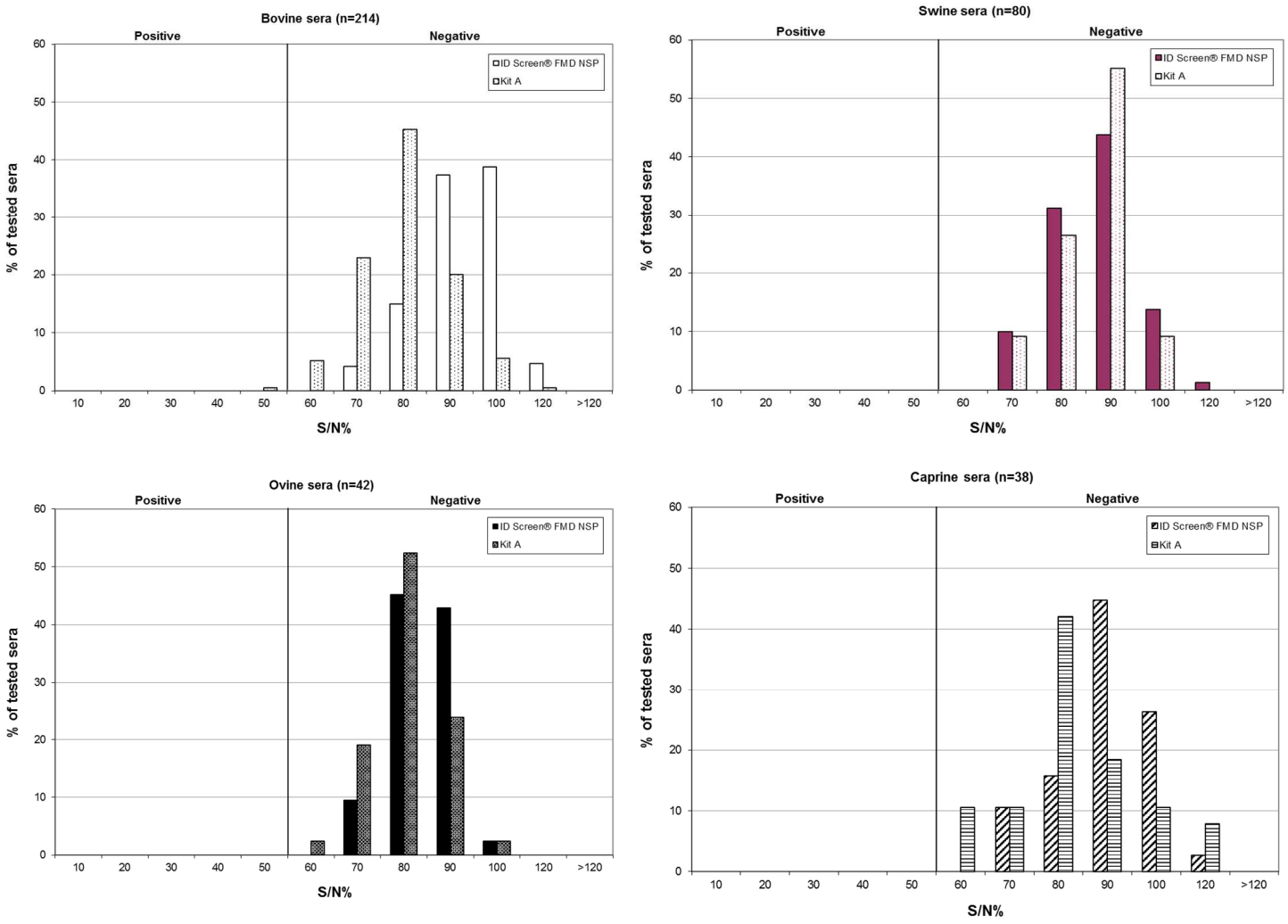

Figure 2: Comparison of S/N% distribution for negative sera from non-endemic, non-vaccinated areas (short protocol).

