



## A complete solution for the diagnosis of Bovine tuberculosis: IDvet PPD antigens & the ID Screen® Ruminant IFN-g ELISA

Bovine TB control programmes aim to identify infected cattle as early as possible and minimise the risk of transmission of the disease within and between cattle herds.

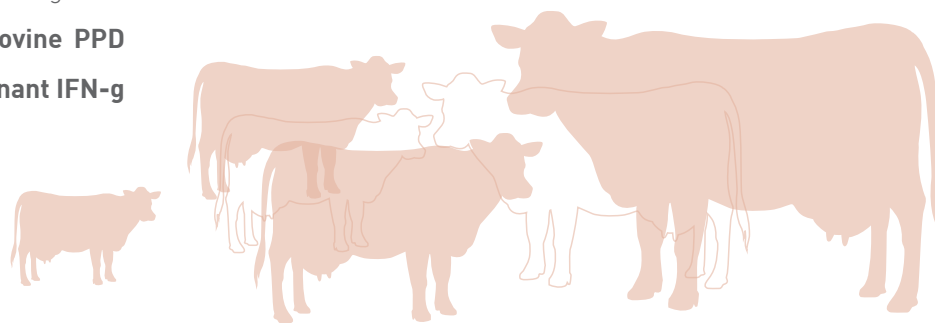
The IGRA (Interferon Gamma Release Assay) method is widely used, alone or in combination with the skin test, to improve the detection of infected cattle.

The IGRA method uses a sandwich ELISA to detect the cellular response to *Mycobacterium bovis* by measuring the difference in IFN-g signals for whole blood samples activated by specific antigens (in this case, bovine PPD) and non-specific antigens (avian PPD).

IDvet offers a complete solution for Bovine TB diagnosis via the IGRA method, including **avian and bovine PPD tuberculin antigens** and the **ID Screen® Ruminant IFN-g sandwich ELISA**.

### Benefits

- » **IDvet PPD antigens allow for improved specificity & sensitivity** thanks to matched potencies of bovine and avian tuberculin
- » **The ID Screen® IFN-g ELISA gives results you can trust:**
  - Results expressed as S/P ratios
  - Stable positive control
  - High repeatability and reproducibility
  - Rigorous interpretation criteria for improved test performance
  - May be used with any stimulating antigen
  - Applicable to multiple ruminant species



# The ID Screen® IFN-g ELISA: results you can trust

## Standardized results

- **Results are expressed as S/P% ratios** using the highly stable positive control included in the kit.
- **Freeze-dried reference material** (bovine, ovine, caprine or buffalo) from activated plasmas is available upon request. This material may be used as internal reference controls to monitor variations in analytical sensitivity between runs, laboratories, or batches.

## Flexible: use with any stimulating antigen and different field situations

- The ID Screen® ELISA may be used with **recombinant / peptide antigens or tuberculin**.
- Laboratories may choose between two protocols depending on the stimulating antigen used and the field situation (weak responses to mitogen, or particularly strong responses to PPDA and/or PPDB).

## Excellent repeatability

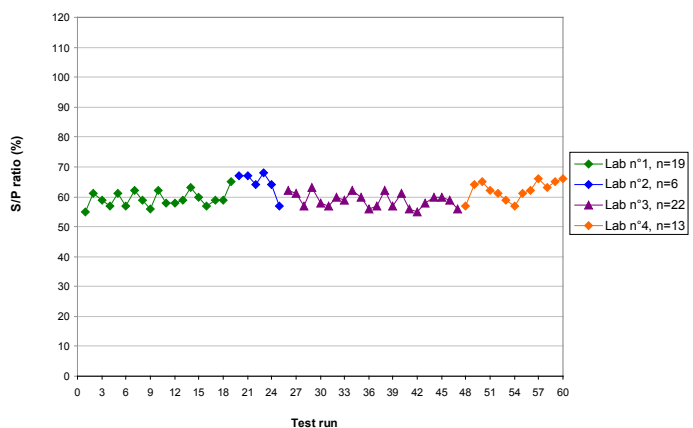
The coefficient of variation for 36 repetitions of a strong positive, activated plasma, and 60 repetitions of a weakly positive, activated plasma, was consistently found to be less than 5%.

## Excellent reproducibility and robustness

60 threshold dilutions of the IDvet freeze-dried, activated plasma (product code MRI-IFNG-B) were tested by 4 French laboratories in 19 independent runs (Figure 1).

- Measured S/P% values were between 55 and 68%.  
SD = 3 ; CV% = 5%.
- The ID Screen® ELISA allows for excellent result reproducibility between runs, operators, and laboratories, which is **essential for diagnostic reliability and multi-centric studies**.

Figure 1: S/P% results of the IDvet freeze-dried, activated plasma reference material



## High correlation with other IFN-g tests

467 activated plasmas were tested in parallel using the ID Screen® ELISA and commercial Kit A. The study was performed by four French Departmental Laboratories and two Italian Regional Laboratories within the framework of Bovine TB control programs.

