Elecsys HIV Duo
510(k) Summary
BK230804

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the Elecsys HIV Duo immunoassay on the **cobas e** 402 analyzer.

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Proprietary Name	Elecsys HIV Duo
Common Name	Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test
Classification Name	Test, HIV Detection
Product Code, Regulation Number	MZF, Regulation Number 866.3956
Predicate Device Number, Trade Name, Product Code	BP190403, Elecsys HIV Duo, MZF

1. DEVICE DESCRIPTION SUMMARY

The Elecsys HIV Duo is a qualitative serologic sandwich immunoassay intended for the detection and differentiation of HIV-1 p24 antigen and antibodies to HIV, HIV-1(group M, and group O) and HIV-2, in human serum and plasma. This assay design consists of two modules, one for detection of HIV-1 p24 antigen using monoclonal antibodies to (HIV-1) p24 and the second for detection of HIV-1 and HIV-2 antibodies using recombinant antigens derived from the Env and Pol-region of HIV-1 (including group O) and HIV-2. The immunoassay is based on the electrochemiluminescence immunoassay (ECLIA) principle.

For HIV Ag detection (HIVAG), 30 µL of sample react with biotinylated monoclonal anti-p24 antibodies and ruthenylated 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 HIV-specific recombinant antigens/peptides, to form a sandwich complex. The incubations are performed in parallel in two separate vessels.

In the second incubation step, after addition of streptavidin-coated microparticles and the complex becomes bound to the solid phase via interaction of biotin and streptavidin.

The reaction mixture is aspirated into the measuring cell of the analyzer where the micro particles are magnetically captured onto the surface of an electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode induces electrochemiluminescent emission which is measured by a photomultiplier.

The Elecsys HIV Duo immunoassay requires the use of quality control reagents, the Elecsys PreciControl HIV Gen II and the Elecsys PreciControl HIV; HIV-2+ Grp O. 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 calibrations. The Elecsys HIV Duo result is calculated automatically based on signal to cutoff ratios (cutoff index, COI) from HIV Ag and anti-HIV.

2. INTENDED USE/INDICATIONS FOR USE

Elecsys HIV Duo is an immunoassay intended for the in vitro simultaneous qualitative detection and differentiation of HIV-1 p24 antigen and antibodies to HIV, HIV-1 (groups M and O) and HIV-2 in human serum and plasma. Elecsys HIV Duo assay is intended to be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1/HIV-2 infection in subjects greater than 2 years of age and in pregnant women. Elecsys HIV Duo is not intended for the screening of donors of blood and blood components or human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Elecsys HIV Duo is an electrochemiluminescence immunoassay "ECLIA" intended for use on the **cobas e** 402 and **cobas e** 801 immunoassay analyzers.

3. INDICATIONS FOR USE COMPARISON

The intended use is the same as the predicate, with the exception that the **cobas e** 402 analyzer is being added to the intended use statement. The intended use population and assay targets are identical to the predicate. The reagent formulation has not changed. The **cobas e** 402 analyzer is being added to the method sheet is a member of the Elecsys instrument family and analytical performance data were produced to show equivalence.

4. TECHNOLOGICAL COMPARISON

The Elecsys HIV Duo immunoassay approved in conjunction with the **cobas e** 801 analyzer has the same technological characteristics when used on the **cobas e** 402 analyzer. The test principle, working solutions, traceability, calibration, quality control, and results calculation are identical. The differences between the instruments are to account for throughput differences (i.e. 300 tests/hour on the **cobas e** 801 analyzer and 120 tests/hour on the **cobas e** 402 analyzer). A summary of the technological differences between **cobas e** 801 and **cobas e** 402 is provided below in the table.

General Instrument Characteristic Differences	Device Elecsys HIV Duo **cobas e** 402 analyzer	Predicate Elecsys HIV Duo **cobas e** 801 analyzer
Throughput:	120 test/hour/module	300 test/hour/module
Sample capacity on-board:	50	300
On-board Reagent Capacity	Reagent compartment (rotor) for 28 reagent containers	Reagent compartment (rotor) for 48 reagent containers
System Cycle Time-Measuring Cell	30 seconds	24 seconds
Reagent Probes	1 polished steel probe	2 polished steel probes
Measuring Units/Channels	1	2

5. NON-CLINICAL AND/OR CLINICAL TEST SUMMARY & CONCLUSIONS

A summary of nonclinical performance testing associated with the Elecsys HIV Duo on **cobas e** 402 analyzer is as follows:

5.1. Precision

Precision measurements were conducted for five days to evaluate repeatability (within-run precision) and the intermediate precision (within-laboratory precision) were calculated following the guidelines of the CLSI EP05-A3. Samples tested included human specimens and controls measured on three lots of Elecsys HIV Duo reagent on one **cobas e** 402 analyzer. Measurements spanned multiple calibration events. Precision measurements were also conducted for five days to evaluate reproducibility. Testing occurred at three sites and with three lots (2 lots per site) of Elecsys HIV Duo reagent on one **cobas e** 402 analyzer per site. Repeatability, intermediate precision and reproducibility were calculated according to a modified version of CLSI EP05-A3.

