Clinical Performance Study Report – CPSR

STANDARD Q HIV/Syphilis Combo Test

Comparison capillary blood vs venous blood

Sponsor:
SD Biosensor
C-4th & 5th, 16, Deogyeng-daero
1556beon-gil
Yeongtong-gu, Suwon-si
Gyeonggi-do, 16690
Republic of Korea.

SD BIOSENSOR

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1 Purpose of the Study

The objective of this evaluation was to establish the performance of the STANDARD Q HIV/Syphilis Combo Test and, to provide data to demonstrate the product is safe and effective for its intended use.

The performance for detecting HIV antibody was evaluated in accordance with the Common Technical Specifications as described in Decision 2002/364/EC and amendments. The performance for detecting *Treponema pallidum* (Tp) antibody was evaluated in accordance with the draft CTS proposal to include the detection of Chagas and Syphilis under the IVD Regulation.

The data obtained will be used in the application for CE certification.

2 Sponsor – investigator – Performance Evaluation Manager

2.1 Sponsor:

SD Biosensor
C-4th & 5th, 16, Deogyeng-daero
1556beon-gil
Yeongtong-gu, Suwon-si
Gyeonggi-do, 16690
Republic of Korea

2.2 Investigation:

Site:

Université Evangélique en Afrique
Laboratoire de Recherche Biomédicale et de Santé Publique.
Quartier Panzi, Commune Ibanda,
B.P: 465 Cyangugu / Rwanda
3323 Bukavu, Sud-Kivu / RD Congo
Bukavu

Principal Investigator:

Prof. Gustave Nachigera Mushagalusa
e-mail: nachigera@yahoo.fr
Tel: +243 993084623

2.3 Study management:

Qarad bvba
Cipalstraat 3
B-2440 Geel
Belgium
Tel. : +32 14 57 05 44

Clinical Performance Study (CPS) Coordinator:

Agnes Goris
Director Device Compliance and Authorized Representative Operations
agnes.goris@qarad.com

3 Scope

3.1 Objectives

The objective of this evaluation was to demonstrate the equivalence of capillary (fingerprick) whole blood and venous whole blood on the STANDARD Q HIV/Syphilis Combo Test.

Samples required:

Paired capillary (fingerprick) and venous whole blood samples taken from the same individuals:

- 25 HIV 1/2 Ab and Tp Ab negative blood donors
- 25 HIV 1/2 Ab positive subjects
- 25 Tp Ab positive subjects

4 Clinical Performance Study Plan - CPSP

The Performance study was conducted as described in the CPSP nr. BSS-UEA 17-035.

5 Timelines:

Study start date: February 2018

Study end date: May 2018

6 Description Device

6.1 Identification

STANDARD Q HIV/Syphilis Combo Test, REF: QHSC01B
9 kits of batch QHI2017003-1, expiry date: 27/12/2019

6.2 Reference test

Determine™ HIV-1/2 REF. 7D2346/2347 (Alere)
Syphilis Quick Test REF. code 353 (Cypress Diagnostics)

7 Study population

7.1 25 HIV Ab and Tp Ab negative blood donors

- Blood donors screened with the laboratory's routine tests: Determine™ HIV-1/2; REF. 7D2346/2347 (Alere) and Syphilis Quick Test; REF. Code 353 (Cypress Diagnostics).
  Blood donors found negative with both routine tests were included in the study.
- From each selected donor, the two sample types were obtained as shown in the sample collection & testing flow in point 7.4.
- Samples were tested as described in section 7.5.