- Repartition of negative sera from various species are at least comparable between the ID Screen® ELISA and Kit A.

Proficiency testing for veterinary laboratories

Panels were tested within the frames of the Proficiency testing for veterinary laboratories in UK (VETQAS) and in Germany (FLI).

Note: While ID Screen® results are expressed as S/N%, data were converted to P/I% (100 - S/N%) in the following table and figures in order to facilitate the comparison of results.

VETQAS ring trial

Vetqas is an independent and accredited service provided by the Animal Health and Veterinary Laboratories Agency (AHVLA). This ring trial took place in September 2014.

The following Vetqas samples were tested in parallel using the ID Screen® ELISA and Kit A:

- 1 serum from a Type A challenged cow. The serum was diluted 1:2;
- 1 serum from a Type A challenged cow. The serum was diluted 1:4;
- 1 negative serum;
- 1 serum from a Type O vaccinated and challenged pig;
- 1 serum from a Type Asia 1 vaccinated lamb.

	ID Screen® FMD NSP (100 – S/N%)				**Kit A**	
	Overnight incubation cut-off: S/N% ≤ 50% POS		Short incubation cut-off: S/N% ≤ 50% POS		cut-off: PI% ≥ 50% POS	
	100 – S/N%	Status	100 – S/N%	Status	PI%	Status
Cow, type A, ½ diluted, challenged	89	(+)	92	(+)	90	(+)
Cow, type A, ¼ diluted, challenged	88	(+)	82	(+)	80	(+)
Negative serum	5	(-)	4	(-)	8	(-)
Pig, Type O, vaccinated and challenged	78	(+)	70	(+)	65	(+)
Lamb, Type Asia 1, vaccinated	8	(-)	8	(-)	7	(-)

Table 3: Comparison of results for 5 samples from the Vetqas FMD NSP reference panel using the ID Screen® ELISA and Kit A

All samples were correctly identified by the ID Screen® ELISA.

FLI ring trial

The following samples from the 2015 FLI FMD ring trial were tested in parallel using the ID Screen® ELISA and Kit A by 11 differents laboratories:

- **Sample A :** Negative sample

- Sample B : Positive sample diluted 1:7

- Sample C : Positive sample diluted 1:3

- Sample D : Positive sample diluted 1:5

The positive sample came from a cow vaccinated with FMDV O1/BFS/1860. After vaccination, the cow was challenged and sampled 20 weeks after infection.

ID Screen® FMD NSP :

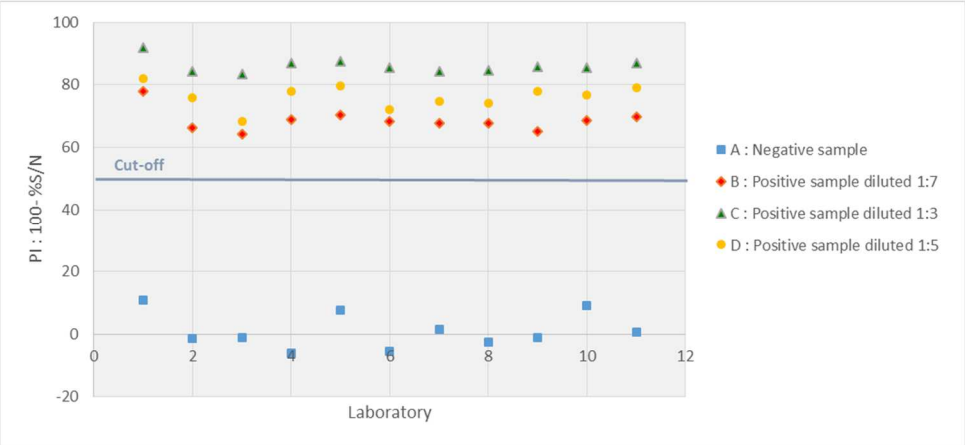

Figure 3: Results from 11 laboratories for 5 samples from the FLI FMD reference panel using the ID Screen® ELISA

- All samples were correctly identified by the ID Screen® ELISA.
- The ID Screen® ELISA shows an excellent reproducibility between all the laboratories.

