Performance Characteristic:

Diagnostic Specificity Report

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Product: One Step HCV Test

Manufacture: Core Technology Co., Ltd.

Drafted by: Yang Li

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Date: 2013.08.16

Approved by: Chen Lizhu

Signature: Chen Lizhu

Date: 2013.8.16

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Abstract

The diagnostic specificity of the Coretests® One Step HCV Test was evaluated using a total of 1740 HCV negative samples from the following population group: blood donors, pregnant women, inpatients, and patients with potentially interfering diseases. Test results were compared with that of a commercially available CE marked HCV EIA test. Data indicated that the diagnostic specificity of the Coretests® One Step HCV Test was similar and comparable to that of the CE marked HCV EIA test.

1. Objective

The objective of this study is to determine the diagnostic specificity of the Coretests® One Step HCV Test.

2. Reference

Please refer to 2009/886/EC for regulations regarding the consistency of in-vitro diagnostic reagents described in CTS.

3. Materials

3.1. Coretests® One Step HCV Test Strips
3.2. Ortho HCV 3.0 EIA (CE marked device)
3.3. Real-time PCR (COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, Roche Molecular Systems, Inc)
3.4. Serum or plasma samples from 200 HCV negative inpatients provided by Aeromedicine Institute of P.L.A. Hospital (Beijing 466 Military Hospital)
3.5. Serum or plasma samples from 200 HCV negative pregnant women provided by Aeromedicine Institute of P.L.A. Hospital (Beijing 466 Military Hospital). 10 of these pregnant women gave birth before.
3.6. Serum or plasma samples from 135 HCV negative donors with potentially interfering diseases provided by Beijing You An Hospital, Capital Medical University
3.7. Serum or plasma samples from 105 HCV negative donors with potentially interfering diseases provided by Xinjiang Uyghur Autonomous Region Centers for Disease Control and Prevention
3.8. Blood samples from 500 HCV negative blood donors provided by Beijing You An Hospital, Capital Medical University
3.9. Blood samples from 600 HCV negative blood donors provided by P.L.A. General Hospital

4. Experiment Design

4.1. HCV negative serum or plasma samples from 200 inpatients, 200 pregnant women, 240 patients infected by potentially interfering diseases (including HAV, HBV, HIV, EBV, RF, CMV, ASOT, CRF, Dengue, Rubella, HTLV and E.coli) and 1100 blood donors were collected.
4.2. These samples were tested with both the Coretests® One Step HCV Test and the Ortho HCV 3.0 EIA. The results from these two devices were compared side-by-side. Samples with inconsistent results were further analyzed using the Real-time PCR method (COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, Roche Molecular Systems, Inc).

5. Evaluation Criteria

Test results were recorded as positive or negative. The Coretests® One Step HCV Test should show negative result for at least 95% of these negative samples.

6. Results

6.1. See Table 1 below for the summary result for samples from HCV negative Inpatient.

Table 1: Test Result Summary for Samples from HCV Negative Inpatient

Total Number of HCV Negative Inpatient Samples	Results of Coretests® One Step HCV Test		Results of Ortho HCV 3.0 EIA	
	Negative	Positive	Negative	Positive
200	199	1	200	0

For the 200 samples from HCV negative inpatients, the Coretests® One Step HCV Test showed negative results for 199 of the samples, and the Ortho HCV 3.0 EIA test, which is a CE marked device showed negative results for all of the 200 samples. Sample #91was the only sample that showed positive result when tested with the Coretests® One Step HCV Test. This sample was further analyzed by PCR（COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, Roche Molecular Systems, Inc）and confirmed to be negative. As a result, the Coretests® One Step HCV Test achieved 99.5% (199/200) accuracy in this study.

6.2. See Table 2 below for the summary result for samples from HCV negative pregnant women.

Table 2: Test Result Summary for Samples from HCV Negative Pregnant Women

Total Number of HCV Negative Pregnant Women	Results of Coretests® One Step HCV Test		Results of Ortho HCV 3.0 EIA	
	Negative	Positive	Negative	Positive
200	199	1	199	1

When tested with the 200 samples from HCV negative pregnant women, both the Coretests® One Step HCV Test and the Ortho HCV 3.0 EIA test showed negative results for 199 of the samples. They showed inconsistent result for two of the 200 samples. One of them was sample #56, which was negative by Coretests® test, but positive by Ortho test. The other sample was #137, which was positive by Coretests® test, but negative by Ortho test. These two samples were further analyzed by PCR（COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, Roche Molecular Systems, Inc）and confirmed to be negative. As a result, the Coretests® One Step HCV Test achieved 99.5% (199/200) accuracy in this study.

