08836973503V1.0

Elecsys HIV Duo

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REF		Σ	SYSTEM
08836973192	08836973503	10 x 300	**cobas e** 402 **cobas e** 801

English

System information

Short name	Assay type	To be used for
HIVDUO	**cobas e** flow	HIV Duo
HIVDUOR	**cobas e** flow	HIV Duo duplicate repeat
HIVAG	HIV Antigen (HIV Ag) embedded application	HIV Duo **cobas e** flow
AHIV	Anti-HIV embedded application	HIV Duo **cobas e** flow

Intended use

Immunoassay for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma. The subresults (HIV Ag and anti-HIV) are intended as an aid in the selection of the confirmation algorithm for reactive samples.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Regulatory approval

This assay has been CE marked according to Directive 98/79/EC. Test performance has been established and certified by a Notified Body according to the Common Technical Specifications (CTS) for diagnostic use and for screening of blood donations and, according to Paul-Ehrlich-Institut (PEI) recommendation,[1] for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).

Summary

The human immunodeficiency virus (HIV), the causative agent of Acquired Immunodeficiency Syndrome (AIDS), belongs to the family of retroviruses. HIV can be transmitted through sexual contact, contaminated blood and blood products or from an HIV-infected mother to her child before, during and after birth.
Two types of HIV, called HIV-1 and HIV-2, have been identified to date.[2,3,4,5] HIV-1 can be divided into 4 distantly related groups: group M (for main), group N (for non-M, non-O), group O (for outlier) and group P.[6,7,8] Based on their genetic relationship, 10 different subtypes (A to D, F to H, J, K, L) as well as several circulating recombinant forms (CRFs) have been identified within HIV-1 group M.[9,10] The large majority of HIV-1 infections are caused by viruses belonging to group M, while geographical distribution of subtypes and CRFs within this group varies strongly.[11] Due to differences in the sequence of immunodominant epitopes, especially in the envelope proteins of HIV-1 group M, HIV-1 group O and HIV-2, specific antigens are necessary to avoid failure in the detection of an HIV infection by immunoassays.[12,13]

HIV p24 antigen in blood specimen of recently infected patients can be detected as early as 2-3 weeks after infection.[14,15] Anti-HIV antibodies are detectable in serum from around 4 weeks post infection.[14,16] The combined detection of HIV p24 antigen and anti-HIV antibodies in 4th generation HIV screening assays leads to improved sensitivity and therefore a shorter diagnostic window compared to traditional anti-HIV assays.[17,18]

With the Elecsys HIV Duo assay, HIV-1 p24 antigen (HIV Ag), as well as antibodies to HIV-1 and HIV-2 (anti-HIV) can be detected in parallel with two separate determinations. On the basis of these determinations, the Elecsys HIV Duo main result is subsequently calculated automatically by the analyzer. The subresults HIV Ag and anti-HIV can be used as an aid in the selection of the confirmation algorithm for reactive samples. The Elecsys HIV Duo assay uses monoclonal antibodies to detect the HIV Ag and recombinant antigens derived from the Env- and Pol-region of HIV-1 (including group O) and HIV-2 to detect anti-HIV antibodies. Repeatedly reactive samples must be confirmed according to recommended confirmatory algorithms.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: For HIV Ag detection (HIVAG), 30 µL of sample react with biotinylated monoclonal anti-p24 antibodies and ruthenylated[a)] monoclonal anti-p24 antibodies, to form a sandwich complex. For anti-HIV detection (AHIV), 30 µL of sample react with biotinylated HIV-specific recombinant antigens/peptides and ruthenylated[a)] HIV-specific recombinant antigens/peptides, to form a sandwich complex. The incubations are performed in parallel in separate vessels.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the sample with the cutoff value obtained by HIV Ag embedded and anti-HIV embedded calibration. The Elecsys HIV Duo result is calculated automatically based on signal to cutoff ratios (cutoff index, COI) from HIV Ag and anti-HIV.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

The **cobas e** pack HIV Ag (M, R1, R2) is labeled as HIVAG.

The **cobas e** pack Anti-HIV (M, R1, R2) is labeled as AHIV.

