Elecsys Syphilis
510(k) Summary

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

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification 510(k).

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the addition of the source plasma claim to the Elecsys Syphilis intended use.

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Date Prepared	September 15, 2023
Proprietary Name	Elecsys Syphilis
Common Name	Treponema pallidum serological reagents
Classification Name	Test, Donor, Syphilis
Product Codes, Regulation Numbers	MYR, 21 CFR 866.3830
Predicate Devices	Elecsys Syphilis
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126 Roche Diagnostics GmbH Penzberg, Germany: 9610529 Roche Diagnostics Indianapolis, IN United States: 1823260.

1. DEVICE DESCRIPTION

Elecsys Syphilis is a double antigen sandwich immunoassay with streptavidin microparticles, biotinylated recombinant TP-specific antigen labeled with a ruthenium complex and electrochemiluminescence detection. The 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. Results greater than or equal to 1.0 COI are considered reactive for Treponema pallidum antibody. The test system contains the calibrators intended for use with the system

Elecsys Syphilis working solutions include:

- Streptavidin-coated microparticles
- Reagent 1 (biotinylated TP-specific recombinant antigens)
- Reagent 2 (ruthenium labeled TP-specific recombinant antigens)

Note: The reagent and calibrators are packaged together in the Elecsys Syphilis assay kit, while the associated PreciControl Syphilis and PreciControl Release Syphilis are packaged separately.

2. INDICATIONS FOR 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, blood components, and source plasma. 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.

3. TECHNOLOGICAL CHARACTERISTICS

Table 1: Technical Characteristics Comparison Table between Elecsys Syphilis (Candidate Device) and Elecsys Syphilis (BK230839)

Feature	**Candidate Device Elecsys Syphilis**	**Predicate Device Elecsys Syphilis (BK230839)**
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, blood components, and source plasma. 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.	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.
Assay Method	Double antigen sandwich assay	Same
Detection Method	electrochemiluminescence immunoassay "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, K_2-EDTA, K_3-EDTA, CPD and Na-citrate	Same
Controls	PreciControl Syphilis PreciControl Release Syphilis	Same
Plasmapheresis samples used in studies	Yes	No

Feature	Candidate Device Elecsys Syphilis	Predicate Device Elecsys Syphilis (BK230839)
Source plasma specificity	A total of 3089 source plasma samples from donors with a non reactive nontreponemal (lipoidal antigen) test of record were collected and tested using the Elecsys Syphilis assay. All initial reactive samples were repeat reactive; therefore, the initial negative percent agreement to the non reactive nontreponemal (lipoidal antigen) test of record for the source plasma specimens was 97.83 % (3022/3089). Repeatedly reactive specimens were further tested using treponemal Syphilis immunoassays. Based on supplemental test results, 59 specimens were positive and 8 specimens were negative for anti treponemal antibodies. The false reactive rate in source plasma donors was estimated in this study to be 0.26 % (8/3030).	NA

4. EXTERNAL (CLINICAL) TESTING

4.1. Clinical Specificity

A total of 3089 source plasma samples from donors with a non-reactive nontreponemal (lipoidal antigen) test of record were collected and tested using the Elecsys Syphilis assay. All initial reactive samples were repeat reactive; therefore, the initial negative percent agreement to the non-reactive nontreponemal (lipoidal antigen) test of record for the source plasma specimens was calculated to be 97.83% (3022/3089) with a 95% confidence interval of 97.25% to 98.29%. The 67 repeatedly reactive specimens were further tested using treponemal Syphilis immunoassays. Two FDA-cleared treponemal Syphilis immunoassays were used to evaluate the cobas® Elecsys Syphilis repeat reactive specimens. Resolution of discrepant results obtained between these two assays were resolved using a third FDA-cleared treponemal Syphilis immunoassay. The final result was derived from the majority results obtained (i.e., two out of three test results). The results obtained are shown in Table 2 below.

Table 2: Agreement of the cobas® Elecsys Syphilis assay with the additional treponemal Syphilis testing.

		Final Results		
		Reactive (R)	NR	
Elecsys Syphilis	Repeat Reactive	59	8	67
	Non-reactive (NR)	0	3022	3022
	Total	59	3030	3089

Based on additional test results, 59 specimens were positive, and 8 specimens were negative for anti-treponemal antibodies. The false reactive rate in source plasma donors was estimated in this study to be 0.26% (8/3030). Therefore, the negative percent agreement to the treponemal test for the source plasma specimen was calculated to be 99.74% (3022/3030) with a 95% confidence interval of 99.48% to 99.87%.

5. CONCLUSIONS

As the **cobas®** Elecsys Syphilis assay reagents were not changed, additional analytical studies were not performed. As the intended use population was extended to include source plasma donors, an additional clinical study was performed to evaluate the specificity of the device with source plasma specimens. The results demonstrated that the **cobas®** Elecsys Syphilis device is as safe, as effective, and performs as well as the predicate device.