For comparison, repeatability and intermediate precision data were collected on the predicate (Elecsys HIV Duo on the **cobas e** 801 analyzer).

All **cobas e** 402 results for repeatability and intermediate precision fulfill the acceptance criteria and show equivalent performance to the **cobas e** 801 analyzer.

5.2. Assay Limits

Limit of Blank was confirmed in accordance with CLSI Guideline EP17-A2. Five serum and five plasma analyte-free samples were tested in duplicate with two lots of Elecsys HIV Duo reagent, over six runs.

Limit of Detection was confirmed in accordance with CLSI Guideline EP17-A2. Five serum and five plasma low-level analyte samples were tested in duplicate with two lots of Elecsys HIV Duo reagent, over six runs.

The **cobas e** 402 results for assay limits fulfill the acceptance criteria and show equivalent performance to the **cobas e** 801 analyzer.

5.3. Cut-off (Antigen) Sensitivity

Cut-off (Antigen) Sensitivity was tested with three lots of Elecsys HIV Duo reagent on one **cobas e** 801 analyzer and one **cobas e** 402 analyzer. Samples tested in duplicate included dilutions of standards and an HIV Antigen Panel.

The acceptance criteria for antigen sensitivity is fulfilled for the Elecsys HIV Duo main results and the HIVAG module sub-results on the **cobas e** 402 and **cobas e** 801 analyzers.

5.4. Recovery of Controls

Recovery of Controls was tested with one lot of Elecsys HIV Duo reagents, five controls, over two runs on two analyzers.

The data demonstrated that the recovery of the values for PreciControl HIV Gen II and PreciControl HIV; HIV-2+GrpO generated on the **cobas e** 402 analyzers are within the assigned target ranges.

5.5. Seroconversion Sensitivity

Seroconversion sensitivity was tested with 20 panels, including early seroconversion samples. Testing include one reagent lot of Elecsys HIV Duo reagent on both the **cobas e** 402 (candidate) analyzer and the **cobas e** 801 analyzer (predicate). The resulting data was assessed to confirm that the switch from negative to positive bleeds in a panel occurred on the same day and/or same bleed.

The seroconversion sensitivity study showed no discrepant results for the Elecsys HIV Duo assay on the **cobas e** 402 analyzer (candidate) versus the **cobas e** 801 analyzer (predicate).

5.6. Method Comparison (MC)

Method Comparison was performed to evaluate the equivalency of performance of the Elecsys HIV Duo immunoassay, main result, on the **cobas e** 402 (one analyzer at each of three sites) and **cobas e** 801 analyzers (2 analyzers). Testing was performed using one lot of reagents with 101 negative and 291 positive samples. 73 anti-HIV-1 group M, 41 anti-HIV group O, 60 anti-HIV-2, 117 HIV Antigen, and 101 negative samples were included. Analysis for each site was conducted separately and a combined analysis for all system configurations was provided. The final status of samples tested on the **cobas e** 402 was determined, in the case of discordant results among the three sites, as the result produced by two out of the three sites. The combined negative percent agreement was 100.00%, while the combined positive percent agreement was 99.39%. with one discordant result.

A summary of individual sites and combined method comparisons can be found in the table below:

	Samples	**MC 1**	**MC 2**	**MC 3**	**MC 4 (combined)**	**Acceptance criteria**
Negative % Agreement	negative	100.00%	100.00%	100.00%	100.00%	-
Positive % Agreement	positive	98.78%	99.39%	100.00%	99.39%	-
Lower limit of two-sided 95% CI of agreement rates	negative	98.34%	98.34%	98.34%	98.34%	≥ 90%
	positive	95.66%	96.63%	97.71%	96.63%	≥ 90%

In addition, the data was analyzed for the subresults (i.e., HIV Antigen and Anti-HIV). Overall agreement ≥ 95 % of results with reference reported result “neg.” or “pos.” were found to be within the respective range. One discordant sample was generated in the anti-HIV subset.

6. CONCLUSIONS

Predefined acceptance criteria were met. Data supports the equivalence of the Elecsys HIV Duo immunoassay on both the **cobas e** 801 and the **cobas e** 402 immunoassay analyzers.

As the Elecsys HIV Duo immunoassay reagents and intended use populations have not changed, additional clinical studies were not completed. Non-clinical studies were used to show performance of the additional analyzer (i.e, the **cobas e** 402 analyzer).

The nonclinical performance testing and method comparison study support a conclusion of substantial equivalence between the Elecsys HIV Duo immunoassay on the candidate (**cobas e** 402) and predicate (**cobas e** 801) analyzers.