HIVAG

M Streptavidin-coated microparticles, 1 bottle, 14.1 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-HIV p24-Ab~biotin, 1 bottle, 14.8 mL: Biotinylated monoclonal anti-HIV p24 antibodies (mouse) approximately 0.75 mg/L; MES[b)] buffer 50 mmol/L, pH 6.5; preservative.

R2 Anti-HIV p24-Ab~$Ru(bpy)_3^{2+}$, 1 bottle, 14.8 mL: Monoclonal anti-p24 antibodies (mouse) labeled with ruthenium complex approximately 0.75 mg/L; MES buffer 50 mmol/L, pH 6.5; preservative.

b) MES = 2-morpholino-ethane sulfonic acid

HIVDUO Cal1 Negative calibrator (lyophilized), 2 bottles for 1.0 mL each: Human serum, non-reactive for anti-HIV-1 and anti-HIV-2.

HIVDUO Cal2 Positive calibrator (lyophilized), 2 bottles for 1.0 mL each: HIV p24 antigen (E. coli, rDNA) in human serum, non-reactive for anti-HIV-1 and anti-HIV-2.

AHIV

M Streptavidin-coated microparticles, 1 bottle, 14.1 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 HIV-1/2-specific recombinant antigens (E. coli)~biotin, HIV-1/2-specific synthetic peptides~biotin, 1 bottle, 14.8 mL: Biotinylated HIV-1/2-specific recombinant antigens (E. coli) and biotinylated HIV-1/2 specific synthetic peptides approximately 0.63 mg/L; TES[c)] buffer 40 mmol/L, pH 7.3; preservative.

R2 HIV-1/2-specific recombinant antigens (E. coli)~$Ru(bpy)_3^{2+}$, HIV-1/2-specific synthetic peptides~$Ru(bpy)_3^{2+}$, 1 bottle, 14.8 mL: HIV-1/2-specific recombinant antigens (E. coli) and HIV-1/2-specific synthetic peptides labeled with ruthenium complex approximately 1.22 mg/L; TES buffer 40 mmol/L, pH 7.3; preservative.

c) TES = 2-[[1,3-dihydroxy-2-(hydroxymethyl)propane-2-yl]amino]ethanesulfonic acid

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HIVDUO Cal3	Negative calibrator (lyophilized), 2 bottles for 1.0 mL each: Human serum, non-reactive for anti-HIV-1 and anti-HIV-2.
HIVDUO Cal4	Positive calibrator (lyophilized), 2 bottles for 1.0 mL each: Anti-HIV-1 positive human serum (inactivated) in human serum negative for anti-HIV-1 and anti-HIV-2.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

Prevention:

P261	Avoid breathing mist or vapours.
P273	Avoid release to the environment.
P280	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

All human material should be considered potentially infectious.

The negative calibrators (HIVDUO Cal1 and HIVDUO Cal3) as well as the HIV Ag positive calibrator (HIVDUO Cal2) have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

The testing methods used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing anti-HIV-1 (HIVDUO Cal4) was inactivated using β-propiolactone and UV-radiation.

However, as no inactivation or testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[19,20]

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

The reagents (M, R1, R2) in the kit are ready-for-use and are supplied in **cobas e** packs.

Calibrators:

Carefully dissolve the contents of 1 bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer the reconstituted calibrators into the supplied empty labeled snap-cap bottles.

Unless the entire volume is necessary for calibration on the analyzer, transfer aliquots of the freshly reconstituted calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C or -20 °C (± 5 °C) for later use.

Perform **only one** calibration procedure per aliquot.

All information required for correct operation is available via the **cobas** link.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the **cobas e** pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the **cobas e** pack:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzers	16 weeks

Stability of the calibrators:	
lyophilized	up to the stated expiration date
reconstituted at 2-8 °C	72 hours
reconstituted at -20 °C (± 5 °C)	16 weeks (1 freeze/thaw cycle possible)
on the analyzers at 20-25 °C	use only once

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Specimen collection and preparation

Specimen collected from living patients, blood donors, or individual organ, tissue or cell donors may be used, including donor samples obtained while the donor's heart is still beating.
Performance for the use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating) was established according to Paul-Ehrlich-Institut recommendation[1] with samples obtained within 24 hours after death.[21] Qualitative differences of neat (non-reactive) or spiked (reactive) specimens from cadaveric compared to living donors were not observed.