Kit A :

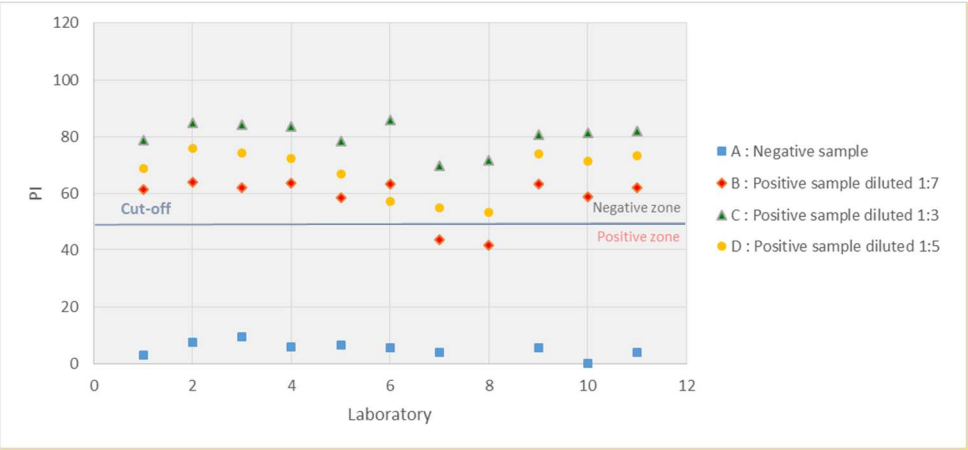

Figure 4: Results from 11 laboratories for 5 samples from the FLI FMD reference panel using the Kit A

- The sample B was not correctly identified by two laboratories (Lab No.7 and 8).
- On this panel, the reproducibility of the Kit A seems to be lower than the one of the ID Screen® ELISA.

Sensitivity

Results obtained with the international reference panel for evaluation of NSP kits

The international reference panel of NSP sera used for kit evaluation is comprised of 36 sera derived from **vaccinated** / **challenged** or **unvaccinated** / **infected** animals at **IAH**, **Pirbright** *(Parida, S., et al. Bovine serum panel for evaluating foot-and-mouth disease virus nonstructural protein antibody tests. J Vet Diagn Invest 19:539–544. 2007).* This panel was tested using the **ID Screen® FMD NSP cELISA.** Results were kindly provided by ANSES, Maisons-Alfort, France and the Pirbright Institute, UK (Table 3).

Note: While results are expressed as S/N% for the ID Screen® kit, data was converted to P/I% (100 - S/N%) in order to facilitate the comparison of results.

