Elecsys Syphilis
Elecsys Anti-CMV
cobas® pro Serology Solution

510(k) Summary - BK251280

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

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Proprietary Name	Elecsys Syphilis, Elecsys Anti-CMV, cobas® pro Serology Solution
Common Name	Syphilis Assay, CMV assay
Classification Name	test, donor, syphilis, antigens, treponemal; test, donor, cmv
Product Codes	MYR, 21 CFR 866.3830; MZE, 21 CFR 866.3175
Predicate Devices	BK241148, Elecsys Syphilis, Elecsys Anti-CMV, cobas® pro Serology Solution
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126 Roche Diagnostics GmbH Penzberg, Germany: 9610529 Roche Diagnostics Indianapolis, IN United States: 1823260.

1. DEVICE DESCRIPTION

This Special 510(k) submission describes the software changes for the serology controller from version 1.2.2 to 1.2.3 in the cobas pro Serology Solution. There are no changes to the cobas pro core software, which remains version 02-03. The cobas pro serology solution is a combination of the cobas pro serology controller, cobas pro integrated solutions (cobas e 801 analytical units only) and applicable licensed blood screening assays. The system automates electrochemiluminescence immunoassay test processing, result interpretation, and data management functions for screening of donations of whole blood and blood components using plasma or serum samples. The software changes are applicable for the Elecsys Syphilis assay and the Elecsys Anti-CMV assay. These assays are intended to screen individual human donors, including volunteer donors of whole blood, and blood components. This Special 510(k) does not introduce changes to the intended use and does not propose changes to the reagents used in these two assays.

2. INDICATIONS FOR USE

Syphilis Assay:

Elecsys Syphilis is an in vitro immunoassay for the qualitative detection of total antibodies (IgG and IgM) to Treponema pallidum in human serum and plasma. Elecsys Syphilis is intended to screen individual human donors including volunteer donors of whole blood and blood components. This test is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens.

The electrochemiluminescence immunoassay "ECLIA" is intended for use with the cobas pro serology solution equipped with cobas e 801 analytical unit.

Anti-CMV Assay:

Elecsys Anti-CMV is an in vitro immunoassay for the qualitative detection of antibodies to Cytomegalovirus in human serum and plasma. Elecsys Anti-CMV is intended to screen individual human donors, including volunteer donors of whole blood, and blood components. This test is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens.

The electrochemiluminescence immunoassay “ECLIA” is intended with cobas pro serology solution equipped with the cobas e 801 analytical unit.

cobas pro serology solution:

The cobas pro serology solution is a combination of the cobas pro serology controller, cobas pro integrated solutions (cobas e 801 analytical units only) and applicable licensed blood screening assays. The system automates electrochemiluminescence immunoassay test processing, result interpretation, and data management functions for screening of donations of whole blood and blood components using plasma or serum samples. The system is intended for use only with licensed blood screening assays in US donor screening laboratories and plasma fractionators. It is intended for use only by personnel who are trained in its operation. The cobas pro serology solution is intended to be used by trained laboratory technicians. Intended customers of the cobas pro serology controller used in combination with cobas pro integrated solutions (cobas e 801 analytical units only) are donor screening and plasma fractionation companies in the United States.

3. TECHNOLOGICAL CHARACTERISTICS

The primary purpose of this submission is to submit software changes to the serology controller, a component of the cobas pro serology solution system, which impacts the Elecsys Syphilis and Elecsys Anti-CMV. The software was updated for the serology controller software application from version 1.2.2 to 1.2.3 in order to resolve two issues for tests that require release quality controls (QC): missing calculated QC results, and connection interruption. These two issues were identified with the release QC measurement procedure that could lead to batch results being released when they should have been invalidated. Software verification and validation testing, and related risk analysis, were conducted to evaluate the software update. The cobas pro software remains the same (version 02-03). There are no changes to the assay reagents. No changes were made to the intended use or indications for use for the two assays, and the Instructions for Use was not changed. The manual was updated to indicate changes to the release QC procedure. The following tables provide a technical comparison of the Elecsys Syphilis, the Elecsys Anti-CMV, and the cobas pro Serology Solution to their respective predicate device.