Criterion: Mean value of cadaveric specimens compared to specimens from living donors within a recovery of 75-125 %.

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, Na-heparin, K_2-EDTA, K_3-EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma.

Li-heparin, K_2-EDTA and K_3-EDTA plasma tubes containing separating gel can be used.

Criterion: Correct assignment of negative and positive samples within a recovery of ± 0.2 COI for negative and 80-120 % for positive samples.

Stability:
For living patients and donor specimens obtained while the donor's heart is still beating: Stable for 7 days at 20-25 °C, 4 weeks at 2-8 °C, 3 months at -20 °C (± 5 °C). The samples may be frozen 5 times.
For cadaveric specimens: Stable for 3 days at 20-25 °C, 7 days at 2-8 °C. The samples may be frozen 3 times.

Sampling devices containing liquid anticoagulants have a dilution effect resulting in lower COI values for individual patient specimens. In order to minimize dilution effects it is essential that respective sampling devices are filled completely according to manufacturer's instructions.

The sample types listed were tested with a selection of sample collection tubes or systems that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube/collection system manufacturer.

Centrifuge samples containing precipitates and thawed samples before performing the assay.

Do not use heat-inactivated samples.

Do not use samples and controls stabilized with azide.

Ensure the samples and calibrators are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples and calibrators on the analyzers should be analyzed/measured within 2 hours.

The performance of the Elecsys HIV Duo assay has not been established with body fluids other than serum and plasma.

Materials provided

See "Reagents – working solutions" section for reagents.

- 8 empty labeled snap-cap bottles

Materials required (but not provided)

- REF 06924107190, PreciControl HIV Gen II, for 6 x 2.0 mL
- REF 06924115190, PreciControl HIV; HIV-2+GrpO, for 4 x 2.0 mL (optional use)
- REF 12001101122, Elecsys HIV Ag Confirmatory Test, 2 x 1.0 mL each of confirmatory reagent and control reagent (optional use)
- General laboratory equipment
- **cobas e** analyzer
- Distilled or deionized water

Additional materials for **cobas e** 402 and **cobas e** 801 analyzers:

- REF 06908799190, ProCell II M, 2 x 2 L system solution
- REF 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- REF 07485409001, Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
- REF 06908853190, PreClean II M, 2 x 2 L wash solution
- REF 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
- REF 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
- REF 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
- REF 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use.

Place the cooled (stored at 2-8 °C) **cobas e** pack on the reagent manager. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the **cobas e** pack.

Calibrators:

Place the reconstituted calibrators in the sample zone.

Perform **only one** calibration procedure per aliquot.

Calibration

Traceability:

HIVAG:
This method has been standardized against the WHO International Standard HIV-1-p24 Antigen, NIBSC (National Institute for Biological Standards and Control) code 90/636.

AHIV:
No internationally accepted standard for anti-HIV-1 and anti-HIV-2 exists.

Calibration frequency: Calibration must be performed once per reagent lot using HIVDUO Cal1, HIVDUO Cal2, HIVDUO Cal3, HIVDUO Cal4 and fresh reagent (i.e. not more than 24 hours since the **cobas e** pack was registered on the analyzer).

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Renewed calibration is recommended as follows:

- after 12 weeks when using the same reagent lot
- after 28 days when using the same **cobas e** pack on the analyzer
- as required: e.g. quality control findings outside the defined limits

Quality control

For quality control, use PreciControl HIV Gen II.
In addition, PreciControl HIV; HIV-2+GrpO can be used (optional). Note that all HIV results are sufficiently controlled if only PreciControl HIV Gen II is used.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per **cobas e** pack, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

The analyzer automatically calculates the cutoff based on the measurement of HIVDUO Cal1 and HIVDUO Cal2, HIVDUO Cal3 and HIVDUO Cal4.

The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index (signal sample/cutoff).

