

# Anigen Rapid **Leishmania Ab**

Evaluation of 5 point-of-care tests for the detection of *Leishmania infantum* antibodies in dogs, <https://doi.org/10.1177/10406387261418209>

## INTRODUCTION

Canine leishmaniosis is a widespread, potentially fatal disease caused by infection with *Leishmania infantum*. We evaluated 5 commercial point-of-care tests (POCTs) for the detection of *L. infantum* antibodies in dog sera and compared their performance with the immunofluorescence assay (IFA) as the reference method.

## PURPOSE

POCTs offer an economical and fast alternative for qualitative antibody detection suitable for veterinary practice. Although sensitivity can vary widely (52.9–100%), specificity is generally high (84.9–100%), which ensures their practical value for confirming CanL in dogs with compatible clinical signs. Although several POCTs for the diagnosis of CanL are available commercially, comparative validation studies under standardized conditions are lacking. This gap limits evidence-based recommendations for clinical practice. Our aim was to address this gap by evaluating 5 POCTs for the detection of *L. infantum* antibodies in dog sera and comparing their performance with the IFA reference method. We determined practicality, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

- ① trüRapid Leish (Biotech)
- ② FASTest Leish (Megacor)
- ③ **Leishmania Ab (Bionote)**
- ④ Uranotest Leishmania 2.0 (Uranovet)
- ⑤ Uranotest Leishmania 3.0 (Uranovet)

## MATERIALS AND METHODS

We evaluated 5 commercial point-of-care tests (POCTs) in comparison with the immunofluorescence assay (IFA) as the reference method. We tested serum samples from 160 dogs that either had lived in or traveled to leishmaniosis-endemic areas using immunochromatography POCTs. These dogs were presented for preventive health care or in the infectious disease service.

## RESULTS

The test results for the comparison of five commercial antibody kits including Bionote were described in **Table 1**, **Table 2**, and **Table 3**.

## CONCLUSION

The sensitivity of the 5 POCTs was 48.9–88.9% and specificity was 90.4–100%. PPV was 78.4–100%; NPV was 83.3–95.6%. (Table 1) The level of agreement between the reference method (IFA) and the POCTs was 85.6–95.6%. The **Leishmania Ab (Bionote)** had the highest agreement with the IFA. Given its comparatively high sensitivity and specificity, the **Leishmania Ab (Bionote)** may be considered for screening dogs from endemic areas and for confirming *Leishmania* infection in clinical dogs.

## Reference

Adel A, et al. Evaluation of immunofluorescence antibody test used for the diagnosis of canine leishmaniasis in the Mediterranean Basin: a systematic review and meta-analysis. PLoS One 2016;11:e0161051.

Table 1. *Leishmania* point-of-care tests (POCTs) performance compared to immunofluorescence assay.

| POCT                           | Sensitivity, %<br>[95% CI]  | Specificity, %<br>[95% CI] | PPV, %<br>[95% CI]         | NPV, %<br>[95% CI]          | Cohen kappa | McNemar test p-value |
|--------------------------------|-----------------------------|----------------------------|----------------------------|-----------------------------|-------------|----------------------|
| <b>Leishmania Ab (Bionote)</b> | <b>88.9</b><br>[97.7, 98.1] | <b>98.3</b><br>[95.9, 100] | <b>95.2</b><br>[89.0, 100] | <b>95.8</b><br>[92.1, 99.4] | <b>0.89</b> | <b>0.45</b>          |
| Uranotest Leishmania 2.0       | 88.9<br>[97.7, 98.1]        | 90.4<br>[85.1, 95.8]       | 78.4<br>[66.4, 90.5]       | 95.4<br>[91.6, 99.2]        | 0.76        | 0.21                 |
| trüRapid Leish                 | 86.4<br>[76.2, 96.5]        | 96.5<br>[93.2, 99.9]       | 90.5<br>[81.8, 99.2]       | 94.9<br>[90.8, 98.9]        | 0.84        | 0.75                 |
| Uranotest Leishmania 3.0       | 84.4<br>[73.9, 95.0]        | 94.8<br>[90.7, 98.9]       | 83.4<br>[76.3, 96.4]       | 94<br>[89.6, 98.3]          | 0.8         | 1                    |
| FASTest Leish                  | 48.9<br>[34.3, 63.5]        | 100                        | 100                        | 83.3<br>[76.5, 90.1]        | 0.58        | <0.001               |

Table 2. Results of the anti-*Leishmania infantum* antibody testing, using immunofluorescence assay (IFA) as the reference method.

| IFA                | trüRapid Leish |     | FASTest Leish |     | Leishmania Ab (Bionote) |     | Uranotest Leishmania 2.0 |     | Uranotest Leishmania 3.0 |     |
|--------------------|----------------|-----|---------------|-----|-------------------------|-----|--------------------------|-----|--------------------------|-----|
|                    | Pos            | Neg | Pos           | Neg | Pos                     | Neg | Pos                      | Neg | Pos                      | Neg |
| Positive (n = 45)  | 38             | 6   | 22            | 23  | 40                      | 5   | 40                       | 5   | 38                       | 7   |
| Negative (n = 115) | 4              | 111 | 0             | 115 | 2                       | 113 | 11                       | 104 | 6                        | 109 |
| Total              | 42             | 117 | 22            | 138 | 42                      | 118 | 51                       | 109 | 44                       | 116 |

Table 3. Combination patterns of *Leishmania* point-of-care test and immunofluorescence assay (IFA) results.

| Samples (n = 160) | IFA | trüRapid Leish | FASTest Leish | Leishmania Ab (Bionote) | Uranotest Leishmania 2.0 | Uranotest Leishmania 3.0 |
|-------------------|-----|----------------|---------------|-------------------------|--------------------------|--------------------------|
| 100               | –   | –              | –             | –                       | –                        | –                        |
| 7                 | –   | –              | –             | –                       | +                        | –                        |
| 3                 | –   | –              | –             | –                       | –                        | +                        |
| 2                 | –   | +              | –             | –                       | +                        | +                        |
| 1                 | –   | +              | –             | –                       | +                        | –                        |
| 1                 | –   | +              | –             | +                       | +                        | +                        |
| 1                 | –   | –              | –             | +                       | –                        | –                        |
| 21                | +   | +              | +             | +                       | +                        | +                        |
| 15                | +   | +              | –             | +                       | +                        | +                        |
| 4                 | +   | –              | –             | –                       | –                        | –                        |
| 2                 | +   | –              | –             | +                       | +                        | –                        |
| 1                 | +   | Invalid        | +             | +                       | +                        | +                        |
| 1                 | +   | +              | –             | +                       | –                        | –                        |
| 1                 | +   | +              | –             | –                       | +                        | +                        |