SUMMARY OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

Device Generic Name: Rapid HIV-1 Antibody Test

Device Trade Name: Uni-Gold™ Recombigen® HIV

Applicant: Trinity Biotech (USA)
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Premarket approval number: BP030025

Date of notice of approval to the applicant; Dec 2003

2 NAME AND INTENDED USE

Uni-Gold™ Recombigen® HIV is a single use rapid test, for the detection of antibodies to HIV-1 in plasma, serum and whole blood (venipuncture). Uni-Gold™ Recombigen® HIV is intended for use in point of care settings as an aid in diagnosis of infection with HIV-1.

This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

3 DEVICE DESCRIPTION

Uni-Gold™ Recombigen® HIV was designed as a rapid immunoassay based on the immunochromatographic sandwich principle and is intended to detect antibodies to HIV-1 in human serum, plasma and whole blood (venipuncture).

Uni-Gold™ Recombigen® HIV test employs genetically engineered recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1. The recombinant proteins are immobilised at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

If antibodies to HIV-1 are present in the sample, they combine with a HIV-1 antigen/colloidal gold reagent and this complex subsequently binds to the immobilized

antigens in the test region of the device forming a visible pink / red band. The control line should always appear as a visible pink / red band in the control region of the device to indicate that the test device is functioning correctly. A positive result is visualized by a pink/red band in the test region of the device. A negative reaction occurs in the absence of detectable levels of human immunoglobulin antibodies to HIV-1 in the specimen; consequently no visually detectable band develops in the test region of the device.

4 RESTRICTIONS

? The sale of Uni-Gold™ Recombigen® HIV is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.
? Uni-Gold™ Recombigen® HIV is approved for use only by an agent of a clinical laboratory.
? The test subjects must receive the "Subject Information Leaflet" prior to specimen collection, and appropriate information when test results are provided.
? Uni-Gold™ Recombigen® HIV is not approved for use to screen donors of blood, plasma, cells or tissues.

5 WARNINGS

1. **Uni-Gold™ Recombigen® HIV is intended for *in vitro* diagnostic use.**

2. **Read the package insert completely before use. It is very important that the correct procedure is followed. Failure to add the patient sample may lead to a false negative result, (i.e. a missed positive).**

3. **The FDA has approved this kit for use with serum, plasma and whole blood (venipuncture) specimens. Use of the kit with specimens other than those specifically approved for use with this device may result in inaccurate test results.**

4. **Uni-Gold™ Recombigen® HIV is for diagnostic use only and not to be used for screening donors of blood, plasma, cells or tissues.**

5. **Perform the test at ambient temperature (15-27°C).**

6 LIMITATIONS OF THE TEST

1. Uni-Gold™ Recombigen® HIV procedure and interpretation of results must be followed closely as described in the package insert when testing for the presence of HIV-1 antibodies in serum, plasma or whole blood (venipuncture).

2. Uni-Gold™ Recombigen® HIV is designed to detect antibodies to HIV-1 in undiluted human serum, plasma and whole blood collected or whole blood (venipuncture). Other body fluids may not give accurate results and must not be used.

3. Immunosuppressed or immunocompromised individuals infected with HIV-1 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results in this incidence and would not be a reliable test method for such patients.

4. The intensity of a line at the "test" region does not necessarily correlate to the titre of antibody in the specimen.

5. A Reactive result by Uni-Gold™ Recombigen® HIV should be interpreted as preliminary positive for HIV-1 antibodies.

6. A Reactive result by Uni-Gold™ Recombigen® HIV suggests the presence of anti-HIV-1 antibodies in the specimen. Uni-Gold™ Recombigen® HIV is intended as an aid in the diagnosis of infection with HIV-1. AIDS and AIDS-related conditions are clinical symptoms and their diagnosis can only be established clinically.

7. A Non-Reactive result with Uni-Gold™ Recombigen® HIV does not exclude the possibility of infection with HIV. A false negative result may occur in the following circumstances:
   - Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels.
   - The test procedure has not been correctly followed.
   - Infection with a variant of the virus that is less detectable by Uni-Gold™ Recombigen® HIV assay configuration.
   - Antibodies to variant strain of HIV-1 in the patient that do not react with specific antigens utilized in the assay configuration.
   - Adverse specimen handling conditions.
   - Failure to add sample.