- 460 / 467 samples gave identical results on both tests.
- The measured percentage of correlation was **98.5%**
- Test agreement :  $\kappa = 0.94$



# A complete and reliable solution for Bovine TB diagnosis

## Excellent specificity

1077 plasmas from TB-free herds were tested, including:

- 100 bovine plasmas from Belgium;
- 583 bovine plasmas from Brittany, France;
- 394 bovine plasmas from Midi-Pyrénées, France.

» **Measured specificity = 99.0%**

(IC<sub>95%</sub>: 98.4-99.6%), n=1077.

Country	Total number of samples	Number tested negative	Measured Sp%
Belgium (TB-free / Paratb Infected)	50	49	98.0
Belgium	50	48	96.0
Brittany, FR	99	99	100.0
Brittany, FR	121	121	100.0
Brittany, FR	105	104	99.0
Brittany, FR	86	86	100.0
Brittany, FR	114	113	99.1
Brittany, FR	58	58	100.0
Midi-Pyrénées, FR	158	154	97.5
Midi-Pyrénées, FR	158	157	99.4
Midi-Pyrénées, FR (TB-free / Paratb Infected)	60	60	100.0
Midi-Pyrénées, FR	18	17	94.4
<b>TOTAL</b>	<b>1077</b>	<b>1066</b>	<b>99.0%</b>

## High sensitivity

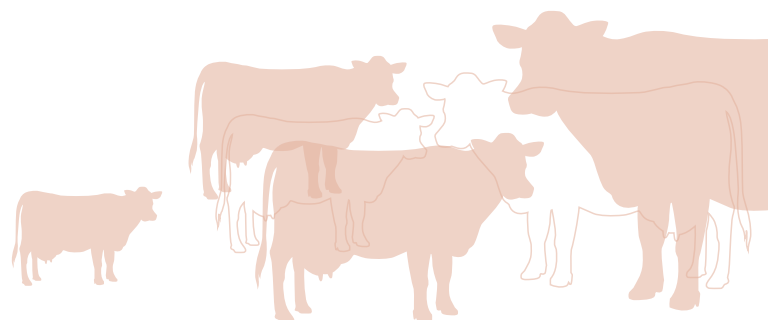
77 plasmas from TB-positive animals were tested, including:

- 28 bovine plasmas from France. Results were obtained by the Dordogne Departmental Laboratory. The positive status of the samples was determined either by PCR, culture or the skin test (results provided by Dr. J.L. Moyen);
- 49 bovine plasmas from Mexico. Animals had been found positive by the skin test.

» **Relative sensitivity = 88.3%**

(IC<sub>95%</sub>: 81.1-95.5%), n=77.

Country	Total number of samples	Number tested positive	Measured Se %
France	28	25	89.3
Mexico	49	43	88.0
<b>TOTAL</b>	<b>77</b>	<b>68</b>	<b>88.3%</b>



## Optimal test performance

The table below summarizes performance data for IDvet and Supplier A.

Supplier	Reagent	Sensitivity	Specificity
Supplier A*	Tuberculin + Assay 1	89%	84%
	Protein cocktail + Assay 2	85%	94%
	Peptide cocktail + Assay 2	80%	97%
IDvet	IDvet PPD + ID Screen® ELISA	<b>88.3%</b>	<b>99%</b>

\*Values as reported by Supplier A in its stimulation antigen product leaflet.

- Thanks to matched potencies of bovine and avian tuberculins and rigorous ELISA interpretation criteria, the IDvet test offers optimal specificity and sensitivity.

## Conclusion

- The ID Screen® Ruminant IFN-g ELISA includes a stable positive control for the calculation of **S/P% ratios**, thereby improving upon current IFN-g technology.
- High repeatability, reproducibility and rigorous interpretation criteria allow for **reliable results**.
- The complete testing solution from IDvet (tuberculins + ELISA) offers **optimal specificity and sensitivity**.

## Product specifications

- PPD PACK avian and bovine tuberculins (for in-vitro diagnostic use only)**
  - Avian Tuberculin PPD, 2 x 5ml (2 x 2500 reactions)
  - Bovine Tuberculin PPD, 2 x 5ml (2 x 2500 reactions)
  - Freeze-dried Mitogen, 1 x 5ml (1 x 5000 reactions)
- ID Screen® Ruminant IFN-g**
  - IFNG-2P: 2 plates (192 reactions)
  - IFNG-4P: 4 plates (384 reactions)
  - IFNG-10P: 10 plates (960 reactions)
- Freeze-dried reference material from activated plasmas**
  - MRI-IFNG-B: 0.5 ml bovine serum
  - MRI-IFNG-O: 0.5 ml ovine serum
  - MRI-IFNG-C: 0.5 ml caprine serum
  - MRI-IFNG-BF: 0.5 ml buffalo serum

## Acknowledgements

IDvet would like to thank all the laboratories and scientists that contributed to this validation study, including:

- French laboratories from Côtes d'Or, Bouches du Rhône, Dordogne, Gard, Hérault, and Finistère;
- the French GDS organisations from Brittany and Finistère;
- IZS Rome and IZS Turin;
- CODA-CERVA, Belgium;
- ARSIA, Ciney, Belgium;
- ANSES, Maisons Alfort, France;
- European Reference Laboratory for Bovine TB, VISAVET Health Surveillance Centre, Spain.