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Evaluation of reagents for the serological diagnosis of dengue

During the EpiNet II Workshop in Noumea (March 2002), it was agreed that laboratories of the Pacific Public Health Surveillance Network (PPHSN) who have accepted to play a regional role and provide services to neighbouring PICTs (Level 2) should all have the capacity to perform quality dengue testing and the most peripheral laboratories (Level 1) should all have access to rapid dengue diagnosis kits, and that the available tests should be evaluated (recommendation 3 of EpiNet II).

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

The following kits could be used for dengue testing as follows:

- *Rapid single test for Level 1 laboratories:*
  Dengue Duo IgM and IgG Rapid Cassette Test, currently in its pre-release phase, PanBio reference DEN-25S (25 tests);
- *Confirmation test for Level 2 laboratories (Guam, Noumea, Papeete and Suva):*
  ELISA (Enzyme linked Immuno Sorbent Assay) Dengue IgM Capture kit, PanBio reference DEN-200 (96 tests).

At the present stage of implementation of the EpiNet II Worshop final technical recommendations, it was necessary for a Level 2 laboratory with enough experience in dengue bioassays to use these reagents under real conditions for a limited period. Indeed, without attempting another complete assessment, it was important for a regional Level 2 laboratory to:

- master handling of these products, in order to provide technical support, if necessary, to the other laboratories of the network;
- verify the stated performance in terms of sensitivity and specificity.

This task, restricted in scope, was performed at the New Caledonia Pasteur Institute (IPNC) in August 2002.

Conclusion

Because of its high sensitivity, comparable to that of the reference method used in this study, the Dengue Rapid Cassette Duo reagent is suitable for initial dengue case screening. It can be implemented without special equipment and by staff who do not have any specialised laboratory technician training. It should be pointed out, however, that the result interpretation procedure must be strictly adhered to: 10 minutes must be allowed for colour to develop, and any trace of colour must be considered as a positive result. If this is done, all those patients who are not infected with dengue will be identified. Nevertheless, because of the time taken for seroconversion, a negative result in a clinico-biological context suggestive of dengue should be followed by the examination of a later sample. With this test, the lack of specificity of the positive results (approx. 45%) makes confirmation by another method absolutely necessary, and this could delay the release of this kit.

The Dengue IgM Capture microplate method offers the required characteristics. Its performances were identical to that of the reference technique, but it provided a higher power of discrimination between positive and negative samples. In addition, it is simple to perform and within the scope of any adequately equipped laboratory.

Both products can be recommended to Level 1 and 2 laboratories in the PPHSN for the serological diagnosis of dengue. (The Dengue Duo Rapid Cassette test is not yet available on the market at this stage).

Results of test kits for the serodiagnosis of dengue fever evaluated in comparison with the New Caledonia Pasteur Institute reference technique (IgM Dengue MAC ELISA test)

NB: The first part of the table (*) and the second part (**) differ from the positive and negative definitions.

Kit assessed			Reference method IgM Dengue MAC ELISA	
			Positive	Negative
Dengue Duo Rapid Cassette (PanBio) (*)	Positive (trace or +)	35	17	18
	Negative	15	0	15

True positives = 17
False negatives = 0
False positives = 18
True negatives = 15
Sensitivity = 100.0%
PPV = 48.6%
Specificity = 45.5%
NVP = 100.0%

Kit assessed			Reference method IgM Dengue MAC ELISA	
			Positive	Negative
Dengue Duo Rapid Cassette (PanBio) (**)	Positive (+)	17	9	8
	Negative or trace	33	8	25

True positives = 9
False negatives = 8
False positives = 8
True negatives = 25
Sensitivity = 52.9%
PPV = 52.9%
Specificity = 75.8%
NVP = 75.8%

Kit assessed			Reference method IgM Dengue MAC ELISA	
			Positive	Negative
Dengue IgM Capture (PanBio)	Positive	18	17	1
	Negative	32	0	32

True positives = 17
False negatives = 0
False positives = 1
True negatives = 32
Sensitivity = 100.0%
PPV = 94.4%
Specificity = 97.0%
NVP = 100.0%

MAC = M Antibody Capture
PPV = positive predictive value
NPV = negative predictive value

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EpiNet II Workshop recommendations 2 and 3:

2. National health authorities should ensure that dengue test strips are available in level 1 laboratories as needed.

3. WHO/SPC should make recommendations as to the most appropriate rapid tests to be adopted by level 1 labs.