6.3. See Table 3 below for the summary result for samples from HCV Negative Patients with potentially interfering diseases.

Table 3: Test Result Summary for Samples from HCV Negative Patients with Potentially Interfering Diseases

Potentially Interfering Diseases	Results of Coretests® One Step HCV Test		Results of CE Marked Ortho HCV 3.0 Test		Total
	Positive	Negative	Positive	Negative	
HAV	0	19	0	19	19
HBV	0	34	0	34	34
HIV	1	33	0	34	34
EBV	0	16	0	16	16
RF	0	16	0	16	16
CMV	1	15	0	16	16
ASOT	0	18	0	18	18
CRF	0	18	1	17	18
Dengue	0	15	0	15	15
Rubella	0	16	0	16	16
HTLV	0	20	0	20	20
E.Coli	0	18	0	18	18
Total	2	238	1	239	240

A total of 240 samples were collected from HCV negative donors with the following potentially interfering diseases: HAV, HBV, HIV, Dengue, EBV, CMV, HTLV, Rubella infection, E.coli infection, CRF, ASOT, and RF. At least 15 samples were collected for each type of disease. Both the Coretests® One Step HCV Test and the Ortho HCV 3.0 EIA test were tested with these samples. The Coretests® One Step HCV Test showed negative results for 238 of the samples, one false positive for HIV disease (sample # 37), and one false positive result for CMV (sample #65). The total accuracy rate was 99.17% (238/240).

6.4. See Table 4 below for the summary result for samples from HCV Negative Blood Donors.

Table 4: Test Result Summary for Samples from HCV Negative Blood Donors

Results of Coretests® One Step HCV Test		Results of Ortho HCV 3.0 EIA		Total
Negative	Positive	Negative	Positive	
1096	4	1097	3	1100

A total of 1100 samples were collected from blood donors. 85 of these samples were from periodic donors. 1096 out of the 1100 samples were tested negative by the Coretests® One Step HCV Test. 1097 out of the 1100 samples were tested negative by the Ortho HCV 3.0 EIA test. Therefore, the Coretests® One Step HCV Test had achieved 99.64% (1096/1100) accuracy rate in this study.

7. Conclusion

Table 5 below summaries the data from the four studies in section 6.0. A total of 1740 known HCV negative samples were used to evaluate the diagnostic specificity of the Coretests® One Step HCV Test. Test results were compared with that of the Ortho HCV 3.0 EIA, a CE marked test. Coretests® One Step HCV Test showed negative results for 1732 out of the 1740 samples, achieving an accuracy rate of 99.54% (1732/1740). This is comparable to the CE marked EIA test, which showed an overall accuracy rate of 99.71% (1735/1740). Overall, The Coretests® One Step HCV Test had demonstrated acceptable diagnostic specificity.

Table 5: Overall Summary for the Study of Diagnostic Specificity

Category	Results of Coretests® One Step HCV Test		Results of CE Marked EIA Test		%Total
	Negative	Positive	Negative	Positive	
Blood Donor	1096	4	1097	3	1100
Hospitalized Patient	199	1	200	0	200
Pregnant Woman	199	1	199	1	200
Potential Interfering Disease	238	2	239	1	240
Total	1732	8	1735	5	1740

8. Report

8.1 Raw data was filed to quality control department for archive.
8.2 Final original report was filed to quality control department for archive.

Performance Characteristic:

Diagnostic Sensitivity Report

Product: One Step HCV Test

Manufacture: Core Technology Co., Ltd.

Drafted by: Yang Li

Signature: Yang Li

Date: 2013.08.16

Approved by: Chen Lizhu

Signature: Chen Lizhu

Date: 2013.8.16

Table of Content

Abstract

The diagnostic sensitivity of the Coretests® One Step HCV Test was evaluated using a total of 30 seroconversion panels and 430 known HCV positive clinical samples. Test results were compared with that of a commercially available CE marked HCV EIA test. Data indicated that the diagnostic sensitivity of the Coretests® One Step HCV Test was similar and comparable to that of the CE marked HCV EIA test.

1. Objective

The objective of this study is to determine the diagnostic sensitivity of the Coretests® One Step HCV Test.

2. Reference

Please refer to 2009/886/EC for regulations regarding the consistency of in-vitro diagnostic reagents described in CTS.

