Performance Characteristic:

Diagnostic Sensitivity Report

Product: One Step HIV 1+2 Test

Manufacture: Core Technology Co., Ltd.

Drafted by: Yang Li

Signature: Yang Li

Date: 2013.08.20

Digitally signed by Guțan Ghenadie
Date: 2022.10.31 09:13:58 EET
Reason: MoldSign Signature
Location: Moldova

Approved by: Chen Lizhu

Signature: Chen Lizhu

Date: 2013.08.20

Table of Content

Abstract

The diagnostic sensitivity of the Coretests® One Step HIV 1+2 Test was evaluated using a total of 30 seroconversion panels and 520 known HIV positive clinical samples. Test results were compared with that of a commercially available CE marked HIV test. Data indicated that the diagnostic sensitivity of the Coretests® One Step HIV 1+2 Test was similar and comparable to that of the CE marked HIV test.

1. Objective

The objective of this study is to determine the diagnostic sensitivity of the Coretests® One Step HIV 1+2 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 HIV seroconversion panels (from BBI and ZMC)
3.2. 20 HIV seroconversion panels provided by Beijing You An Hospital
3.3. 520 known HIV positive serum or plasma samples
3.4. Coretests® One Step HIV 1+2 Test Strips
3.5. Ortho HIV 1/2 ELISA Test (commercially available CE marked test)
3.6. Abbott HIV 1/2 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 (466 hospital). 10 commercial HIV seroconversion panels were tested with the Coretests® One Step HIV 1+2 Test Strips. Test results were compared with data of the Ortho HIV 1/2 test and the Abbott HIV 1/2 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 HIV seroconversion panels were tested with the Coretests® One Step HIV 1+2 Test Strips. Test results were compared with that from the Ortho HIV 1/2 test.

Study #3: 300 serum or plasma samples from Xinjiang Uyghur Autonomous Region Centers for Disease Control and Prevention were tested with the Coretests® One Step HIV 1+2 Test Strips. These samples were known to be HIV 1+2 positive and 45 of the 300 samples had known subtypes. Test results were compared with that of the Ortho HIV 1/2 test.

Study #4: 220 serum or plasma samples from Beijing You An Hospital were tested with the Coretests® One Step HIV 1+2 Test Strips. These samples were known to be HIV positive and 35 of the 220 samples had known HIV-1 subtypes. Test results were compared with that of the Ortho HIV 1/2 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 HIV test will be used as a reference sample and this will be marked at “0”.

b. If the Coretests® One Step HIV 1+2 Test shows its first positive result for the same sample, the relative sensitivity value will be "0". If the Coretests® One Step HIV 1+2 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 HIV 1+2 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, 520 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	Period of Detection from the First Bleed Day			
	Abbott HIV-1/2	Ortho HIV-1/2	*Coretests*® One Step HIV 1+2 Test	Core results value compared with Abbott /Ortho
PRB943	14	14	14	0/0
PRB950	28	28	28	0/0
PRB955	12	14	12	0/-1
HIV9014	10	10	10	0/0
HIV9015	35	35	35	0/0
HIV9018	33	33	33	0/0
HIV9019	8	8	8	0/0
HIV9022	32	32	32	0/0
HIV9026	Not detected	44	44	-1/0
HIV9089	24	20	20	-1/0

In Panel #PRB955, the Coretests® One Step HIV 1+2 Test was able to detect the HIV antibody one sample earlier than the Ortho HIV 1/2 test. Therefore, the Diagnostic Sensitivity relative to Ortho HIV 1/2 test was -1 for this panel. In Panel #HIV9026 and HIV9089, the Coretests® One Step HIV 1+2 Test was able to detect the HIV antibody one sample earlier than the Abbott HIV 1/2 test.Therefore, the Diagnostic Sensitivity relative to Abbott HIV 1/2 test was -1 for these two panels.