The following formula is used to calculate the main Elecsys HIV Duo result based on the HIVAG and AHIV subresults:

$$\text{HIVDUO (COI)} = \sqrt{(\text{HIVAG [COI]})^2 + (\text{AHIV [COI]})^2}$$

Interpretation of the results

Main result HIVDUO

Numeric result	Result message	Interpretation/ further steps
COI < 1.00	Non-reactive	Negative for HIV-1 Ag and negative for anti-HIV-1/2 antibodies. No further testing needed.
COI ≥ 1.00	Reactive	Reactive in the Elecsys HIV Duo assay. All initially reactive samples should be redetermined in duplicate with the Elecsys HIV Duo assay. Redetermination of samples with an initial COI ≥ 1.00 can be performed automatically (see section **cobas e flows**).

Main result HIVDUOR

Numeric result	Result message	Interpretation/ further steps
Both of the duplicate retests have a COI < 1.00	Non-reactive	Negative for HIV-1 Ag and negative for anti-HIV-1/2 antibodies. No further testing needed.

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Numeric result	Result message	Interpretation/ further steps
One or both of the duplicate retests have a COI ≥ 1.00	Repeatedly reactive	Repeatedly reactive samples must be confirmed according to recommended confirmatory algorithms. Confirmatory tests include Western Blot and HIV RNA tests. For the right choice of method the module-specific subresult for HIVAG and AHIV can be used.

Subresult HIVAG

Numeric result	Result message	Interpretation/ further steps
COI < 1.00	Non-reactive	Negative for HIV-1 p24 antigen.
COI ≥ 1.00	Reactive	Reactive in the HIV Ag module.

Subresult AHIV

Numeric result	Result message	Interpretation/ further steps
COI < 1.00	Non-reactive	Negative for anti-HIV-1/2 antibodies.
COI ≥ 1.00	Reactive	Reactive in the anti-HIV module.

Please note: In case the HIVAG and AHIV results are both in the range of COI 0.708-0.999, the combined Elecsys HIV Duo main result will have a COI ≥ 1.00 and will be reported as reactive.

cobas e flows

cobas e flows are procedures programmed into the system to enable a fully automated sequence of measurements and the calculation of assay combinations to perform decision algorithms.
The HIVDUO **cobas e** flow is required to enable simultaneous separate measurement of HIVAG and AHIV with subsequent calculation of the main result.
A second HIV **cobas e** flow is available to perform a repetition of measurements in duplicate automatically for samples with an initial cutoff index ≥ 1.00 (short name HIVDUOR). Both subresults and the overall result message will be reported.

Limitations - interference

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 1129 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.311 mmol/L or ≤ 500 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
Rheumatoid factors	≤ 1200 IU/mL

Criterion: Correct assignment of negative and positive samples within a recovery of ± 0.15 COI for negative samples and 80-120 % for positive samples.

No false negative result due to high-dose hook effect was found with the Elecsys HIV Duo assay.

Occurrence of high-dose hook effect cannot be completely excluded.

Pharmaceutical substances
In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found.

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

A negative test result does not completely rule out the possibility of an infection with HIV. Serum or plasma samples from the very early (pre-seroconversion) phase or the late phase of HIV infection can occasionally yield negative findings. Yet unknown HIV variants can also lead to a negative HIV finding. The presence of antibodies to HIV is not a diagnosis of AIDS.

Limits and ranges

Antigen detection (HIVAG/HIVDUO)
≤ 1.0 IU/mL
Antigen sensitivity was determined based on serial dilutions of the WHO International Standard HIV-1 p24 antigen, NIBSC (National Institute for Biological Standards and Control) code 90/636, in human HIV negative serum.