Reading test results earlier or later than 10 minutes may give erroneous results

7 ALTERNATE PRACTICES AND PROCEDURES

HIV-1 infection can be detected by a variety of tests. Virus can be directly detected by assays for the various virus components or more commonly HIV-1 infection is diagnosed by tests that assess whether an individual's immune system has produced an HIV-1-specific immune response. Standard testing algorithms are employed to determine HIV-1 status. Samples are screened with an EIA and positives are confirmed with Western Blot or IFA.

Uni-Gold™ Recombigen® HIV detects antibodies to HIV-1 using colloidal gold to give a visible result. Uni-Gold™ Recombigen® HIV can be carried out in the absence of instrumentation, standard laboratory equipment, even electricity. The excellent sensitivity

and specificity of Uni-Gold™ Recombigen® HIV means that it can be used test in a multi-test algorithm.

8 POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

No known adverse effects have been found with the Uni-Gold™ Recombigen® HIV in any study performed to date.

9 SUMMARY OF NON-CLINICAL STUDIES

The following is a brief summation of the non-clinical laboratory studies that have been conducted to assess the performance of Uni-Gold™ Recombigen® HIV.

9.1 HIV Positive Samples from Worldwide Sources

The objective of this study was to determine the ability of the Uni-Gold™ Recombigen® HIV to detect HIV-1 positive samples using a large number of sera from different geographic locations representing known variants of HIV-1.

Two hundred (200) world-wide HIV – 1 positive samples were tested by Uni-Gold™ Recombigen® HIV. These included samples from the different geographic locations where non-B variants predominate and 10 group O samples.

In all geographic samples except those from Uganda the Uni-Gold™ Recombigen® HIV rapid test performed optimally giving 100% sensitivity.

9.2 Evaluation of HIV-1 seroconversion.

Eleven HIV-1 seroconversion panels were tested in comparison to FDA licensed EIA and Western blot tests. Each panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of 79 specimens. The results of this study are shown in Table 2. The Uni-Gold™ Recombigen® HIV test detected HIV-1 antibodies at the same bleed or at an earlier bleed than the most sensitive of the licensed EIA's in 8 out of 11 panels. In the remaining 3 panels the Uni-Gold™ Recombigen® HIV test detected HIV-1 antibodies one bleed later that the most sensitive EIA.

Table 1: Summary of Seroconversion panel results as presented in comparison to FDA licensed EIAs.