3. Materials

3.1. 10 commercial chronic HCV seroconversion panels (from BBI and ZMC)
3.2. 20 chronic HCV seroconversion panels provided by Beijing You An Hospital
3.3. 430 known HCV positive serum or plasma samples
3.4. Coretests® One Step HCV Test Strips
3.5. Ortho HCV2.0/3.0 EIA (commercially available CE marked test)
3.6. Abbott HCV 2.0/4.0 EIA (commercially available CE marked test)

4. Experiment Design

Study #1: This study was carried out in the Aeromedicine Institute of P.L.A. Hospital. 10 commercial HCV seroconversion panels were tested with the Coretests® One Step HCV Test Strips. Test results were compared with data of the Ortho HCV 2.0/3.0 EIA test and the Abbott HCV2.0/4.0 EIA test, which was provided on the Product Specification Sheet of the seroconversion panels.

Study #2: This study was carried out in the Beijing You An Hospital. 20 HCV seroconversion panels were tested with the Coretests® One Step HCV Test Strips. Test results were compared with that from the Ortho HCV 3.0 EIA test.

Study #3: 210 serum or plasma samples from Xinjiang Uyghur Autonomous Region Centers for Disease Control and Prevention were tested with the Coretests® One Step HCV Test Strips. These samples were known to be HCV positive and 89 of the 210 samples had known genotypes. Test results were compared with that of the Ortho HCV 3.0 EIA test.

Study #4: 220 serum or plasma samples from Beijing You An Hospital were tested with the Coretests® One Step HCV Test Strips. These samples were known to be HCV positive and 103 of the 220 samples had known genotypes. Test results were compared with that of the Ortho HCV 3.0 EIA test.

5. Evaluation Criteria

5.1. For Study #1 and Study #2:

a. The first sample in the sequence of a seroconversion panel that shows positive result in the commercial CE marked HCV test will be used as a reference sample and this will be marked at “0”.

b. If the Coretests® One Step HCV Test shows its first positive result for the same sample, the relative sensitivity value will be "0". If the Coretests® One Step HCV Test shows its first positive result two samples ahead of the reference sample in the sequence, the relative sensitivity value will be "-2". If the Coretests® One Step HCV Test shows its first positive result one sample after the reference sample in the sequence, the relative sensitivity value will be "+1".

5.2. For Study #3 and Study #4, 430 positive samples were tested. The device should be able to show positive result for at least 95% of the samples.

6. Results

6.1. See Table 1 below for the result summary for the 10 commercial seroconversion panels.

Table 1: Study #1 Data: Result Summary for Seroconversion Panels (Commercial Source)

Panel Code	Detection Period Starts From First Day of Bleeding				
	Abbott HCV 2.0/4.0 EIA	Ortho HCV 2.0/3.0	Coretests® One Step HCV Test	Coretests® Diagnostic Sensitivity Relative to:	
				Abbott	Ortho
PHV911	13	13	13	0	0
PHV913	7	Not detected	7	0	-2
PHV919	32	28	32	0	+1
HCV6213	43	43	43	0	0
HCV6215	20	20	20	0	0
HCV6224	23	Not detected	23	0	-2
HCV6226	39	39	9	0	0
HCV6227	74	74	74	0	0
HCV6228	36	31	31	-1	0
HCV6241	61	61	61	0	0

In Panel #PHV913 and HCV#6224, the Coretests® One Step HCV Test was able to detect the HCV antibody two samples earlier than the Ortho HCV EIA. Therefore, the Diagnostic Sensitivity relative to Ortho HCV EIA was -2 for these two panels. In Panel #PHV919, the Ortho HCV EIA test detected the HCV antibody 1 sample earlier than the Coretests® One Step HCV Test. Therefore, the Diagnostic Sensitivity relative to Ortho HCV EIA was +1 for this panel. In Panel #HCV6228, the Coretests® One Step HCV Test detected the HCV antibody 1 sample earlier than the Abbot HCV 2.0/4.0 EIA. Therefore, the Diagnostic Sensitivity Relative to Abbot test was -1.

6.2. See Table 2 below for the result summary for the 20 public seroconversion panels.

Table 2: Study #2 Data: Result Summary for Seroconversion Panels (Public Source)

Panel Code	Detection Period Starts From First Day of Bleeding		
	Ortho HCV 3.0	Coretests® One Step HCV Test	Coretests® Diagnostic Sensitivity Relative to Ortho 3.0
HCV-973	10	10	0
HCV-976	10	10	0
HCV-982	41	41	0
HCV-983	20	20	0
HCV-986	41	41	0
HCV-989	6	3	-1
HCV-991	4	4	0
HCV-011	27	27	0
HCV-012	24	24	0
HCV-032	14	14	0
HCV-033	16	16	0
HCV-041	19	39	+1
HCV-042	27	27	0
HCV-043	29	29	0
HCV-072	11	11	0
HCV-074	14	14	0
HCV-081	15	15	0
HCV-102	4	4	0
HCV-103	9	9	0
HCV-111	7	7	0

In Panel # HCV-989 the Coretests® One Step HCV Test detected the HCV antibody 1 sample earlier than the Ortho HCV 3.0 test. Therefore, the Diagnostic Sensitivity Relative to Ortho 3.0 was -1 for this panel. In Panel # HCV-041 the Ortho HCV 3.0 detected the HCV antibody 1 sample earlier than the Coretests® One Step HCV Test. Therefore, the Diagnostic Sensitivity Relative to Ortho 3.0 was +1 for this panel.