Antibody detection (AHIV/HIVDUO)
No internationally accepted standard for HIV-specific antibody detection exists.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using Elecsys reagents, samples and controls in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute): 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

cobas e 402 and **cobas e** 801 analyzers					
		Repeatability		**Intermediate precision**	
Sample	Mean COI	SD COI	CV %	SD COI	CV %
HSP[d], negative	0.107	0.006	5.4	0.008	7.7
HSP, positive for HIV-1 p24 antigen	2.22	0.039	1.7	0.062	2.8
HSP, positive for anti-HIV-1	1.85	0.029	1.6	0.062	3.4
HSP, positive for anti-HIV-1	19.3	0.304	1.6	0.627	3.2
HSP, positive for anti-HIV-2	1.85	0.028	1.5	0.066	3.6
HSP, positive for anti-HIV GrpO	1.65	0.024	1.4	0.057	3.5
PC[e] HIV1	0.158	0.007	4.2	0.009	5.8
PC HIV2	3.30	0.035	1.1	0.091	2.8
PC HIV3	9.80	0.105	1.1	0.211	2.2
PC HIV4	3.78	0.033	0.9	0.103	2.7
PC HIV5	5.04	0.045	0.9	0.153	3.0

d) HSP = human specimen (serum/plasma)

e) PC = PreciControl

Analytical specificity

196 samples containing potentially interfering substances were tested with the Elecsys HIV Duo assay comprising specimens:

- containing antibodies against HAV, HBV, HCV, HTLV, CMV, EBV, HSV, Rubella, Treponema pallidum

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- containing autoantibodies and elevated titers of rheumatoid factor
- positive for Candida, E. coli, Plasmodium falciparum/vivax, Mycobacterium tuberculosis
- after vaccination against HAV, HBV and influenza
- from patients with monoclonal gammopathy and multiple myeloma/lymphoma

	N	Elecsys HIV Duo assay, RR*	WB**	WB negative, HIV Ag negative	Analytical specificity (95 % lower confidence limit)
Specimens containing potentially interfering substances	196	0	0	0	100 % (98.14 %)

* RR = repeatedly reactive

** Western Blot (WB) confirmed positive/indeterminate

Clinical sensitivity

Of 1701 samples from HIV infected patients in different stages of the disease and infected with HIV-1 group M, N, O, P and HIV-2, 1701 were found to be repeatedly reactive with the Elecsys HIV Duo assay. The sensitivity of the Elecsys HIV Duo assay in this study was 100 %. The 95 % lower confidence limit was 99.78 %.

Group	N	Reactive
Infection with HIV-1 group M (subtypes A-K)	1395	1395
Infection with HIV-1 group O	52	52
Infection with HIV-1 group N	1	1
Infection with HIV-1 group P	1	1
Infection with HIV-2	202	202
Positive for HIV Ag	50	50

58 different virus lysates of cell culture supernatants including different HIV-1 group M subtypes (A-H), HIV-1 group N, HIV-1 group O, HIV-1 group P and HIV-2 were tested and found reactive in the Elecsys HIV Duo assay.

Seroconversion panels

Seroconversion sensitivity of the Elecsys HIV Duo assay has been shown by testing 139 commercial seroconversion panels in comparison to other registered HIV combination assays or anti-HIV assays and/or HIV Ag assays.

Of 356 samples from early HIV seroconversion phase (according to CS definition), 350 were found positive with the Elecsys HIV Duo assay.

Clinical specificity

In a group of 13330 randomly selected blood donors from Europe and Asia the specificity of the Elecsys HIV Duo assay was found 99.87 % (IR and RR). The 95 % lower confidence limit was 99.80 %.

In a group of 2368 samples from unselected daily routine, dialysis patients and pregnant women the specificity of the Elecsys HIV Duo assay was found 99.92 % (IR and RR). The 95 % lower confidence limit was 99.70 %.

	N	Elecsys HIV Duo assay		WB**	**Clinical specificity (95 % lower confidence limit)**
		IR* COI ≥ 1	RR COI ≥ 1		
Blood donors	13330	17	17	0	99.87 % (99.80 %)
Unselected samples from daily routine	1000	0	0	0	100 % (99.63 %)
Dialysis patients	280	1	1	0/1	100 % (98.69 %)
Pregnant women	1090	3	3	1/0	99.82 % (99.34 %)

* IR = initially reactive

** Western Blot confirmed positive/indeterminate. Samples with indeterminate WB were excluded from the calculation.

References

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20 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

21 Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

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For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number

CE 0123

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