



Elecsys HIV combi PT

cobas®

| REF |  |  | SYSTEM |
|-------------|---|---|---|
| 08924180119 | 08924180500 | 200 | cobas e 411 cobas e 601 cobas e 602 |

English

System information

For **cobas e 411** analyzer: test number 2260

For **cobas e 601** and **cobas e 602** analyzers: Application Code Number 209

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. This assay is indicated as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. This assay is also indicated as a donor screening test for the detection of HIV 1 p24 antigen and antibodies to HIV-1 and HIV-2 in serum or plasma specimens from individual human blood donors. It may also be used to screen individual organ donors when specimens are obtained while the donor's heart is still beating. The assay does not discriminate among HIV-1 antibody, HIV-2 antibody, or HIV p24 antigen reactivity.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Note: Please note that the catalogue number appearing on the package insert retains only the first 8 digits of the licensed 11-digit Catalogue Number: 08924180190 for the Elecsys HIV combi PT assay. The last 3 digits -190 have been replaced by -119 for logistic purposes.

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, 9 different subtypes (A to D, F to H, J, K) as well as several circulating recombinant forms (CRFs) have been identified within HIV-1 group M.⁹ 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.¹⁰ 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.^{11,12}

HIV p24 antigen in blood specimen of recently infected patients can be detected as early as 2-3 weeks after infection.^{13,14} Anti-HIV antibodies are detectable in serum from around 4 weeks post infection.^{13,15} 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.^{16,17}

With the Elecsys HIV combi PT assay the HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 can be detected simultaneously within one determination. The assay uses recombinant antigens derived from the *env*- and *pol*-region of HIV-1 (including group O) and HIV-2 to determine HIV-specific antibodies. For the detection of HIV-1 p24 antigen specific monoclonal antibodies are used. Repeatedly reactive samples must be confirmed according to recommended confirmatory algorithms. Confirmatory tests include Western Blot and HIV RNA tests.

Test principle

Sandwich principle. Total duration of assay: 27 minutes.

- 1st incubation: Pretreatment of 40 µL of sample with detergent agent.
- 2nd incubation: Biotinylated monoclonal anti-p24 antibodies/HIV-specific recombinant antigens/HIV-specific peptides, and monoclonal anti-p24 antibodies/HIV-specific recombinant antigens/HIV-specific peptides labeled with a ruthenium complex^{a)} react to form a sandwich complex.
- 3rd 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/ProCell 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 reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)₃²⁺)

Reagents - working solutions

The reagent rackpack (M, R0, R1, R2) is labeled as HIVCPT2.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R0 MES^{b)} buffer 50 mmol/L, pH 5.5; 1.5 % Nonidet P40; preservative (white cap), 1 bottle, 6.5 mL.
- R1 Anti-HIV p24-Ab~, HIV-1/2-specific recombinant antigens (E. coli)~, HIV-1/2-specific peptides~biotin (gray cap), 1 bottle, 12 mL: Biotinylated monoclonal anti-p24 antibodies (mouse), biotinylated HIV-1/2-specific recombinant antigens (E. coli), biotinylated HIV-1/2-specific peptides > 1.3 mg/L; TRIS^{c)} buffer 50 mmol/L, pH 7.5; preservative.
- R2 Anti-HIV p24-Ab~, HIV-1/2-specific recombinant antigens (E. coli)~, HIV-1/2-specific peptides~Ru(bpy)₃²⁺ (black cap), 1 bottle, 12 mL: Monoclonal anti-p24 antibodies (mouse), HIV-1/2-specific recombinant antigens, HIV-1/2-specific peptides labeled with ruthenium complex > 1.5 mg/L; TRIS^{c)} buffer 50 mmol/L, pH 7.5; preservative.

b) MES = 2-morpholino-ethane sulfonic acid

c) TRIS = Tris(hydroxymethyl)-aminomethane

- HIVCPT2 Cal1 Negative calibrator (white cap; lyophilized), 1 bottle for 1.0 mL: Human serum, non reactive for anti-HIV-1 and anti-HIV-2.
- HIVCPT2 Cal2 Positive calibrator (black cap; lyophilized), 1 bottle for 1.0 mL: 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:

2-methyl-2H-isothiazol-3-one hydrochloride

EUH 208 May produce an allergic reaction.



Warning

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.
 H412 Harmful to aquatic life with long lasting effects.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ eye protection/ face protection.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337 + P313 If eye irritation persists: Get medical advice/attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.

Product safety labeling follows EU GHS guidance.

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

All human material should be considered potentially infectious.

The negative calibrator (HIVCPT2 Cal1) has 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 (HIVCPT2 Cal2) 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.^{18,19}

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

Reagent handling

The reagents (M, R0, R1, R2) in the kit are ready-for-use and are supplied in bottles compatible with the system.