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	Period of Detection from the First Bleed Day		
	Ortho HIV 1/2	*Coretests*® One Step HIV 1+2 Test	Core results value compared with Ortho
HIV-986	14	14	0
HIV-989	24	24	0
HIV-994	17	17	0
HIV-995	23	23	0
HIV-102	15	15	0
HIV-017	26	26	0
HIV-018	32	32	0
HIV-023	14	18	+1
HIV-025	13	13	0
HIV-037	14	14	0
HIV-062	24	22	-1
HIV-083	17	17	0
HIV-084	10	10	0
HIV-085	17	17	0
HIV-092	18	18	0
HIV-096	22	22	0
HIV-108	28	28	0
HIV-116	13	13	0
HIV-117	27	27	0
HIV-122	21	21	0

In Panel # HIV-023, the Coretests® One Step HIV 1+2 Test was able to detect the HIV antibody 1 sample later than the Ortho HIV 1/2 test. Therefore, the Diagnostic Sensitivity Relative to Ortho was +1 for this panel. In Panel # HIV-062 the Coretests® One Step HIV 1+2 Test detected the HIV antibody 1 sample earlier than the Ortho HIV 1/2 Test. Therefore, the Diagnostic Sensitivity Relative to Ortho was -1 for this panel.

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

Table 3: Study #3: Coretests® One Step HIV 1+2 Test Results Using HIV Positive Samples from Xinjiang Uyghur Autonomous Region Centers for Disease Control

Genotype/subtype		Results of *Coretests*® One Step HIV 1+2 Test		Results of CE Marked Test		Subtotal
		Positive	Negative	Positive	Negative	
HIV-1	A	2	0	2	0	2
	B	7	0	7	0	7
	C	3	0	3	0	3

	D	2	0	2	0	2
	F	3	0	3	0	3
	G	3	0	3	0	3
	B'	6	0	6	0	6
	E	3	0	3	0	3
	AE	5	0	5	0	5
	AG	3	0	3	0	3
	BC	8	0	8	0	8
	Unknown subtype	195	0	195	0	195
HIV-2		59	1	60	0	60
Subtotal		299	1	300	0	300

Table 4: Study #4: Coretests® One Step HIV 1+2 Test Results Using HIV Positive Samples from Beijing You An Hospital, Capital Medical University

Genotype/subtype		Results of *Coretests*® One Step HIV 1+2 Test		Results of CE Marked Test		Subtotal
		Positive	Negative	Positive	Negative	
HIV-1	A	3	0	3	0	3
	B	5	0	5	0	5
	C	2	0	2	0	2
	D	2	0	2	0	2
	F	2	0	2	0	2
	G	1	0	1	0	1
	B'	6	0	6	0	6
	E	1	0	1	0	1
	AE	5	0	5	0	5
	AG	2	0	2	0	2
	BC	6	0	6	0	6
	Unknown subtype	126	1	127	0	127
HIV-2		58	0	58	0	58
Subtotal		219	1	220	0	220

Table 5: Overall Coretests® One Step HIV 1+2 Test Results Using Positive HIV 1+2 Samples

Genotype/subtype		Results of *Coretests*® One Step HIV 1+2 Test		Results of CE Marked Test		Subtotal
		Positive	Negative	Positive	Negative	
HIV-1	A	5	0	5	0	5

	B	12	0	12	0	12
	C	5	0	5	0	5
	D	4	0	4	0	4
	F	5	0	5	0	5
	G	4	0	4	0	4
	B'	12	0	12	0	12
	E	4	0	4	0	4
	AE	10	0	10	0	10
	AG	5	0	5	0	5
	BC	14	0	14	0	14
	Unknown subtype	321	1	322	0	322
HIV-2		117	1	117	1	118
Subtotal		518	2	519	1	520

As shown in Table 5, a total of 520 HIV positive serum or plasma samples containing 2 genotypes (HIV-1, HIV-2) and 11 HIV-1 subtypes were tested with the Coretests® One Step HIV 1+2 Test and the CE marked Ortho HIV 1/2 test. Out of the 520 samples, 518 of them were tested positive by the Coretests® One Step HIV 1+2 Test, and 519 were tested positive by the CE marked HIV test. All the samples with known HIV-1 subtypes were tested positive by both tests. In the two samples which were tested negative by the Coretests® One Step HIV 1+2 Test, one is HIV-1 but unknown subtype and another is HIV-2. The two samples were further confirmed by CLIA method to be positive.