6.3. See Table 3, Table 4, and Table 5 for the summary data for the HCV positive samples.

Table 3: Study #3: Coretests® One Step HCV Test Results Using HCV Positive Samples from Xinjiang Uyghur Autonomous Region Centers for Disease Control

Genotype		Results of Coretests® One Step HCV Test		Results of CE Marked Test		Total
		Positive	Negative	Positive	Negative	
1	1a	2	0	2	0	21
	1b	19	0	19	0	
2	2a	12	0	12	0	19
	2b	5	0	5	0	
	2a/2b	2	0	2	0	
3	3a	9	0	9	0	16
	3b	7	0	7	0	
4	4	4	0	4	0	11
	4a	3	0	3	0	
	4c/4d	4	0	4	0	
5a		4	0	4	0	4
6	6a	13	0	13	0	16
	6e	3	0	3	0	
1b/2a		2	0	2	0	2
Unknown Genotype		120	1	121	0	121
Total		209	1	210	0	210

Table 4: Study #4: Coretests® One Step HCV Test Results Using HCV Positive Samples from Beijing You An Hospital, Capital Medical University

Genotype		Results of Coretests® One Step HCV Test		Results of CE Marked Test		Total
		Positive	Negative	Positive	Negative	
1	1a	4	0	4	0	32
	1b	28	0	28	0	
2	2a	14	0	14	0	20
	2b	5	0	5	0	
	2a/2b	1	0	1	0	
3	3a	10	0	10	0	15
	3b	5	0	5	0	
4	4	4	0	4	0	11
	4a	5	0	5	0	
	4c/4d	2	0	2	0	

Genotype		Results of Coretests® One Step HCV Test		Results of CE Marked Test		Total
		Positive	Negative	Positive	Negative	
5a		5	0	5	0	5
6	6a	12	0	12	0	18
	6e	6	0	6	0	
1b/2a		2	0	2	0	2
Unknown Genotype		116	1	117	0	117
Total		219	1	220	0	220

Table 5: Overall Coretests® One Step HCV Test Results Using Positive HCV Samples

Genotype		Results of Coretests® One Step HCV Test		Results of CE Marked EIA Test		Total
		Positive	Negative	Positive	Negative	
1	1a	6	0	6	0	53
	1b	47	0	47	0	
2	2a	26	0	26	0	39
	2b	10	0	10	0	
	2a/2b	3	0	3	0	
3	3a	19	0	19	0	31
	3b	12	0	12	0	
4	4	8	0	8	0	22
	4a	8	0	8	0	
	4c/4d	6	0	6	0	
5a		9	0	9	0	9
6	6a	25	0	25	0	34
	6e	9	0	9	0	
1b/2a		4	0	4	0	4
Unknown Genotype		236	2	238	0	238
Total		428	2	430	0	430

As shown in Table 5, a total of 430 HCV positive serum or plasma samples containing genotypes 1 to 6 were tested with the Coretests® One Step HCV Test and the CE marked Ortho HCV 3.0 EIA test. Out of the 430 samples, 428 of them were tested positive by the Coretests® One Step HCV Test, and 430 were tested positive by the CE marked EIA test. All the samples with known genotype were tested positive by both tests. The two samples that were tested negative by the

Coretests® One Step HCV Test had unknown genotype and they were further confirmed by PCR method to be positive.

7. Conclusion

When tested with seroconversion panels, the Coretests® One Step HCV Test was able to detect HCV antibody and its results were comparable to that of the CE marked HCV EIA test(s). In 9 out of the 10 commercial seroconversion panels, the Coretests® One Step HCV Test detected the HCV antibody at the same time or earlier than the two CE marked tests. In 29 out of the 30 public seroconversion panels, the Coretests® One Step HCV Test detected the HCV antibody at the same time or earlier than the CE marked test(s).

When tested with HCV positive samples, 428 out of the 430 samples containing genotype 1 to 6 were tested positive by the Coretests® One Step HCV Test. Only two samples showed false negative results, and these two samples contained unknown genotype. Overall, the Coretests® One Step HCV test results showed 99.53% (428/430) agreement with that of the CE marked EIA test.

8. Report

8.1 Raw data was filed to quality control department for archive.
8.2 Final original report was filed to quality control department for archive.