					Results from: Parida *et al.*, 2007					Results obtained at ANSES, France		Results obtained at Pirbright, UK	
Sera	Vaccine strain	Challenge exposure virus	Days after challenge that blood collected	Carrier status	IDEXX (ex-Bommelli)	Prionics (ex-Cedi)	Boehringer Ingelheim (ex-Svanova)	UBI	IZS Brescia	ID Screen® FMD NSP (100 – S/N%)		ID Screen® FMD NSP (100 – S/N%)	
					iELISA cut-off: 20% (S/P%)	cELISA cut-off: 50% (PI%)	iELISA cut-off: 48% (S/P%)	iELISA cut-off: 23% (S/P%)	iELISA cut-off: 10% (S/P%)	cut-off: 50% night incub	cut-off: 50% short incub	cut-off: 50% night incub	cut-off: 50% short incub
1	O Manisa	O UKG	174	C	29	71	28	11	13	81	68	67	67
2				C	12	57	16	11	4	57	42	46	38
3				C	32	78	37	14	16	89	81	89	88
4				C	20	80	24	23	14	88	79	85	79
5				C	16	86	46	45	10	86	71	81	76
6				C	7	66	27	8	2	67	59	59	62
7			21	C	37	88	52	18	22	82	82	79	76
8				C	23	65	23	7	9	77	67	74	75
9	A Iran 96	A Iran 96	28	C	79	87	75	47	83	88	89	86	86
10				C	12	38	29	13	13	65	62	57	56
11				C	64	81	59	60	63	90	87	88	88
12				C	16	38	13	8	21	40	40	43	26
13	Asia 1 Shamir	Asia 1 Shamir	29	C	45	80	51	26	26	79	61	69	64
14				C	99	83	65	24	48	86	74	74	76
15			35	C	104	91	95	110	99	91	90	90	92
16				C	40	90	68	55	48	79	72	72	69
17			29	C	227	84	87	44	84	89	89	84	86
18	SAT2 3218	SAT2 Eritrea	34	C	94	89	95	108	66	82	79	76	76
19			30	C	77	88	56	52	68	82	86	78	81
20				C	16	67	13	9	11	56	59	49	48
21	N/A	A Iran 96	28	C	166	81	94	126	85	90	88	90	87
22				C	165	91	108	167	102	92	92	89	93
23		O UKG	107	C	34	85	68	83	22	90	83	81	76
24				C	52	94	82	114	45	93	91	92	93
25			174	C	32	90	47	20	40	85	78	78	72
26			40	C	82	90	75	76	88	92	87	91	94
27				C	114	90	76	55	69	91	87	86	87
28	Asia 1 Shamir	Asia 1 Shamir	43	-	23	67	28	7	18	73	63	59	49
29				-	139	93	99	113	57	93	91	91	96
30	A Iran 96	A Iran 96	32	-	31	45	55	34	40	75	73	72	69
31	O Manisa	O UKG	106	-	10	57	25	12	10	76	57	73	69
32	N/A	Asia 1 Shamir	42	-	214	92	74	54	83	92	92	92	95
33				-	185	90	84	105	97	83	84	80	77
34		O UKG	107	-	58	86	56	42	52	90	87	90	90
35		UKG 34/01	37	-	125	86	67	103	58	71	66	85	90
36		O UKG	174	-	24	82	39	23	14	87	83	78	72
TOTAL					28/36	33/36	22/36	22/36	33/36	35/36	34/36	33/36	32/36

Table 4: Results obtained with the ID Screen® FMD NSP cELISA on the international reference panel of NSP sera (Parida et al. 2007).

Discussion:

- The ID Screen® FMD NSP cELISA **correctly detected** all **13 strains** present in the international reference panel for evaluation of NSP ELISA tests.
- The ID Screen® **test performance** was **equivalent** to the **best commercial ELISAs** evaluated in the 2007 study by Parida, S. *et al*, which included a number of commercial ELISAs.
- As shown in the previous chapter, the ID Screen® short and overnight protocols produced **similar results**.
- The ID Screen® test **efficiently detected** experimentally-infected animals, including **carrier animals**.

** Publication of the Pirbright Institute results is pending.*

Results obtained with the IAEA FMDV reference serum panel

The IAEA (through the Animal Production and Health Sub-programme of the Joint FAO/IAEA Division) offers a serum panel from infected cattle which include 6 FMDV serotypes (A, O, Asia 1, SAT1, SAT2 and SAT3).

These sera were tested on the **ID Screen® FMD NSP Competition.**

Results are shown in Table 4 below.

	ID Screen® NSP cELISA cut-off : S/N% ≤ 50% POS	
Subtype	*Overnight protocol (S/N%)*	*Short Protocol*
A	13 (+)	19 (+)
O	26 (+)	35 (+)
Asia 1	17 (+)	25 (+)
SAT 1	9 (+)	11 (+)
SAT 2	39 (+)	48 (+)
SAT 3	28 (+)	33 (+)

Table 5: Results obtained with the ID Screen® FMD NSP cELISA on the IAEA FMDV reference serum panel.

