Elecsys Anti-CMV
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 Elecsys Anti-CMV.

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Proprietary Name	Elecsys Anti-CMV PreciControl Anti-CMV PreciControl Release Anti-CMV
Common Name	Cytomegalovirus serological reagents
Classification Name	Test, Donor, CMV
Product Codes, Regulation Numbers	MZE, 21 CFR 866.3175
Predicate Devices	Beckman Coulter PK CMV-PA System
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 Anti-CMV is a double antigen sandwich immunoassay with streptavidin microparticles, biotinylated recombinant CMV-specific antigens and recombinant CMV-specific antigens labeled with a ruthenium complex for 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 anti-CMV antibodies. The test system contains the human serum-based calibrators intended for use with the system.

1.1. Elecsys Anti-CMV

The reagent working solutions include:

Reagent **cobas e** pack (kit placed on the analytical unit)

- M Streptavidin-coated microparticles, 1 bottle, 14.1 mL:
  Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 CMV-Ag~biotin, 1 bottle, 18.8 mL:
  Biotinylated CMV-specific antigen (recombinant, *E. coli*), > 400 µg/L, MES[b)] buffer 50 mmol/L, pH 6.5; preservative.
- R2 CMV-Ag~Ru(bpy) , 1 bottle, 18.8 mL:
  CMV-specific antigen (recombinant, *E. coli*) labeled with ruthenium complex > 400 µg/L; MES buffer 50 mmol/L, pH 6.5; preservative.

b) MES = 2-morpholino-ethane sulfonic acid

Calibrators (packed with the reagent **cobas e** pack)

- ACMVB Cal1
  Non-reactive calibrator 1, 2 vials of 1.0 mL each:
  Human serum, non-reactive for anti-CMV antibodies;
  preservative.

- ACMVB Cal2
  Reactive calibrator 2, 2 vials of 1.0 mL each:
  Human serum, reactive for anti-CMV antibodies;
  preservative.

1.2. PreciControl Anti-CMV

The PreciControl Anti-CMV is a ready-for-use control serum based on human serum, containing one control level reactive for anti-CMV antibodies, and one control level non-reactive for anti-CMV antibodies. The controls are used for monitoring the accuracy of the Elecsys Anti-CMV immunoassay.

1.3. PreciControl Release Anti-CMV

The PreciControl Release Anti-CMV is a ready-for-use control serum based on human serum, reactive for anti-CMV antibodies. The control is used to validate the **cobas pro** serology solution and to release sample results for the Elecsys Anti-CMV immunoassay.

2. INDICATIONS FOR USE

2.1. Elecsys Anti-CMV

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 **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended with **cobas pro** serology solution equipped with the **cobas e** 801 analytical unit.

2.2. PreciControl Anti-CMV

PreciControl Anti-CMV is used for quality control of the Elecsys Anti-CMV immunoassay on **cobas pro** serology solution.

2.3. PreciControl Release Anti-CMV

PreciControl Release Anti-CMV is used to validate the **cobas pro** serology solution and to release sample results for the Elecsys Anti-CMV immunoassay. The recovery of the release control within Roche specified limits ensures the specified sensitivity of the assay under customer site conditions.

The release control is tested at user-defined intervals with a maximum span of every 300 samples or 350 determinations and must be tested in order to release the test results. For release control values that fall outside the defined limits, samples measured before a failed release control are flagged as invalid by the **cobas pro** serology controller and need to be repeated. Reactive results will not be invalidated by a failed release control and must be retested in duplicate.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the Elecsys Anti-CMV with its predicate device, Beckman Coulter PK CMV-PA System (BK200476).

Table 1: Technical Characteristics Comparison Table between Elecsys Anti-CMV and PK CMV-PA System

Feature	Candidate Device Elecsys Anti-CMV	Predicate Device Beckman Coulter PK CMV-PA System (BK200476)
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 **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use with **cobas pro** serology solution equipped with the **cobas e** 801 analytical unit.	The PK CMV-PA System is a passive particle agglutination assay intended for the qualitative detection of IgG and IgM antibodies to cytomegalovirus (CMV) in human EDTA plasma and serum from blood donors using the Beckman Coulter PK7300 and/or PK7400 Automated Microplate Systems. This test is not intended for diagnostic use.
Assay Method	Double antigen sandwich principle	Passive particle agglutination