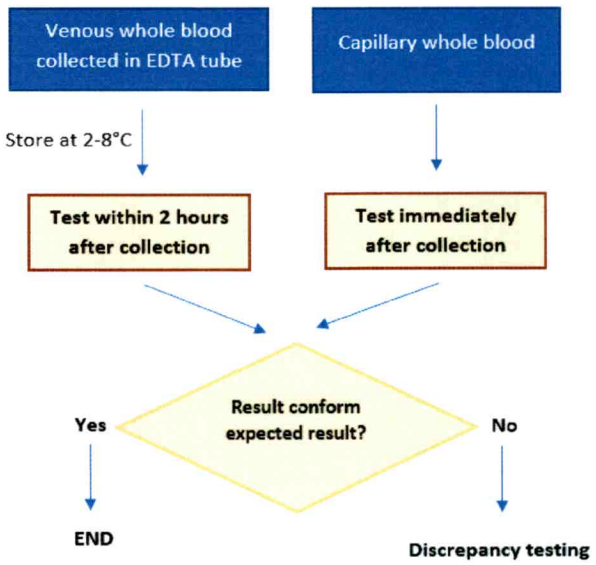
7.2 25 HIV Ab positive patients

- Blood donors found positive for HIV Ab or patients visiting the reference center (Panzi hospital) for follow-up by CD4 count on their HIV therapy were included and tested on the two sample types
- From each patient, the two sample types were obtained as shown in the sample collection & testing flow in point 7.4.
- Samples were tested as described in section 7.5.

7.3 25 Tp Ab positive samples

- Blood donors found positive for Tp Ab or patients diagnosed with Syphilis were included and tested on the two sample types.
- From each patient, the two sample types were obtained as shown in the sample collection & testing flow in point 7.4.
- Samples were tested as described in section 7.5
- Three samples were also positive for HIV on the STANDARD Q HIV/Syphilis Combo Test, the HIV positive result was confirmed with the reference test Determine™ HIV 1/2 (Alere). As a result, the sample originated from a dual infection (Syphilis and HIV) and was integrated in the sample group 7.2 as well.

7.4 Sample collection flow



7.5 Test procedure

All samples were tested with STANDARD Q HIV/Syphilis Combo Test according to the 'Test Procedure' described in the Instructions for Use supplied with the respective reagents.

The sample number was put on the devices and on the device interpretation form (DIF).

For the purpose of collecting raw data, the devices were placed on the device picture form (DPF), filled with the required information.

The results were interpreted by two independent readers. The test interpretation results were recorded in the device interpretation forms (DIF).

After test interpretation by the readers, a picture was taken of the DPF filled with the developed devices within the time period that test interpretation can be done (between 15 and 20 minutes after sample addition). These pictures are considered the raw data for this study.

8 Performance Evaluation Protocol Amendments and Deviations

Deviation:

Four negative samples, recorded as MK03, BM013, CZ020 and IB027 on the SRF, were excluded and replaced by 4 new negative samples due to an identification error:

- MK03 and BM013: on two devices the same sample ID 'MK03' was recorded when testing capillary whole blood. There was no device on which sample ID 'BM013' was recorded. Since it could not be verified which of both devices corresponded to the correct sample ID, traceability is missing and both samples were excluded from the study.
- CZ 020 and IB 027: for both samples, the sample ID recorded on the SRF (CZ 020 and IB 027) and on the device (MZ 820 and IM27) was not identical. It was doubtful if the correct samples were tested, therefore both samples were excluded from the study.

9 Results

9.1 25 HIV Ab and Tp Ab negative blood donors

Table A below shows the results obtained on the 2 sample types of 25 negative subjects, run on the STANDARD Q HIV/Syphilis Combo Test. Each test was interpreted by two technicians, the results of both readers were identical in all cases.

Table A: Results on 2 sample types of 25 HIV Ab and Tp Ab negative persons

Sample ID	Venous whole blood	Capillary whole blood
SN 02	NEG	NEG
CM 04	NEG	NEG
NM 05	NEG	NEG
AM 06	NEG	NEG
CK 07	NEG	NEG
SZ 08	NEG	NEG
FK 09	NEG	NEG
SN 010	NEG	NEG
RM 011	NEG	NEG
MB 014	NEG	NEG
VP 015	NEG	NEG
DC 017	NEG	NEG
BM 019	NEG	NEG
SB 021	NEG	NEG
ZE 022	NEG	NEG
AB 023	NEG	NEG
BM 024	NEG	NEG
CZ 025	NEG	NEG
LM 026	NEG	NEG
BC 028	NEG	NEG
IB 012	NEG	NEG
AB 076	NEG	NEG
CM 077	NEG	NEG
NM 078	NEG	NEG
BM 079	NEG	NEG

9.2 28 HIV positive subjects

Table B below shows the results obtained on the 2 sample types of 28 HIV positive patients, run on the STANDARD Q HIV/Syphilis Combo Test. Among them, 3 samples were also positive for Syphilis. Each test was interpreted by two technicians, the results of both readers were identical in all cases.