- **All 6 serotypes in the panel were correctly identified as positive by the ID Screen® FMD NSP cELISA.**

Results obtained with field samples

36 sera from an endemic FMD area were analysed:

- 14 were sampled from convalescent cattle, 90 days post-vaccination (O, A, Asia 1 vaccine);
- 19 were from convalescent cattle, vaccinated 7 months before infection and collected 60 days post-infection.
- 3 animals were in acute phase, showing clinical signs of the disease.

These sera were tested on 3 kits using recombinant 3ABC proteins: two competitive ELISAs (ID Screen® FMD NSP Competition and kit A) and one blocking ELISA (Kit B).

Sera	Convalescent	Acute Phase	ID Screen® FMD NSP (100 – S/N%)		Kit A	Kit B
			cut-off: S/N%≤ 50% POS short incub	cut-off: S/N% ≤ 50% POS night incub	cELISA cut-off: PI%≥ 50% POS	bELISA cut-off: OD<0.6 POS
1	yes	no	**97**	**95**	**94**	**0,084**
2	yes	no	**96**	**93**	**90**	**0,358**
3	yes	no	**93**	**91**	**92**	**0,128**
4	yes	no	**96**	**94**	**92**	**0,442**
5	yes	no	**92**	**93**	**92**	**0,118**
6	no	yes	**75**	**81**	**87**	**0,196**
7	yes	no	**80**	**88**	**91**	**0,105**
8	yes	no	**92**	**93**	**92**	**0,112**
9	yes	no	**96**	**96**	**94**	**0,117**
10	yes	no	**90**	**91**	**88**	**0,147**
11	yes	no	**78**	**83**	**85**	**0,296**
12	yes	no	**77**	**83**	**86**	**0,140**
13	yes	no	**95**	**94**	**92**	**0,090**
14	yes	no	**92**	**92**	**94**	**0,170**
15	no	yes	**97**	**96**	**96**	**0,041**
16	yes	no	**83**	**82**	**76**	**0,339**
17	yes	no	**76**	**80**	**78**	**0,286**
18	yes	no	**72**	**73**	**75**	**0,247**
19	yes	no	**84**	**84**	**63**	**0,273**
20	no	yes	**64**	**65**	**64**	**0,394**
21	yes	no	**60**	**76**	**71**	**0,295**
22	yes	no	**52**	**62**	**64**	**0,662**
23	yes	no	**79**	**85**	**75**	**0,509**
24	yes	no	**94**	**93**	**94**	**0,069**
25	yes	no	**56**	**59**	**72**	**0,447**
26	yes	no	**95**	**94**	**94**	**0,097**
27	yes	no	**95**	**94**	**95**	**0,078**
28	yes	no	**95**	**94**	**93**	**0,071**
29	yes	no	**93**	**94**	**93**	**0,291**
30	yes	no	**76**	**77**	**84**	**0,665**
31	yes	no	**96**	**96**	**94**	**0,112**
32	yes	no	**95**	**96**	**92**	**0,222**
33	yes	no	**93**	**94**	**93**	**0,242**
34	yes	no	**84**	**89**	**91**	**0,211**
35	yes	no	**90**	**92**	**89**	**0,397**
36	yes	no	**95**	**96**	**92**	**0,188**
TOTAL			36/36	36/36	36/36	34/36

Table 6: Results obtained with the ID Screen® FMD NSP cELISA, Kit A and Kit B on field samples (positive values are shown in red).

- **All animals in the panel were correctly identified as positive by the ID Screen® FMD NSP cELISA.**
- 2 animals were not properly identified with the ELISA kit B.

Analytical sensitivity

IDvet has developed an internal standard* from caprine serum containing anti-3ABC NSP antibodies to assess analytical sensitivity.

Using this internal standard, IDvet is able to guarantee that the kit's analytical sensitivity remains constant between batches.

The internal reference material (MRI-FMDNSP) was tested at different dilutions in negative serum.

