SVANOVIR® BLV gp51-Ab

The assay which is successful in control & eradication programmes worldwide

SUMMARY | SVANOVIR® BLV gp51-Ab is based on the gp51 envelope protein, enabling the detection of antibodies to BLV during early phase of infection. It fulfils the EU standard E05 (EEC directive 88/406/EEC) and has repeatedly shown high sensitivity and specificity in serum and milk samples (individuals and pools) from field infected animals.

YOUR CHALLENGE is an inapparent disease
BLV causes enzootic bovine leukemia, a disease that is mainly prevalent in adult cattle. The infection can persist without apparent clinical signs but lead to reduction of yield. Only a few animals may develop fatal lymphosarcoma. Once an animal is infected, the virus remains present for life and may spread to susceptible animals through contact with contaminated blood e.g. during vaccination, ear tagging or dehorning.

YOUR GOAL is to accurately identify infected cattle
BLV is present in cattle worldwide, but prevalence varies between herds and regions. Control procedures include identifying positive herds, isolating and culling positive individuals, and retesting the remaining cattle. Timely identification of infected cattle prevents spread of disease and maintains production yield.

ASSAY OVERVIEW
SVANOVIR® BLV gp51-Ab
Species Bovine
Samples Serum/plasma, individuals and pools of ≤10
Milk, individuals and pools of ≤50
Type Indirect ELISA based on the envelope glycoprotein gp-51

<table>
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<th>Plates</th>
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* Samples: Max. number of samples for analysis, wells for kit controls excluded.
* Confirmation assay: recommended for herds with high prevalence.
* Screening assay: recommended for herds with low prevalence, in combination with confirmation assay.

Field-proven assay – used for the control of BLV in Scandinavia, Netherlands, Croatia, Canada and Australia

High analytical sensitivity, repeatedly proven in bulk tank milk and dilution studies

Fulfils detection of E05 in those dilutions stated in EU directive 88/406/EEC

Accurate results in proficiency tests organised by the OIE Reference Laboratory for Enzootic Bovine Leukosis in Poland, in 2011 and 2014

Prescribed test method for international trade by OIE
The performance of the SVANOVIR® BLV gp51-Ab has been evaluated in several external and internal studies and has unanimously received best assessments. During several years of Proficiency testing organized by the OIE Reference National Laboratory for Enzootic Bovine Leukosis, Pulawy, Poland the SVANOVIR® BLV gp51-Ab has achieved results fully matching those expected by the laboratory (Kuzmak, 2011-2014).

Excellent sensitivity and specificity were seen in serum and milk samples (individuals and pools) from field infected animals when compared to immuno-diffusion test (AGID) (Table, Klintevall et al., 1991).

The analytical sensitivity of SVANOVIR® BLV gp51-Ab was superior to all other assays and was the only assay that provided a positive result for E4 serum after a dilution up to 640 times (Kramps, 1994). Titration of the E05 in negative serum showed that SVANOVIR® BLV gp51-Ab revealed a positive result at a dilution of 1/16 384 (Jalali, 2010). In another dilution trial including 10 negative and 40 strongly positive samples, the SVANOVIR® BLV gp51-Ab was detecting antibodies in samples diluted up to 1/20 800 (Simard et al., 2000). Studies from bulk tank milk analyses suggest accurate results of tank milk samples containing milk from at least 50-100 animals and detecting a herd as positive with a prevalence of as low as 4% (Klintevall et al., 1991).

Table: Overview of performance characteristics of SVANOVIR® BLV gp51-Ab in sera compared to immuno-diffusion test (AGID).

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Reference method</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Serum^a N=414/n pos=214</td>
<td>100%</td>
<td>99.8%</td>
<td>AGID</td>
<td>Klintevall et al., 1991</td>
</tr>
<tr>
<td>Serum^b N= 1200/n pos=490</td>
<td>99.0%*</td>
<td>99.6%</td>
<td>AGID</td>
<td>Simard et al., 2000</td>
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<tr>
<td>Serum^c N=45/n pos=16</td>
<td>100%</td>
<td>100%</td>
<td>Experimentally infected field sera: AGID</td>
<td>Kramps, 1994</td>
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<td>Agreement milk vs. serum^d N=414/ n pos=214</td>
<td>100%</td>
<td>99.4%</td>
<td>Not applicable</td>
<td>Klintevall, 1991</td>
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</tbody>
</table>

Samples from ^a Sweden, ^b Canada, ^c Netherlands ^d Both false negatives found in the first run were positive after retesting.

More information about the assay and the validation studies is provided in the “Performance Review” document.

References
Jalali, A (2010): Titration of the New Standard Serum E05 for the EBL diagnostics in serum and tank milk in order to establish the size of milk pools for the SVANOVIR® BLV gp 51-Ab-ELISA. Internal Report.