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.

cobas e 411 analyzer: The reconstituted calibrators should only be left on the analyzer during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C.

Due to possible evaporation effects, not more than 5 calibration procedures per calibrator bottle set should be performed.

cobas e 601 and **cobas e 602** analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the reconstituted calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C for later use.

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

All information required for correct operation is read in from the respective reagent barcodes.

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for **cobas 8000** systems only. If using a **cobas 8000** system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the Elecsys reagent kit **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

| Stability of the reagent rackpack | |
|-----------------------------------|----------------------------------|
| unopened at 2-8 °C | up to the stated expiration date |
| after opening at 2-8 °C | 12 weeks |
| on the analyzers | 28 days |

| Stability of the calibrators | |
|--|----------------------------------|
| lyophilized | up to the stated expiration date |
| reconstituted at 2-8 °C | 12 weeks |
| on cobas e 411 at 20-25 °C | up to 5 hours |
| on cobas e 601 and cobas e 602 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

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, K₂-EDTA, K₃-EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma as well as Li-heparin plasma tubes containing separating gel.

Sampling devices containing liquid anticoagulants have a dilution effect resulting in lower cutoff index (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.

Stability:

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.

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, calibrators and controls are at 20-25 °C prior to measurement.

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

The performance of the Elecsys HIV combi PT assay has not been established with cadaveric samples or body fluids other than serum and plasma.

Materials provided

See "Reagents – working solutions" section for reagents.

- 2 x 4 bottle labels
- 4 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] 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- General laboratory equipment
- **cobas e** analyzer
- Distilled or deionized water

Additional materials for the **cobas e 411** analyzer:

- [REF] 11662988122, ProCell, 6 x 380 mL system buffer
- [REF] 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- [REF] 11930346122, Elecsys SysWash, 1 x 500 mL washwater additive
- [REF] 11933159001, Adapter for SysClean
- [REF] 11706802001, AssayCup, 60 x 60 reaction cups
- [REF] 11706799001, AssayTip, 30 x 120 pipette tips
- [REF] 11800507001, Clean-Liner

Additional materials for **cobas e 601** and **cobas e 602** analyzers:

- [REF] 04880340190, ProCell M, 2 x 2 L system buffer
- [REF] 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- [REF] 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- [REF] 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- [REF] 03004899190, PreClean M, 5 x 600 mL detection cleaning solution
- [REF] 12102137001, AssayTip/AssayCup, 48 magazines x 84 reaction cups or pipette tips, waste bags
- [REF] 03023150001, WasteLiner, waste bags
- [REF] 03027651001, SysClean Adapter M

Additional materials for all analyzers:

- [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. Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

cobas e 601 and **cobas e 602** analyzers: PreClean M solution is necessary.

Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Calibrators:

Place the reconstituted calibrators in the sample zone.

All the information necessary for calibrating the assay is automatically read into the analyzer.

After calibration has been performed, store the calibrators at 2-8 °C or discard (**cobas e 601** and **cobas e 602** analyzers).

Calibration

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

This method has been standardized against the Human Immunodeficiency Virus Type 1 (HIV-1 p24 Antigen) - 1st International Reference Reagent 1992, code 90/636 - available from NIBSC (National Institute for Biological Standards and Control).

Calibration frequency: Calibration must be performed once per reagent lot using HIVCPT2 Cal1, HIVCPT2 Cal2 and fresh reagent (i.e. not more than 24 hours since the reagent kit 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 1 month (28 days) when using the same reagent lot
- after 7 days (when using the same reagent kit on the analyzer)
- as required: e.g. quality control findings outside the defined limits

Range for the electrochemiluminescence signals (counts) for the calibrators:

Negative calibrator (HIVCPT2 Cal1):

1200-3500 (**cobas e 411** analyzer)

550-2200 (**cobas e 601** and **cobas e 602** analyzers)

Positive calibrator (HIVCPT2 Cal2):

17000-75000 (**cobas e 411** analyzer)

14000-70000 (**cobas e 601** and **cobas e 602** analyzers)

Quality control

For quality control, use PreciControl HIV Gen II. The use of PreciControl HIV; HIV-2+GrpO is optional. Note that all HIV results are sufficiently controlled if only PreciControl HIV Gen II is used.

All controls should be run individually at least once every 24 hours when the test is in use, once per reagent kit, 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.

Note:

For technical reasons re-assigned target values valid only for a specific reagent and control lot combination must be entered manually on all analyzers (except for the **cobas e 602** analyzer). Therefore always refer to the value sheet included in the reagent kit or PreciControl kit to make sure that the correct target values are used.

When a new reagent or control lot is used, the analyzer will use the original values encoded in the control barcodes.