Table 1: Similarities and Differences between the Elecsys Syphilis (Candidate Device) and Elecsys Syphilis (BK241148).

Comparator	Candidate Device: Elecsys Syphilis	Predicate Device: Elecsys Syphilis (BK241148)
Intended Use	Elecsys Syphilis is an in vitro immunoassay for the qualitative detection of total antibodies (IgG and IgM) to Treponema pallidum in human serum and plasma. Elecsys Syphilis is intended to screen individual human donors including volunteer donors of whole blood and blood components. This test is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens. The electrochemiluminescence immunoassay "ECLIA" is intended for use with the cobas pro serology solution equipped with cobas e 801 analytical unit	Same
Assay Method	Double antigen sandwich assay	Same
Detection Method	**e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA"	Same
Applications/Test Time	18 minutes	Same
Instrument Platform	**cobas pro** serology solution	Same
Sample Type	Human serum, plasma	Same
Sample Anticoagulants	Li Heparin, K2EDTA, K3EDTA, CPD, and Na Citrate	Same
Controls	PreciControl Syphilis PreciControl Release Syphilis	Same
Control usage	Due to possible evaporation effects, not more than 4 quality control procedures per vial should be performed.	Same

Table 2: Similarities and Differences between the Elecsys Anti-CMV (Candidate Device) and Elecsys Anti-CMV (BK241148).

Comparator	Candidate Device: Elecsys Anti-CMV	Predicate Device: Elecsys Anti-CMV (BK241148)
Intended Use	Elecsys Anti-CMV is an in vitro immunoassay for the qualitative detection of antibodies to Cytomegalovirus in human serum and plasma. Elecsys Anti-CMV is intended to screen individual human donors, including volunteer donors of whole blood, and blood components. This test is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens. The electrochemiluminescence immunoassay "ECLIA" is intended with cobas pro serology solution equipped with the cobas e 801 analytical unit.	Same
Assay Method	Double antigen sandwich principle	Same
Detection Method	**e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA"	Same
Applications/Test Time	18 minutes	Same
Instrument Platform	**cobas pro** serology solution	Same
Sample Type	Serum and plasma	Same
Sample Anticoagulants	Li Heparin, K2EDTA, K3EDTA, CPD and Na Citrate	Same
Controls	PreciControl CMV IgG PreciControl Release CMV IgG	Same
Control usage	Due to possible evaporation effects, not more than 4 quality control procedures per vial should be performed.	Same

Table 3: Technical Characteristics Comparison Table between cobas pro serology solution in BK241148 versus the Candidate Device.

Comparator	Candidate Device: cobas® pro serology solution	Predicate Device: cobas® pro serology solution (BK241148)
BASIC FEATURES		

Comparator	Candidate Device: cobas® pro serology solution	Predicate Device: cobas® pro serology solution (BK241148)
Intended Use	Fully automated immunoassay analyzer intended for the in vitro quantitative/ qualitative determination of analytes in body fluids.	same
Measurement principle	ECLIA	same
Workflow principle	Batch/random	same
Throughput	300 tests/hour/module	same
Analyzer size	Floor model	same
Configurations	Modular	same
SAMPLE HANDLING		
Typical sample volumes	4-60 µL	same
Sample types	Serum, plasma, urine and other water based liquid samples, e.g. CSF	same
Sample handling system	Input and transport of samples using universal sample racks, modular sample buffer input, core/transportation unit and STAT port	same
Sample capacity onboard	300	same
Sample identification	Barcode or Rack Position	same
Assay cups	disposable	same
REAGENT HANDLING		
Reagent volume	6-60 µL	same
Reagent container	Plastic bottles closed via snap caps	same
Reagent access	Snap caps opened by instrument	same
Reagent kits	E packs	same
No. of channels	48	same
On-board storage temperature	5-10 °C	same
On-board evaporation protection	automatically opened & closed	same
Reagent bottle/Cassette ID	RFID	same
On-board reagent capacity storage	Reagent compartment (rotor) for 48 reagent containers onboard	same
System reagents	ProCell, CleanCell, Sys Clean, PreClean,	same
System cycle time measuring cell	24 sec	same
Auto rerun	available	same
Application information transfer to instrument	Electronic transfer via cobas link	same

