

Performance Study of the NADAL[®] Hb/Hp Complex Test (272031RU) with Clinical Specimens

Clinical Performance of the NADAL[®] Hb/Hp Complex Test (Hb)

The diagnostic performance of the Hb/Hp Complex Test was evaluated in randomized controlled clinical trials. They were performed in 3 major hospitals in China from Sep 28th, 2010 to Oct 18th, 2010. These clinical trials were aimed to evaluate the performance of Hb/Hp Complex Test by comparing with a commercially available predicate rapid test. Following is a summary of the results obtained from these clinical trials.

Clinical trial location:

- The First Affiliated Hospital of Medical College of Zhejiang University, Hangzhou, Zhejiang Province, China
- The Second Affiliated Hospital of Medical College of Zhejiang University, Hangzhou, Zhejiang Province, China
- The People's Hospital of Jiangxi Province, Nanchang, Jiangxi Province, China

Commercial rapid tests used for comparison

DIMA[®] FOB Test
DIMA[®] Hb-Hp Test

Methods

NADAL[®]Hb/Hp Complex Test was used to run the clinical specimens collected. The results were recorded and compared with the results obtained by predicate rapid test using the same clinical specimens.

Summary of Results

a) For Hb Parameter of NADAL[®] Hb/Hp Complex Test

The specimen correlation study was performed on 1374 feces specimens. 1374 feces specimens were tested by the other rapid test and the NADAL[®] Hb/Hp Complex Test. Specimens were rated either as positive (appearance of T-line) or negative (no T-line) at the respective reading time of the test.

The results are presented in the following table:

		Other rapid test (Hb)		
		+	-	Total
NADAL [®] Hb/Hp Complex Test (Hb parameter)	+	325	16	341
	-	9	1024	1028
	Total	334	1040	1374

Relative sensitivity: $325/(325+9)=97\%$

Relative specificity: $1024/(1024+16)=98\%$

Overall agreement: $(325+1024)/(325+1024+9+16)=98\%$

b) For Hb-Hp Parameter of NADAL® Hb/Hp Complex Test

The specimen correlation study was performed on 163 feces specimens. 163 feces specimens were tested by the other rapid test and the NADAL® Hb/Hp Complex Test. Specimens were rated either as positive (appearance of T-line) or negative (no T-line) at the respective reading time of the test.

The results are presented in the following table:

		Other rapid test (Hb-Hp)		
		+	-	Total
NADAL® Hb/Hp Complex Test (Hb-Hp parameter)	+	52	4	56
	-	3	104	107
	Total	55	108	163

Relative sensitivity: $52/(52+3)=95\%$

Relative specificity: $104/(104+4)=96\%$

Overall agreement: $(52+104)/(52+104+3+4)=96\%$

Conclusion

By the data obtained from these clinical investigations, we conclude that the NADAL® Hb/Hp Complex Test has relatively high sensitivity, specificity and accuracy as compared to another rapid test. It is a fast and convenient test method, which requires only room temperature storage conditions. It does not need any instruments to read the result. The background of the test is clean and the interpretation of test result is clear. The test has been determined to be effective and safe.