Calculation

The analyzer automatically calculates the cutoff based on the measurement of HIVCPT2 Cal1 and HIVCPT2 Cal2.

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).

Interpretation of the results

Samples with a cutoff index < 0.90 are non-reactive in the Elecsys HIV combi PT assay. These samples are considered negative for HIV-1 Ag and HIV-1/2 specific antibodies and do not need further testing. Samples having a cutoff index in the range ≥ 0.90 to < 1.0 are considered borderline in the Elecsys HIV combi PT assay.

Samples with a cutoff index ≥ 1.0 are considered reactive in the Elecsys HIV combi PT assay.

All initially reactive or borderline samples should be redetermined in duplicate with the Elecsys HIV combi PT assay. If cutoff index values < 0.90 are found in both cases, the samples are considered negative for HIV-1 Ag and HIV-1/2 specific antibodies.

Initially reactive or borderline samples giving cutoff index values of ≥ 0.90 in either of the redeterminations are considered repeatedly reactive. Repeatedly reactive samples must be confirmed according to recommended confirmatory algorithms. Confirmatory tests include Western Blot and HIV RNA tests.

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.

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Endogenous substances

| Compound | Concentration tested |
|--------------------|-------------------------------|
| Bilirubin | ≤ 1026 μmol/L or ≤ 60 mg/dL |
| Hemoglobin | ≤ 0.310 mmol/L or ≤ 500 mg/dL |
| Intralipid | ≤ 1500 mg/dL |
| Biotin | ≤ 4912 nmol/L or ≤ 1200 ng/mL |
| Rheumatoid factors | ≤ 1500 IU/mL |

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

Pharmaceutical substances

In vitro tests were performed on 18 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 HIV antigen or antibodies to HIV is not a diagnosis of AIDS.

Limits and ranges

Antigen detection

Detection limit: ≤ 2 IU/mL

The stated sensitivity was determined by reading off the HIV Ag concentration corresponding to the signal of the cutoff value from standard curves obtained by serial dilutions of the Human Immunodeficiency Virus Type 1 (HIV-1 p24 Antigen) - 1st International Reference Reagent 1992, code 90/636 - in human HIV-negative serum.

Antibody detection

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 411 analyzer | | | | | |
|--|-------------|-----------------------------|---------|---|---------|
| Sample | Mean COI | Repeatability ^{d)} | | Intermediate precision ^{e)} | |
| | | SD COI | CV % | SD COI | CV % |
| HS ^{f)} , negative | 0.141 | 0.022 | - | 0.041 | - |
| HS, positive for HIV Ag | 1.65 | 0.040 | 2.4 | 0.058 | 3.5 |
| HS, positive for anti-HIV-1 | 1.85 | 0.044 | 2.4 | 0.056 | 3.0 |
| HS, positive for anti-HIV-1 | 41.7 | 0.602 | 1.4 | 0.861 | 2.1 |
| HS, positive for anti-HIV-2 | 1.80 | 0.044 | 2.4 | 0.065 | 3.6 |
| HS, positive for anti-HIV-1 group O | 1.63 | 0.034 | 2.1 | 0.060 | 3.7 |
| PreciControl HIV1 | 0.205 | 0.020 | - | 0.036 | - |
| PreciControl HIV2 | 4.66 | 0.074 | 1.6 | 0.103 | 2.2 |
| PreciControl HIV3 | 4.55 | 0.065 | 1.4 | 0.124 | 2.7 |

| cobas e 411 analyzer | | | | | |
|----------------------|-------------|-----------------------------|---------|---|---------|
| Sample | Mean COI | Repeatability ^{d)} | | Intermediate precision ^{e)} | |
| | | SD COI | CV % | SD COI | CV % |
| PreciControl HIV4 | 4.25 | 0.062 | 1.5 | 0.080 | 1.9 |
| PreciControl HIV5 | 4.99 | 0.101 | 2.0 | 0.118 | 2.4 |