Panel	Relative Day of Bleed	Uni-Gold™ Recombigen® HIV	EIA 1	EIA 2	EIA 3	EIA 4	EIA 5	Western Blot
D	0	NR	NR	NR	NR	NR	NR	NEG
	21	NR	NR	NR	NR	NR	NR	NEG
	49	NR	NR	NR	NR	NR	NR	NEG
	92	R	RR	RR	RR	RR	RR	POS
	99	R	RR	RR	RR	RR	RR	POS
P	0	NR	NR	NR	NR	NR	NR	NEG
	4	NR	NR	NR	NR	NR	NR	NEG
	9	NR	NR	NR	NR	NR	NR	NEG
	15	NR	NR	NR	NR	NR	NR	NEG
	30	R	RR	RR	RR	RR	RR	NEG
	35	R	RR	RR	RR	RR	RR	POS
X	0	NR	NR	NR	NR	NR	NR	NEG
	2	NR	NR	NR	NR	NR	NR	NEG
	8	NR	NR	NR	NR	NR	NR	NEG
	10	NR	NR	NR	NR	NR	NR	NEG
	26	NR	NR	NR	NR	NR	NR	NEG
	33	R	NR	RR	NR	NR	NR	NEG
	35	R	RR	RR	NR	NR	NR	NEG
	40	R	RR	RR	NR	NR	RR	POS
AD	0	NR	NR	NR	NR	NR	NR	NEG
	4	NR	NR	NR	NR	NR	NR	NEG
	14	NR	NR	NR	NR	NR	NR	NEG
	18	NR	NR	NR	NR	NR	NR	NEG
	21	NR	NR	NR	NR	NR	NR	NEG
	25	R	NR	RR	NR	NR	NR	IND
	28	R	NR	RR	NR	RR	RR	POS
AF	0	NR	NR	NR	NR	NR	NR	NEG
	2	NR	NR	NR	NR	NR	NR	NEG
	7	NR	NR	NR	NR	NR	NR	NEG
	9	NR	NR	NR	NR	NR	NR	NEG
	15	NR	NR	NR	NR	NR	NR	NEG
	28	R	NR	RR	NR	NR	NR	NEG
	33	R	RR	RR	NR	RR	RR	POS
	35	R	RR	RR	RR	RR	RR	POS
	42	R	RR	RR	RR	RR	RR	POS
AJ	0	NR	NR	NR	NR	NR	NR	NEG
	10	NR	NR	NR	NR	NR	NR	NEG
	16	NR	NR	NR	NR	NR	NR	NEG
	21	NR	NR	NR	NR	NR	NR	NEG
	24	NR	NR	NR	NR	NR	NR	NEG
	28	NR	NR	NR	NR	NR	NR	NEG
	43	R	RR	RR	RR	NR	RR	POS
AK	0	NR	NR	NR	NR	NR	NR	NEG
	5	NR	NR	NR	NR	NR	NR	NEG
	7	NR	NR	NR	NR	NR	NR	NEG
	12	NR	NR	NR	NR	NR	NR	NEG
	14	NR	NR	NR	NR	NR	NR	NEG
	19	NR	NR	RR	NR	NR	NR	NEG
	21	R	RR	RR	NR	NR	RR	IND
AL	0	NR	NR	NR	NR	NR	NR	NEG
	7	NR	NR	NR	NR	NR	NR	NEG
	9	NR	NR	NR	NR	NR	NR	NEG
	14	NR	NR	NR	NR	NR	NR	NEG
	16	NR	NR	NR	NR	NR	NR	NEG
	21	NR	NR	RR	NR	NR	NR	NEG

Table 1: Continued; Summary of Seroconversion panel results as presented in comparison to FDA licensed EIAs.

Panel	Relative Day of Bleed	UniGold™ Recombigen® HIV result	EIA 1	EIA 2	EIA 3	EIA 4	EIA 5	Western Blot
AN (e)	0	NR	NR	NR	NR	NR	NR	NEG
	2	NR	NR	NR	NR	NR	NR	NEG
	7	NR	NR	NR	NR	NR	NR	NEG
	9	NR	NR	NR	NR	NR	NR	NEG
	14	NR	NR	NR	NR	NR	NR	NEG
	16	NR	NR	NR	NR	NR	NR	NEG
	21	NR	NR	NR	NR	NR	NR	NEG
	23	NR	NR	NR	NR	NR	NR	NEG
	103	R	RR	RR	RR	RR	RR	POS
AP	0	NR	NR	NR	NR	NR	NR	NEG
	7	NR	NR	NR	NR	NR	NR	NEG
	11	R	NR	RR	NR	NR	NR	NEG
	15	R	NR	RR	NR	NR	NR	IND
	18	R	RR	RR	NR	NR	RR	IND
	22	R	RR	RR	NR	RR	RR	IND
	25	R	RR	RR	RR	RR	RR	IND
	29	R	RR	RR	NR	RR	RR	IND
AS	0	NR	NR	NR	NR	NR	NR	NEG
	5	NR	NR	NR	NR	NR	NR	NEG
	7	NR	NR	NR	NR	NR	NR	NEG
	12	NR	NR	NR	NR	NR	NR	NEG
	14	NR	NR	RR	NR	NR	NR	NEG
	19	R	NR	RR	NR	NR	NR	NEG
	21	R	RR	RR	NR	NR	NR	IND

Table Key; R= Reactive, NR = Not Reactive, POS = Positive, NEG = Negative, IND = Indeterminate. EIA = FDA licensed EIA

9.3 Evaluation of Low-Titre HIV-1 Antibody panels

Two commercially available low titre HIV 1 panels and one in-house produced low titre panel were tested by Uni-Gold™ Recombigen® HIV in comparison with FDA licensed EIA tests. In this study Uni-Gold™ Recombigen® HIV was shown to have comparable sensitivity to FDA licensed EIAs. Results are presented in Tables 2, 3 and 5.

