Prospective evaluation of LeptoTek Lateral-Flow and LeptoTek Dri-Dot in the serodiagnosis of human leptospirosis

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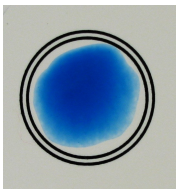
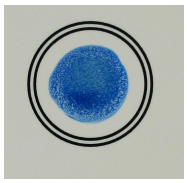
Background:
Laboratory testing for human leptospirosis in The Netherlands is performed at the Leptospirosis Reference Laboratory. Culture, IgM-ELISA and Microscopic Agglutination Test (MAT) are used as standard tests, which are laborious and time consuming. Therefore, we performed a prospective evaluation of two simple and rapid serological tests, the LeptoTek Lateral-Flow and the LeptoTek Dri-Dot to study its performance and diagnostic value.

2001-2004:
1790 samples from 1406 subjects prospective tested in
- in-house IgM-ELISA
- MAT
- Culture (when appropriate)
- LeptoTek Lateral-Flow
- LeptoTek Dri-Dot

Drid-Dot





Lateral Flow

- ❑ Leptospirosis case:
  MAT titre ≥1:160 and IgM-ELISA titre ≥ 1:80) and/or positive culture
- ❑ LeptoTek Lateral-Flow, positive when a clear band is observed
- ❑ LeptoTek Dri-Dot, positive when agglutination within 30 secs

Results
97 Leptospirosis cases
54 % of the cases had been infected in the Netherlands, the others probably in other European and Asian countries.

Lateral Flow	Days post onset		
	1-10	**11-30**	**>30**
Neg	11	2	2
Pos	41	52	35
Total	52	54	37
Sensitivity	79%	96%	95%
Specificity	1369/1477 = 93%		

Dri-Dot	Days post onset		
	1-10	**11-30**	**>30**
Neg	19	1	8
Pos	33	53	29
Total	52	54	37
Sensitivity	64%	98%	78%
Specificity	1391/1477 = 94%		

Sensitivity	Days post onset		
	1-10	**11-30**	**>30**
Lateral Flow	79%	96%	95%
Dri-Dot	64%	98%	78%
MAT	38%	85%	76%
ELISA	60%	87%	65%

Conclusion:
This prospective evaluation shows, compared to earlier studies, a higher sensitivity and specificity for the rapid serological tests. These rapid tests can be recommended as a simple, quick and affordable tool for human leptospirosis, also in laboratories that have ELISA, MAT and culture available. However, some experience and clear instructions are needed for the proper reading an interpretation of the test results.