d) Repeatability = within-run precision

e) Intermediate precision = between-run

f) HS = human serum

| cobas e 601 and cobas e 602 analyzers | | | | | |
|--|-------------|---------------|---------|---------------------------|---------|
| Sample | Mean COI | Repeatability | | Intermediate precision | |
| | | SD COI | CV % | SD COI | CV % |
| HS, negative | 0.104 | 0.007 | - | 0.010 | - |
| HS, positive for HIV Ag | 1.65 | 0.037 | 2.2 | 0.047 | 2.9 |
| HS, positive for anti-HIV-1 | 1.93 | 0.045 | 2.3 | 0.057 | 3.0 |
| HS, positive for anti-HIV-1 | 46.0 | 0.762 | 1.7 | 0.995 | 2.2 |
| HS, positive for anti-HIV-2 | 1.94 | 0.054 | 2.8 | 0.070 | 3.6 |
| HS, positive for anti-HIV-1 group O | 1.79 | 0.037 | 2.1 | 0.056 | 3.2 |
| PreciControl HIV1 | 0.163 | 0.009 | - | 0.011 | - |
| PreciControl HIV2 | 4.85 | 0.090 | 1.9 | 0.120 | 2.5 |
| PreciControl HIV3 | 4.52 | 0.088 | 1.9 | 0.115 | 2.5 |
| PreciControl HIV4 | 4.57 | 0.090 | 2.0 | 0.133 | 2.9 |
| PreciControl HIV5 | 4.74 | 0.089 | 1.9 | 0.127 | 2.7 |

Analytical specificity

1182 samples containing potentially interfering substances were tested with the Elecsys HIV combi PT assay comprising specimens:

- containing antibodies against HAV, HBV, HCV, HTLV, CMV, EBV, HSV, VZV, Toxoplasma gondii, Treponema pallidum, Borrelia, Parvovirus B19
- 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 combi PT assay | | Western Blot ^{g)} | Analytical specificity |
|---|------|-------------------------------|-----------------------------|-------------------------------|---|
| | | IR ^{h)} COI ≥ 1 | RR ⁱ⁾ COI ≥ 1 | | |
| Specimens containing potentially interfering substances | 1182 | 1 ^{j)} | 1 | 0 | 99.92 % 95 % lower confidence limit: 99.53 % |

g) Western Blot confirmed positive/indeterminate

h) IR = initially reactive

i) RR = repeatedly reactive

j) Patients with monoclonal gammopathy: 1 out of 21

Clinical sensitivity

Of 179 HIV samples from early seroconversion phase (according to CTS definition), 172 samples were found positive with the Elecsys HIV combi PT assay.

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Of 1532 samples from HIV infected patients in different stages of the disease and infected with HIV-1 group M, O and HIV-2, 1532 were found to be reactive with the Elecsys HIV combi PT assay. The sensitivity of the Elecsys HIV combi PT assay in this study was 100 %.

The 95 % lower confidence limit was 99.76 %.

| Group | N | Reactive |
|---|-----|----------|
| HIV-1 infected persons from various stages of disease | 338 | 338 |
| Infection with HIV-1 group M (subtypes A-J) | 629 | 629 |
| Infection with HIV-1 group O | 8 | 8 |
| Infection with HIV-2 | 472 | 472 |
| HIV Ag positive specimens | 85 | 85 |

* 255 subtype B samples, 2 subtypes H and 1 subtype J were tested; serotyping or genotyping were used for subtype determination

53 lysates of cell culture supernatants including different HIV-1 group M subtypes (A-H), HIV-1 group O, and HIV-2 were tested and found reactive in the Elecsys HIV combi PT assay.

In 46 panels of early HIV infections, 100 out of 105 samples were detected positive with the Elecsys HIV combi PT assay.

Clinical specificity

In a group of 7343 randomly selected blood donors from Europe and Asia the specificity of the Elecsys HIV combi PT assay was found 99.88 % (RR). The 95 % lower confidence limit was 99.77 %.

In a group of 4103 samples from unselected daily routine, dialysis patients and pregnant women the specificity of the Elecsys HIV combi PT assay was found 99.81 % (RR). The 95 % lower confidence limit was 99.62 %.

| | N | Elecsys HIV combi PT assay | | Western Blot ^{k)} | Clinical specificity (95 % lower confidence limit) |
|---------------------------------------|------|----------------------------|---------------|----------------------------|--|
| | | IR COI ≥ 1 | RR COI ≥ 1 | | |
| Blood donors | 7343 | 13 | 11 | 1/1 | 99.88 % (99.77 %) |
| Unselected samples from daily routine | 2721 | 33 | 33 | 26 | 99.74 % (99.47 %) |
| Dialysis patients | 251 | 1 | 1 | 0 | 99.60 % (97.80 %) |
| Pregnant women | 1131 | 1 | 1 | 1 | 100 % (99.67 %) |

k) Western Blot (WB) confirmed positive/indeterminate. Samples with indeterminate WB were excluded from calculation.

Seroconversion panels

Seroconversion sensitivity of the Elecsys HIV combi PT assay has been shown by testing 102 commercial seroconversion panels in comparison to registered HIV combi assays or anti-HIV immunoassays and/or HIV Ag assays.

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- Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 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.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information 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):

| | |
|--|---|
| | Contents of kit |
| | Analyzers/Instruments on which reagents can be used |
| | Reagent |
| | Calibrator |
| | Volume after reconstitution or mixing |
| | Global Trade Item Number |

Elecsys HIV combi PT

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