Table B: Results on 2 sample types of 28 anti-HIV positive persons

Sample ID	Venous whole blood	Capillary whole blood
MK 01	HIV-1	HIV-1
VN 016	HIV-1	HIV-1
LN 018	HIV-1	HIV-1
FM 039	HIV-1	HIV-1
RM 040	HIV-1	HIV-1
MS 041	HIV-1	HIV-1
NM 042	HIV-1	HIV-1
CM 043	HIV-1	HIV-1
BK 044	HIV-1	HIV-1
EK 045	HIV-1	HIV-1
NK 046	HIV-1	HIV-1
DB 047	HIV-1	HIV-1
TM 048	HIV-1	HIV-1
DS 049	HIV-1	HIV-1
FS 050	HIV-1	HIV-1
JN 051	HIV-1	HIV-1
GN 052	HIV-1	HIV-1
MM 053	HIV-1	HIV-1
TB 054	HIV-1	HIV-1
BF 055	HIV-1	HIV-1
SA 056	HIV-1	HIV-1
WB 057	HIV-1	HIV-1
DM 058	HIV-1	HIV-1
ZC 059	HIV-1	HIV-1
FM 060	HIV-1	HIV-1
SM 073(1)	HIV1/HIV2/TP (2)	HIV1/HIV2/TP (2)
BB 061(1)	HIV1/TP	HIV1/TP
BN 074(1)	HIV1/TP	HIV1/TP

Note (1): samples originating from a dual infection (Syphilis and HIV). The samples were also integrated in the sample group 'Syphilis positive samples'.

Note (2): The intensity of the HIV-1 line was higher than the HIV-2 line, according to the instructions for use of the assay, this should be interpreted as HIV-1.

9.3 25 Tp positive subjects

Table C below shows the results obtained on the 2 sample types of 25 Syphilis positive patients, run on the STANDARD Q HIV/Syphilis Combo Test. Among them, 3 samples were also positive for HIV. Each test was interpreted by two technicians, the results of both readers were identical in all cases.

Table C: Results on 2 sample types of 25 anti-Tp positive persons

Sample ID	Venous whole blood	Capillary whole blood
KZ 033	TP	TP
SM 073(1)	HIV1/HIV2/TP (2)	HIV1/HIV2/TP (2)
BB 061(1)	HIV1/TP	HIV1/TP
BN 074(1)	HIV1/TP	HIV1/TP
MK 029	TP	TP
MC 030	TP	TP
CN 031	TP	TP
BM 032	TP	TP
CM 034	TP	TP
MF 035	TP	TP
DM 036	TP	TP
MK 037	TP	TP
SA 038	TP	TP
CB 063	TP	TP
LN 064	TP	TP
AC 062	TP	TP
BF 065	TP	TP
AY 066	TP	TP
RN 067	TP	TP
ZW 068	TP	TP
BV 069	TP	TP
SB 070	TP	TP
SW 071	TP	TP
MF 072	TP	TP
CC 075	TP	TP

Note (1): samples originating from a dual infection (Syphilis and HIV). The samples were also integrated in the sample group 'HIV positive samples'.

Note (2): The intensity of the HIV-1 line was higher than the HIV-2 line, according to the instructions for use of the assay, this should be interpreted as HIV-1.

10 Conclusion

The evaluation demonstrated the equivalence of capillary (fingerprick) whole blood and venous whole blood on the STANDARD Q HIV/Syphilis Combo Test.

For all samples groups, anti-HIV/anti-Tp negative and positive samples, the same results were obtained on venous whole blood and whole blood obtained by fingerprick.

11 Ethical Principles

Participants all have signed the informed consent.

12 Unused devices

After finalization of testing, the remaining devices have been destroyed according to local rules.

13 Approval

UEA:
Principal Investigator
Prof. Gustave Nachigera Mushagalusa

Date: June 16, 2018

UNIVERSITE EVANGELIQUE EN AFRIQUE RECTORAT

QARAD:
Mrs. Agnes Goris
Director Device Compliance and Authorized Representative Operations

Date: JUNE 5, 2018

qarad
Qarad BVBA
Cipalstraat 3
B-2440 Geel
Belgium