



Dated : 24th November 2009

**EVALUATION REPORT**

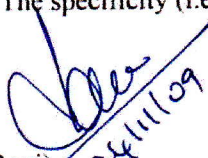
**Name of the test evaluated** : Real Time H1N1 Bigtec Micro PCR  
**Name of the manufacturer** : M/s Bigtec Pvt. Ltd.  
N0.100/1, 3<sup>rd</sup> Floor, Anchorage Building 1,  
Richmond Road, Bangalore 560025.  
**Batch / Lot Numbers** : 2009 Evaluation Batch  
**Configuration of the Panel** : A total 115 samples including 45 H1N1 positive samples,  
and 70 negative samples (all confirmed by WHO/CDC approved  
Real Time PCR)  
**Principle of the Test** : Micro Chip based Real Time PCR assay  
**Protocol** : The study design was prospective in nature. A total of 115 Throat and  
/ or nasal swabs were parallely collected for H1N1 testing at NIMHANS and Bigtec labs. The true identity  
of th samples was not known to the investigators at the time of sample collection and testing. The  
CDC/WHO approved real time PCR kit (ABI, USA) and the **ABI 7000/7500 Real Time PCR machine**  
**were used as the reference assay.** Amongst the 115 samples evaluated, 45 were confirmed by WHO/CDC  
approved Real Time PCR as H1N1 positive, and 70 were confirmed as H1N1 and Influenza A negative.

**RESULTS OBTAINED IN THE EVALUATION**

Confirmed H1N1 positive samples detected as positive in the Bigtec RT PCR assay : 44/45 (97.80%)  
Confirmed Negative samples detected as negative by Bigtec RT PCR assay: 70/70 (100%)

**Comments :**

1. This test takes totally 60 minutes to complete (including RNA extraction and RT-PCR run time). It is convenient and easy to use. One sample can be tested at a time without having to batch several samples
2. The Sensitivity (i.e Detection of true positive samples as positives)of this kit for detection of H1N1 samples is 97.8% (44/45)
3. The specificity (i.e Detection of true negative samples as negatives) of this assay is 100%

  
(Dr. V. Ravi) 24/11/09  
Professor & HOD and Officer-In-Charge,  
National Influenza Laboratory,  
Department of Neurovirology, NIMHANS