MRI-FMDNSP dilution	ID Screen® FMD NSP (100- S/N%)		Kit A	Kit B
	cut off: S/N%≤ 50% POS short incub	cut off: S/N%≤ 50% POS night incub	cELISA cut-off: PI%≥ 50% POS	bELISA cut-off: OD<0.6 POS
pure	**93**	**93**	**80**	0,687
1:2	**84**	**82**	**65**	0,871
1:4	**68**	**57**	44	0,959
1:8	47	36	34	0,998

Table 7: Results obtained with the MRI-FMDNSP (positive values are shown in red).

- The MRI-FMDNSP serum was found positive at a 1:4 dilution with the ID Screen® FMD NSP Competition ELISA.
- Kit A and notably Kit B were less sensitive than the ID Screen® kit in their ability to detect the MRI-FMDNSP serum.

** Available for purchase, product code: MRI-FMDNSP.*

Repeatability

Intra-plate repeatability was evaluated by measuring the coefficient of variation of 48 repetitions of a pool of negative bovine and porcine sera, and 48 repetitions of a weak positive bovine serum.

Results are considered conform if the CV% is less than 15%.

OD results are shown in Table 7 below.

0.442	0.437	0.452	0.457	1.461	1.444	1.481	1.427	0.415	0.402	0.403	0.434
0.444	0.450	0.458	0.436	1.469	1.403	1.465	1.443	0.409	0.395	0.415	0.415
0.443	0.420	0.427	0.464	1.422	1.316	1.425	1.380	0.417	0.407	0.398	0.405
1.485	1.358	1.370	1.423	1.428	1.340	1.373	1.298	1.387	1.378	1.310	1.348
1.563	1.393	1.369	1.449	1.375	1.331	1.366	1.335	1.354	1.356	1.384	1.342
0.450	0.439	0.423	0.424	1.419	1.343	1.386	1.356	0.404	0.382	0.398	0.382
0.471	0.453	0.445	0.440	1.389	1.405	1.409	1.371	0.401	0.425	0.426	0.383
0.441	0.429	0.443	0.459	1.395	1.385	1.458	1.464	0.395	0.393	0.426	0.394

	Average OD	Standard deviation	Minimum	Maximum	CV%
Negative pool serum	1.396	0.053	1.298	1.481	4
Weak (+) serum	0.424	0.024	0.382	0.471	6

Table 8: Repeatability study for the ID Screen® ELISA (results expressed as OD values)

- The CV% obtained were 4% for the negative pool serum and 6% for weak positive serum, demonstrating excellent test repeatability.

Stability

The shelf-life of the product is evaluated by the technique of accelerated ageing. The stability of the plates and the conjugate was tested by evaluating the residual activity of individual components after storage at 37°C ± 2°C, with respect to storage at 5°C ± 3°C. The measured residual activity at 37°C ± 2°C should be greater than 75% after two weeks.

Results are shown in Figure 5.

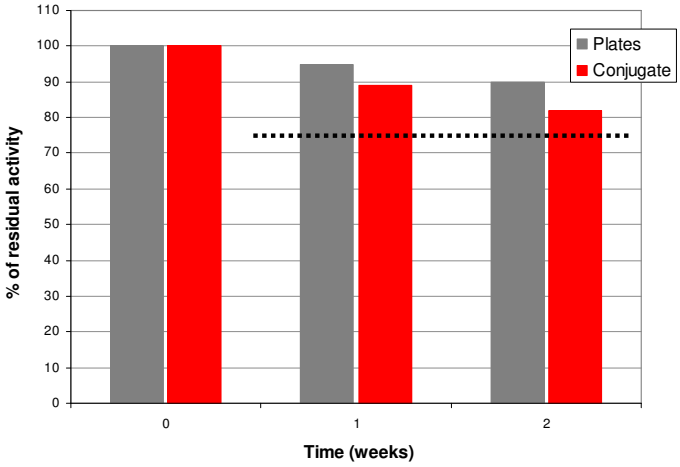

Figure 5: Percentage of residual activity of plates and conjugate after stability testing at 37°C.