Table 2: Result Summary of First Low Titre Panel: PRB 107

Panel Member PRB 107	UniGold™ Recombigen® HIV	EIA 1	EIA 2	EIA 3	EIA 4	EIA 5	Western Blot
01	R	NR	RR	RR	NR	NR	NEG
02	R	NR	RR	RR	RR	NR	IND
03	R	NR	RR	NR	NR	NR	NEG
04*	R	RR	RR	RR	RR	NR	NEG
05	NR	NR	NR	NR	NR	NR	NEG
06	R	RR	RR	RR	RR	NR	NEG
07	NR	NR	RR	RR	NR	NR	NEG
08	R	NR	RR	NR	RR	NR	NEG
09	NR	NR	RR	NR	NR	NR	NEG
10	R	RR	RR	RR	RR	RR	NEG
11	R	RR	RR	NR	RR	RR	POS
12	R	NR	RR	NR	NR	NR	NEG
13	R	NR	RR	RR	NR	NR	IND
14	R	RR	RR	RR	RR	RR	POS
15	R	RR	RR	RR	RR	RR	IND

Key: R= Reactive, NR = Not Reactive, RR = Repeatedly Reactive
POS = Positive, NEG = Negative, IND = Indeterminate (according to Western Blot specifications)

Table 3 Result Summary of Second Low Titre Panel: PRB 108

Panel Member PRB 108	UniGold™ Recombigen® HIV	EIA 1	EIA 2	EIA 3	Western Blot	Rapid Test
01	R	RR	RR	RR	POS	R
02	NR	NR	NR	NR	NEG	NR
03	R	RR	RR	RR	IND	R
04	R	RR	RR	RR	POS	NR
05	R	RR	RR	RR	POS	R
06	R	RR	RR	RR	IND	NR
07	R	RR	RR	RR	POS	R
08	R	RR	RR	RR	POS	R
09	R	RR	RR	NR	POS	NR
10	R	RR	NR	NR	IND	NR
11	R	RR	RR	RR	POS	R
12	NR	RR	NR	NR	NEG	NR
13	R	RR	NR	NR	IND	R
14	NR	RR	NR	NR	NEG	NR
15	R	RR	RR	RR	IND	NR

Key: R= Reactive, NR = Not Reactive, RR = Repeatedly Reactive
POS = Positive, NEG = Negative, IND = Indeterminate (according to Western Blot specifications)

Table 4: Third Low Titre panel: In-House

In- House Panel Member	UniGold™ Recombigen® HIV	EIA 1	EIA 2	Western Blot
CRC 42015	R	R	NR	POS
CRC 42013	R	R	NR	POS
CRC 42025	R	R	NR	IND
CRC 42049	R	R	NR	IND
CRC 42071	R	R	NR	POS
CRC 42075	R	R	NR	POS
CRC 42119	R	R	NR	POS

Key: R= Reactive, NR = Not Reactive, POS = Positive, NEG = Negative, IND = Indeterminate, EIA = FDA licensed EIA

9.4 Effect of unrelated medical conditions and interfering substances

The sensitivity of Uni-Gold™ Recombigen® HIV was further investigated by testing samples from persons with unrelated medical conditions and interfering substances. HIV-1 positive serum was used to spike over 200 samples from subjects with other medical conditions, such as Cytomegalovirus, Rubella IgG, Epstein Barr Virus, Anti-Nuclear Antibody, Hepatitis B Core Antibody, Hepatitis B Surface Antigen, Hepatitis C Virus Antibody, other auto immune diseases, other disease states and samples from persons recently vaccinated against Viruses do not affect the performance of Uni-Gold™ Recombigen® HIV. Samples with interfering substances, such as hemolysed, lipemic, high protein, high bilrubin, sarcoid and multiple myeloma samples were spiked with HIV-1 positive serum. The potentially interfering substances did not affect the performance of Uni-Gold™ Recombigen® HIV.

