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Evaluation of reagents for the serological diagnosis of leptospirosis

At the EpiNet I Workshop (Guam, December 2001), it was agreed that outlying laboratories (i.e. Level 1) of the Pacific Public Health Surveillance Network (PPHSN) should have access to rapid tests for the diagnosis of leptospirosis and that the available tests should be evaluated (recommendation 3 of EpiNet I). This assessment is a short version of the study on leptospirosis that was recommended at the EpiNet I Workshop.

The full report is available online on the PPHSN website:
http://www.spc.int/phs/PPHSN/Services/LabNet/kits-Lepto-eval-VE.pdf.

The following tests, which are available in the region, could be used for leptospirosis testing as follows:

- *Rapid single test for Level 1 laboratories*:
  Dip-S-Ticks IgM Leptospira, PanBio reference 5065M-02-10 or 5065M-01-50 (10 or 50 tests)
- *Confirmation test for Level 2 laboratories (Guam, Noumea, Papeete and Suva)*:
  Leptospirosis: ELISA IgM microwell kit, PanBio reference LPM-200 (96 tests)

At the current stage of implementation of the EpiNet I Workshop final technical recommendations, it was necessary for a Level 2 laboratory with enough experience in leptospirosis testing to use these reagents under real conditions for a limited period. In fact, without attempting a complete re-evaluation, it was important for a regional Level 2 laboratory to:

- master handling of these products so as to provide technical assistance, if necessary, to other laboratories in the network;
- verify the reported performances, in terms of sensitivity and specificity.

This work, which was limited in scope, was conducted by the New Caledonia Pasteur Institute (IPNC) in August 2002.

Conclusion

Several types of rapid single test reagents were proposed for screening for leptospirosis (see full report). Few of them combined the optimum characteristics of sensitivity and specificity.

The performances we measured for the PanBio Dip-S-Tick were close to those of other recent studies: it was found to have an excellent specificity (100%) but only a mediocre sensitivity (80%) in comparison with the micro-agglutination test. As an acceptable compromise, it is possible to use the Dip-S-Tick for screening, especially as there are no specific difficulties in conducting this test and it is easy to read. However, negative results in a suspicious clinical and biological context must be reconfirmed by another, more sensitive method, and the test should be repeated on a later sample.

The IgM Capture test sensitivity was evaluated at 90% against the micro-agglutination test. With its ease of use and its moderate sensitivity level, it can be used as a confirmation method.

However, it is still important to use the micro-agglutination test to study any epidemiologically or clinically suspect samples which test negative, as well as the positive ones, in order to be able to determine the involved serogroup. This information cannot be obtained by other serological techniques and is of significant epidemiological interest for the investigation into the mode of contamination, in order to undertake leptospirosis control at the community level. The micro-agglutination test also makes it possible to exclude leptospirosis in the event of reactivity limited to non-pathogenic serovars.

Our evaluation confirmed that the macro-agglutination test, the oldest screening technique, has performances which are inadequate for use as a reliable field test. For that reason, its use is inadvisable.

The two PanBio products evaluated can be recommended to Level 1 and Level 2 PPHSN laboratories for the serodiagnosis of leptospirosis. They are easy to procure in the Pacific. With a view to better describing the still poorly known regional epidemiology of this disease, it would be interesting to have all positive samples reconfirmed by the micro-agglutination technique.

Results of test kits for the diagnosis of leptospirosis evaluated in comparison with the New Caledonia Pasteur Institute reference technique micro-agglutination test (MAT)

Kit assessed			Reference method MAT	
			Positive	Negative
Dip-S-Tick Lepto (PanBio)	Positive	16	16	0
	Negative	38	4	34

True positives = 16
False negatives = 0
False positives = 4
True negatives = 34
Sensitivity = 80.0%
PPV = 100.0%
Specificity = 100.0%
NPV = 89.5%

Kit assessed			Reference method MAT	
			Positive	Negative
IgM Lepto (PanBio)	Positive	19	18	1
	Negative	35	2	33

True positives = 18

False negatives = 1
False positives = 2
True negatives = 33
Sensitivity = 90.0%
PPV = 94.7%
Specificity = 97.1%
NPV = 94.3%

Kit assessed			Reference method MAT	
			Positive	Negative
TR Agglutination	Positive	17	9	8
	Negative	37	11	26

True positives = 9
False negatives = 8
False positives = 11
True negatives = 26
Sensitivity = 45.0%
PPV = 52.9%
Specificity = 76.5%
NPV = 70.3%

MAT = Micro-agglutination test, positivity threshold: 1/200
PPV = positive predictive value
NPV = negative predictive value

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EpiNet I workshop recommendation 3:

3. PPHSN should organise a study to determine the epidemiology of leptospirosis in the Pacific islands, in both the vector and the human population. This study should include a field trial to evaluate rapid tests for the diagnosis of leptospirosis in Level 1 laboratories.