PERFORMANCE EVALUATION REPORT ON

EV71 IgM Rapid Test (Colloid Gold)

1. GENERAL INTRODUCTION

Wantai's EV71 IgM Rapid Test (colloid gold) is a single use, rapid device intended for qualitative detection of IgM-class antibodies to human enterovirus-71 (EV71) in serum, plasma or whole blood samples. It is intended to be used in clinical laboratories for early diagnosis and management of patients related to infection with EV71.

Wantai has evaluated this new EV71 IgM Rapid Test (colloid gold) using a direct comparison with the PCR method. This study was performed in April of 2010 at the Capital Institute of Pediatrics, Beijing, CHINA.

2. OBJECTIVE

The aim of this study is to evaluate the technical performance of Wantai's EV71 IgM Rapid Test, to build confidence on this new rapid test.

3. METHODS

Use the EV71 IgM Rapid Test to test the patients' serum samples. The assay procedure is as per the instructions for use of the device. The reading of the results is manually. All these samples also were tested by PCR method which is as a confirmatory method to give the confirmed positive or negative results. The results from two methods will be compared to calculate the sensitivity and specificity of this rapid test.

3.1 TESTS USED FOR THE EVALUATION

Name	Specification	Lot Number	Expiry date
EV71 IgM Rapid Test (colloid gold)	6 tests/kit	20100401	31/10/2011

3.2 SAMPLES

All the samples tested were serum collected from the clinical patients at the age of 1 year old to 11 years old. Total 212 samples have to be tested.

4. RESULTS

In total 212 clinical serum samples were tested including 26 EV71 PCR positive samples, 186 non-EV71 hand, foot and mouth diseases samples. The test demonstrated sensitivity of 88.5% (23/26) and specificity of 95.2% (177/186).

Sample	Wantai EV71 IgM Rapid Test Positive	Wantai EV71 IgM Rapid Test Negative	Sensitivity	Specificity
EV71 PCR positive samples	23	3	88.5% (23/26)	—
Non-EV71 hand, foot and mouth diseases samples	9	177	—	95.2% (177/186)

5. CONCLUSION

This EV71 IgM Rapid Test presented a wonderful sensitivity and specificity during this performance evaluation, which indicates that it will be applicable for clinical laboratories for early diagnosis and management of patients related to infection with EV71.

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