9.5 Reproducibility

Uni-Gold™ Recombigen® HIV was found to be consistent and stable when three different lots of Uni-Gold™ Recombigen® HIV were tested, by 2 operators, at 2 separate sites, testing 7 coded and blinded samples, 5 times a day, over 4 days. Hence 840 tests were run (420 per site), with a total of 60 test per coded sample. The overall reproducibility of the device was found to be excellent.

The evaluation of the sensitivity and specificity of Uni-Gold™ Recombigen® HIV test involved 15 operators, at 3 separate sites (5 per site), running 3000 samples per site over a period of 3 months. When the sensitivity and specificity achieved by each operator is evaluated there is no statistical difference in the performance of the product from one operator to another.

Concordant results were observed when 3 lots of Uni-Gold™ Recombigen® HIV was tested on the 14 member FDA HIV lot release panel. All Uni-Gold™ Recombigen® HIV results matched with the expected results as indicated on the data sheet provided by the FDA.

9.6 Animal studies

No animal studies were performed using Uni-Gold™ Recombigen® HIV.

10 SUMMARY OF CLINICAL STUDIES

10.1 Sensitivity

The sensitivity of Uni-Gold™ Recombigen® HIV was evaluated testing fresh serum, plasma and whole blood (venipuncture) samples. A total of 1032 HIV-1 positive samples were run on Uni-Gold™ Recombigen® HIV. 1000 of these were collected from individuals known to be HIV-1 sero-positive, and previously confirmed as positive by western blot. A further 32 samples were collected from individuals from high risk populations of unknown HIV serostatus who were subsequently found to be repeatedly reactive using a licensed HIV-1 EIA and positive by Western Blot. Uni-Gold™ Recombigen® HIV test was reactive for all these samples when tested using the serum, plasma and whole blood (venipuncture) portion of each sample set, to give 100% sensitivity in these studies (1032/1032 = 100% 95% C.I. = 99.5 – 100.0%). Two samples reactive by Uni-Gold™ Recombigen® HIV from individuals known to be positive for HIV-1 were initially non-reactive by the FDA licensed screening assay. These samples were treated as per the protocol as positive samples and included in the calculations presented in Table 5. In the calculations the sensitivity of Uni-Gold™ Recombigen® HIV has been based on the initial and not repeat test result.

Table 5 : Performance of Uni-Gold™ Recombigenâ HIV on initial serum, plasma and whole blood samples, in comparison to EIA and western blot from individuals sero-positive for HIV-1

Test Group	Uni-Gold™ Recombigenâ HIV Serum Positive	Uni-Gold™ Recombigen â HIV Plasma Positive	Uni-Gold™ Recombigen â HIV Whole Blood Positive	EIA reactive	Western Blot positive
High risk (n=1000)	35	34	34	32	32
Known HIV positive (n=1000)	1000	1000	1000	998?	1000
TOTAL	1035	1034	1034	1030	1032

? 2 samples were initially non reactive by the EIA. These samples were reactive on EIA repeat testing.

Eleven HIV-1 seroconversion panels were tested in comparison to FDA licensed EIA and Western blot tests. Each panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of 79 specimens. The results of this study are shown in Table 2. The Uni-Gold™ Recombigen® HIV test detected HIV-1 antibodies at the same bleed or at an earlier bleed than the most sensitive of the licensed EIA's in 8 out of 11 panels. In the remaining 3 panels the Uni-Gold™ Recombigen® HIV test detected HIV-1 antibodies one bleed later that the most sensitive EIA

10.2 Specificity

The specificity of Uni-Gold™ Recombigen® HIV was evaluated testing fresh serum, plasma and venipuncture whole blood samples. A total of 1968 HIV-1 EIA negative individual samples were run as serum, plasma and whole blood on Uni-Gold™ Recombigen® HIV.

1000 of these were collected from individuals of unknown HIV-1 serostatus in a low risk population, and subsequently confirmed as negative by EIA. Of these 1000 samples 2 were reactive in initial test by plasma and serum and 3 by whole blood when tested by Uni-Gold™ Recombigen® HIV.

Therefore in a low risk population the specificity of Uni-Gold™ Recombigen® HIV in these studies was
99.8% (95% Confidence interval = 99.3 – 100%) for serum
99.8% (95% Confidence interval = 99.3 – 100%) for plasma and
99.7% (95% Confidence interval = 99.0 - 100%) for whole blood.