Comparator	Candidate Device: cobas® pro serology solution	Predicate Device: cobas® pro serology solution (BK241148)
PIPETTING SYSTEM		
Reagent probes	2 polished steel probes	same
Sample probes	Steel probe with disposable tip	same
Probe cleaning	Automatic for reagent probe	same
Liquid level detection	Capacitance for sample and reagents	same
Clot detection	Yes	same
TEST REACTION CHAMBER		
Temperature control	Incubation at 37oC	same
Timing	9 min, 18 min and 27 min	same
DETECTION INFORMATION		
Measuring units/Channels	2	same
Detection unit	ECL unit with sipper, measuring cell and photomultiplier	same
CALIBRATION AND QUALITY CONTROL		
Calibrators	single use	same
Calibration modes	2 point recalibration (3,4,5 pt. cal. optional)	same
Calibration stability	Up to 12 weeks	same
On-board QC	No	same
Control storage on instrument	No	same
Calibrator/ control value transfer	Via remote transfer	same
INTERFACES		
Host interface	Ethernet (HL7)	same
Printer	Laser	same
Display	Touch-screen without physical keyboard and mouse	same
cobas pro SOFTWARE		
Software Version	cobas pro modular system software Version 02-03	same
Configuration	One PC and one core in combination with several e-modules or c analytical modules	same
Units controlled	cobas pro c 503, cobas pro ISE and cobas e 801	same
Operating System	Windows 10	same
PC (Controller Unit) functions	Data input (keyboard, disc), data output (screen, printer)	same

Comparator	Candidate Device: cobas® pro serology solution	Predicate Device: cobas® pro serology solution (BK241148)
Core unit functions	Real time database, data input and output (via Data Manager communication), control of sample conveyor	same
Analytical unit(s) functions	Control of analytic processes (pipetting, incubation, detection) and primary signal processing	same
Data storage	Real time database in Core unit (storage of System and Application parameters, Calibration Data, QC Data, Sample results, Alarm history)	same
Software-controlled test countdown	Available	same
Result calculation	Automated measuring of ECL signal and automated calculation of concentrations via calibration curve	same
Flagging of errors	available	same
Serology Controller Software		
Software Version	Serology Controller version 1.2.3	Serology Controller version 1.2.2
Capacity	control of up to 20 cobas pro quad lines/40 cobas pro dual lines	same
Workstation terminal	workstation terminal to operate up to 4 cobas pro lines	same
Analytical units managed	Control of up to 80 analytical modules (either 20 core units with 4x e801 modules each, or 40 core units with 2x e801 modules each)	same
Server	Multiple servers, high availability server environment with built-in redundancy	same
Operating System	Server: Windows Server 2019 (64-bit) Workstation: Windows 10 Enterprise LTSC (64-bit)	same

4. NON-CLINICAL PERFORMANCE EVALUATION

No non-clinical testing was performed as there were no changes to the assay reagents.

5. CLINICAL PERFORMANCE EVALUATION

No clinical testing was performed as there were no changes to the assay reagents.

6. CONCLUSIONS

As the Elecsys Syphilis and Elecsys Anti-CMV assay reagents and intended use population have not changed, additional clinical and non-clinical studies were not performed. Software verification and validation testing and related risk analysis were conducted, and the results demonstrated that the cobas Elecsys Syphilis and the Elecsys Anti-CMV with the updated software version 1.2.3 of cobas pro Serology Solution are as safe, as effective, and perform as well as the predicate devices.