7. Conclusion

When tested with seroconversion panels, the Coretests® One Step HIV 1+2 Test was able to detect HIV 1+2 antibody and its results were comparable to that of the CE marked HIV 1/2 test(s). In 8 out of the 10 commercial seroconversion panels, the Coretests® One Step HIV 1+2 Test detected the HIV 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 HIV 1+2 Test detected the HIV antibody at the same time or earlier than the CE marked test(s).

When tested with HIV positive samples, 518 out of the 520 samples containing 2 genotypes (HIV-1, HIV-2) and 11 HIV-1 subtypes were tested positive by the Coretests® One Step HIV 1+2 Test. Only 2 samples showed false negative results, and these 2 samples contained one unknown HIV-1 subtype and one HIV-2. Overall, the Coretests® One Step HIV 1+2 test results showed 99.62% (518/520) agreement with that of the CE marked 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.

Performance Characteristic:

Diagnostic Specificity Report

Product: One Step HIV 1+2 Test

Manufacture: Core Technology Co., Ltd.

Drafted by: Yang Li

Signature: Yang Li

Date: 2014.11.22

Approved by: Chen Lizhu

Signature: Chen Lizhu

Date: 2014.11.22

Table of Content

Abstract

The diagnostic specificity of the Coretests® One Step HIV 1+2 Test was evaluated using a total of 1710 HIV 1+2 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 HIV 1/2 test. Data indicated that the diagnostic specificity of the Coretests® One Step HIV 1+2 Test was similar and comparable to that of the CE marked HIV 1/2 test.

1. Objective

The objective of this study is to determine the diagnostic specificity of the Coretests® One Step HIV 1+2 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 HIV 1+2 Test Strips
3.2. Ortho HIV 1/2 ELISA Test (CE marked device)
3.3. CLIA (VITROS Immunodiagnostic Products Anti-HIV 1+2, ORTHO CLINICAL DIAGNOSTICS)
3.4. Serum or plasma samples from 205 HIV negative inpatients provided by Aeromedicine Institute of P.L.A. Hospital (Beijing 466 Military Hospital)
3.5. Serum or plasma samples from 205 HIV 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 101 HIV negative donors with potentially interfering diseases provided by Beijing You An Hospital, Capital Medical University
3.7. Serum or plasma samples from 99 HIV negative donors with potentially interfering diseases provided by Xinjiang Uyghur Autonomous Region Centers for Disease Control and Prevention
3.8. Blood samples from 500 HIV negative blood donors provided by Beijing You An Hospital, Capital Medical University
3.9. Blood samples from 600 HIV negative blood donors provided by P.L.A. General Hospital

4. Experiment Design

4.1. HIV negative samples from 205 inpatients, 205 pregnant women, 200 patients infected by potentially interfering diseases (including HAV, HBV, HCV, 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 HIV 1+2 Test and the Ortho HIV test. The results from these two devices were compared side-by-side. Samples with inconsistent results were further analyzed using the CLIA method (VITROS Immunodiagnostic Products Anti-HIV 1+2, ORTHO CLINICAL DIAGNOSTICS).

5. Evaluation Criteria

Test results were recorded as positive or negative. The Coretests® One Step HIV 1+2 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 HIV negative Inpatient.