A further 968 samples were collected from individuals of unknown HIV-1 sero-status, from a high risk population, who were subsequently found to be HIV-1 sero-negative by EIA. Of these 968 samples, 2 were reactive by plasma and whole blood and 3 by serum when tested by Uni-Gold™ Recombigen® HIV.

Therefore in a high risk population the specificity of Uni-Gold™ Recombigen® HIV in these studies was
99.7% (95% Confidence interval = 99.0 – 99.9%) for serum
99.8% (95% Confidence interval = 99.2 – 100%) for plasma and
99.8% (95% Confidence interval = 99.2 – 100%) for whole blood.

This data is combined and summarized in Table 6.

Table 6: Performance of Uni-Gold™ Recombigen â HIV from individuals presumed negative for HIV infection. Protocols 1 and 2 (Combining negative samples from low and high risk populations)

Test Group	Uni-Gold™ Recombigen® HIV serum negative	Uni-Gold™ Recombigen® HIV plasma negative	Uni-Gold™ Recombigen® HIV negative testing whole blood	**EIA negative**
Low risk (n=1000)	998	998	997	1000
High Risk? (n=1000)	965	966	966	968

?This sample set consisted of 32 true HIV-1 positive samples

11 CONCLUSIONS DRAWN FROM THE STUDIES

Risk/ Benefit Analysis

There are minimal risks from performing this test. Any physical risks that may be experienced in the performance of the test are expanded upon in the package insert.

HIV-1 is one of the causative agents of AIDS. AIDS is the end stage of a protracted process in which the immune system of an infected person and its ability to control infections or malignant proliferative disorders are progressively destroyed. HIV-1 is predominately transmitted by unprotected sexual intercourse, perinatally from mother to child, postnatally by breast feeding or parenteral transmission. Most frequently HIV-1 infection is diagnosed by tests that assess whether an individual's immune system has produced an HIV-1-specific immune response.

In the USA the standard laboratory test algorithm may take 48 hours to one week before results may be made available. This algorithm consists of screening with an enzyme immunoassay (EIA) and confirmation by retest by EIA followed by definitive confirmation by Western Blot (WB) or immuno-fluorescent (IFA) methods.

During the past two decades, HIV-1 infection and severe HIV-1-related diseases (e.g., acquired immunodeficiency syndrome [AIDS]) have become a leading cause of illness and death in the United States. As of December 31, 2000, a total of 774,467 persons were reported with AIDS and 448,060 of these persons had died; the number of persons living with AIDS (322,865) was the highest ever reported. Approximately 800,000-900,000 persons in the United States are infected with HIV and approximately 275,000 of these persons might not know they are infected. Approximately 25 million persons each year in the United States are tested for HIV. Publicly funded counselling and testing programs conduct approximately 2.5 million of these tests each year. In 1995, 25% of each persons testing HIV positive and 33% of persons testing HIV negative at publicly funded clinics did not return for their test results. Uni-Gold™ Recombigen® HIV will detect HIV antibody in 10 minutes, enabling healthcare providers to supply definitive negative and preliminary positive results to patients at the time of testing, potentially increasing the overall effectiveness of counselling and testing programs. In comparison, results from enzyme immunoassays (EIAs) currently used for HIV screening are often not available for 1-2

weeks. Using rapid tests, during 1995, a total of 697,495 more persons would have learned their HIV status.

Many advances have been made in HIV/AIDS prevention and treatment, including the development of effective antiretroviral therapies that have reduced HIV-related illness and death. Early knowledge of HIV infection is now recognized as a critical component in controlling the spread of HIV infection. Rapid HIV testing allows clients to receive results the same day, which is useful in urgent medical circumstances and setting where clients tend not to return for HIV test results (e.g., some STD clinics). Advances in these areas have resulted in revised recommendations for HIV screening of pregnant women, treating opportunistic infections and other sexually transmitted and bloodborne disease and managing occupational and non-occupational exposures and prophylaxis.

Safety

No adverse reactions were observed in any of the studies conducted.