- The plates and conjugate showed residual activity of 89% and 82%, respectively, indicating high component stability.

Robustness

A pool of infected sera from animals from an endemic country was diluted in a negative serum pool in order to generate a weak positive sample.

This threshold dilution was tested in 18 independent runs by different operators and on different days.

Results are shown in Figure 6.

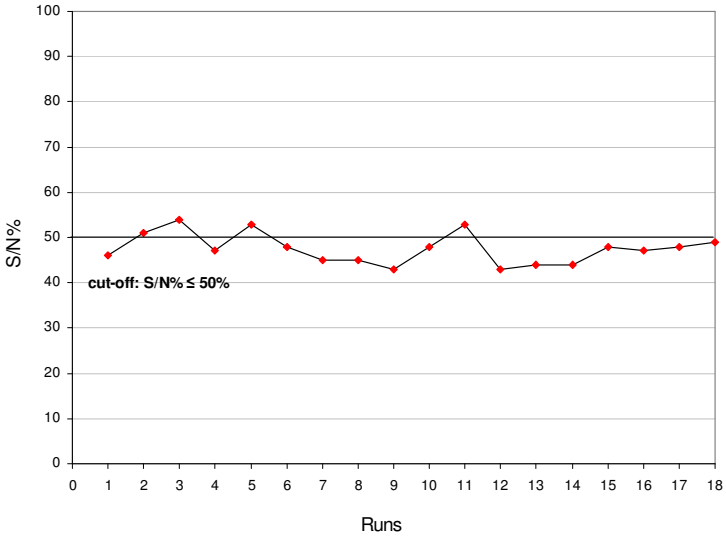

Figure 6: S/N% results of a positive serum pool diluted in a negative serum pool and tested in 18 independent runs.

- S/N% values were between 43 and 54%, with a standard deviation (SD) of 3 and a coefficient of variation (CV %) = 7%.
- These results illustrate the high robustness and reproducibility of the ID Screen® test.

Conclusion

- The **ID Screen® FMD NSP Competition ELISA** demonstrates **high specificity** and excellent performance on reference panels. The ELISA correctly identified all strains tested and **efficiently detected carrier animals**.
- The kit offers both **short and overnight protocols**. These protocols give similar results, meaning that laboratories have the possibility of offering **same-day results** to their customers if the short protocol is used.
- The test is applicable to **multiple species**, including ruminants and swine.
- Easy-to-use, the kit includes coloured and **ready-to-use reagents**

References

(1) OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2012. Chapter 2.1.5: Foot and Mouth Disease.

(2) Parida, S., et al. Bovine serum panel for evaluating foot-and-mouth disease virus nonstructural protein antibody tests. J Vet Diagn Invest 19:539–544. 2007).

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Related products

- **ID Screen® FMD Type O Competition** (product code FMDOC-5P and FMDOC-10P).
- **ID Screen® FMD Type A Competition** (product code FMDAC-5P): coming soon!
- **FMD 3ABC NSP positive freeze-dried serum** (product code MRI-FMDNSP): Freeze-dried caprine serum containing anti-3ABC NSP antibodies (from a goat immunized with 3ABC recombinant protein). To be used as internal reference material for quality control. This serum does not contain any infectious material.
- **FMD type O, A and Asia 1 positive freeze-dried serum** (product code MRI-FMDO): Freeze-dried multivalent serum from vaccinated and uninfected cattle containing anti-FMD type O, A and Asia 1 antibodies, to be used as internal reference material for quality control. The serum is gamma-irradiated and does not contain any infectious material.

History of revisions

Version	Edit date	Reference	Type of revision	Revision made
0914	08/2019	DOC799	**Update**	Update: Addition/Edition of validation data
0914	03/2018	DOC619	**Update**	Addition of specificity data on unvaccinated and vaccinated animals. Addition of the 2015 FLI Ring trial results

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