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

Total Number of HIV Negative Inpatient Samples	Results of Coretests® One Step HIV 1+2 Test		Results of Ortho HIV 1/2	
	Negative	Positive	Negative	Positive
205	204	1	205	0

For the 205 samples from HIV negative inpatients, the Coretests® One Step HIV 1+2 Test showed negative results for 204 of the samples, and the Ortho HIV 1/2 test, which is a CE marked device showed negative results for all of the 200 samples. Sample #176 was the only sample that showed positive result when tested with the Coretests® One Step HIV 1+2 Test. This sample was further analyzed by CLIA and confirmed to be negative. As a result, the Coretests® One Step HIV 1+2 Test achieved 99.51% (204/205) accuracy in this study.

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

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

Total Number of HIV Negative Pregnant Women	Results of Coretests® One Step HIV 1+2 Test		Results of Ortho HIV 1/2	
	Negative	Positive	Negative	Positive
205	205	0	204	1

When tested with the 205 samples from HIV negative pregnant women, the Coretests® One Step HIV 1+2 Test showed negative results for 205 of the samples, and the Ortho HIV 1/2 test, which is a CE marked device showed negative results for 204 of the samples. As a result, the Coretests® One Step HIV 1+2 Test achieved 100% (205/205) accuracy in this study.

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

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

Interference Diseases	Results of *Coretests*® One Step HIV 1+2 Test		Results of CE Marked Ortho HIV 1/2 Test		Subtotal
	Positive	Negative	Positive	Negative	
HAV	0	16	0	16	16
HBV	0	30	0	30	30
HCV	0	26	0	26	26
EBV	0	12	1	11	12
RF	0	21	0	21	21
CMV	0	11	0	11	11
ASOT	0	15	0	15	15
CRF	0	11	0	11	11
Dengue	0	12	0	12	12
Rubella	1	12	0	13	13
HTLV	0	14	0	14	14
E.Coli	0	19	0	19	19
Subtotal	1	199	1	199	200

A total of 200 samples were collected from HIV negative donors with the following potentially interfering diseases: HAV, HBV, HCV, Dengue, EBV, CMV, HTLV, Rubella infection, E.coli infection, CRF, ASOT, and RF. At least 10 samples were collected for each type of disease. Both the Coretests® One Step HIV 1+2 Test and the Ortho HIV 1/2 test were tested with these samples. The Coretests® One Step HIV 1+2 Test showed negative results for 199 of the samples, one false positive for Rubella disease (sample # 70). The total accuracy rate was 99.5% (199/200).

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

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

Results of Coretests® One Step HIV 1+2 Test		Results of Ortho HIV /2		Total
Negative	Positive	Negative	Positive	
1097	3	1098	2	1100

A total of 1100 samples were collected from blood donors. 89 of these samples were from periodic donors. 1097 out of the 1100 samples were tested negative by the Coretests® One Step HIV 1+2 Test. 1098 out of the 1100 samples were tested negative by the Ortho HIV 1/2 test. Therefore, the Coretests® One Step HIV 1+2 Test had achieved 99.73% accuracy rate in this study.

7. Conclusion

Table 5 below summaries the data from the four studies in section 6.0. A total of 1710 known HIV 1+2 negative serum or plasma samples were used to evaluate the diagnostic specificity of the Coretests® One Step HIV 1+2 Test. Test results were compared with that of the Ortho HIV 1+2, a CE marked test. Coretests® One Step HIV 1+2 Test showed negative results for 1705 out of the 1710 samples, achieving an accuracy rate of 99.71%(1705/1710). This is comparable to the CE marked EIA test, which showed an overall accuracy rate of 99.77% (1706/1710). Overall, The Coretests® One Step HIV 1+2 Test had demonstrated acceptable diagnostic specificity.

Table 5: Overall Summary for the Study of Diagnostic Specificity

Category	Results of *Coretests*® One Step HIV 1+2 Test		Results of CE Marked Test		Subtotal
	Negative	Positive	Negative	Positive	
Blood Donors	1097	3	1098	2	1100
inpatients	204	1	205	0	205
Pregnant Women	205	0	204	1	205
potentially interfering diseases	199	1	199	1	200
Subtotal	1705	5	1706	4	1710

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.