Feature	Candidate Device Elecsys Anti-CMV	Predicate Device Beckman Coulter PK CMV-PA System (BK200476)
Detection Method	**e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA"	Photometric
Applications/Test Time	18 minutes	60 minutes
Instrument Platform	**cobas pro** serology solution	PK7300 and/or PK7400
Sample Type	Serum and plasma	Serum and plasma
Sample Anticoagulants	Li-heparin, K_2-EDTA, K_3-EDTA, CPD and Na-citrate	EDTA
Controls	PreciControl Anti-CMV PreciControl Release Anti-CMV	PK CMV-PA System Controls
Reagent Stability	Unopened at 2-8 ºC = up to the stated expiration date On the **cobas e** 801 analytical unit = 16 weeks	Unopened at 2-8 ºC = up to the stated expiration date Reconstituted = stable for 7 days at 2-8 ºC

4. NON-CLINICAL PERFORMANCE EVALUATION

The following performance data are provided in support of the substantial equivalence determination:

- Analytical sensitivity
- Sample handling and preparation
- Analytical specificity
- Cross-Reactivity
- Matrix equivalency
- Stability

All performance specifications were met.

4.1. Analytical Sensitivity – Limit of Blank (LoB) and Limit of Detection (LoD)

The Limit of Blank (LoB) and Limit of Detection (LoD) were determined in accordance with CLSI guideline EP17-A2 - Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition.

The limit of blank (LoB): LoB for the Elecsys Anti-CMV assay was estimated using five analyte-free serum and five analyte-free plasma samples measured with one reagent kit lot in duplicate determination over 3 days and six runs on one **cobas e** 801 analytical unit. Sixty measured values of analyte-free samples were obtained. The LoB for serum was determined to be 0.110 COI and the LoB for plasma was determined to be 0.122 COI. Results for LoB for serum and plasma met the acceptance criteria.

The limit of detection (LoD): LoD for the Elecsys Anti-CMV assay was estimated using five serum and five plasma samples with low-analyte concentration (approximately four times the LoB) measured with one lot of Elecsys Anti-CMV in duplicate determination over 3 days in six runs on one **cobas e** 801 analytical unit. Sixty measured values of samples with low analyte concentration were obtained. The LoD for serum was determined to be 0.126 COI and the LoD for plasma was determined to be 0.193 COI. Results for LoD for serum and plasma met the acceptance criteria.

4.2. Sample handling and preparation

Only the following specimens listed were tested and found acceptable.

Serum and Li-heparin, K_2-EDTA, K_3-EDTA, CPD and Na-citrate plasma collected using standard sampling tubes.

Serum and Li-heparin, K_2-EDTA plasma collected in tubes containing separating gel.

Stable on-the-clot for 7 days at 15-30°C and 14 days at 2-8°C. Do not freeze samples on-the-clot.

Samples off-the-clot are stable for 7 days at 20-25°C, 14 days at 2-8°C and 12 months at -20°C (± 5°C). Samples off-the-clot may be frozen up to four times.

All whole-blood samples and samples containing precipitates need to be centrifuged before performing the assay for 10 to 15 minutes at 2000 to 4000 RCF (relative centrifugal force = x g).

4.3. Analytical specificity

4.3.1. Endogenous Interferences

The effect of the following endogenous substances on assay performance was tested with the Elecsys Anti-CMV on the **cobas e** 801 analytical unit. The interfering agents were tested using native or spiked serum samples. For each interfering substance five sample replicates of three human serum samples (anti-CMV non-reactive, and two Anti-CMV reactive with one near the cutoff and one above the cutoff) were tested with one reagent kit lot. The mean recovery (absolute deviation or percent recovery) was calculated for each sample compared to the expected (reference) value.

Interferences were tested up to the listed concentrations and no impact on results was observed.

Table 2: Endogenous interferents and concentrations tested

Compound	Concentration tested
Bilirubin	≤ 753 µmol/L or ≤ 44 mg/dL
Hemoglobin	≤ 0.311 mmol/L or ≤ 500 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
Albumin	≤ 7.0 g/dL

Additionally, 50 samples with naturally elevated levels of bilirubin, rheumatoid factor, triglycerides (lipemic), hemoglobin (hemolyzed), and albumin were tested with the Elecsys Anti-CMV assay on the **cobas e** 801 analytical unit. For each interfering substance 10 human serum samples with naturally elevated levels of the interferent were tested in single determination with 1 reagent kit lot; no false reactive results were found.

4.3.2. Drug Interference

Seventeen common therapeutic drugs and two special pharmaceutical compounds were tested for potential interference. Each drug tested was spiked into one anti-CMV non-reactive sample and one anti-CMV reactive sample. Samples were tested in five replicates and compared to unspiked serum (reference).

Table 3: Drugs tested for interference and concentrations claimed

Compound	Tested Concentration
Acetylcysteine	150 mg/L
Acetylsalicylic Acid	30 mg/L
Ampicillin-Na	75 mg/L
Ascorbic acid	52.5 mg/L
Cefoxitin	750 mg/L
Doxycycline	18 mg/L
Heparin	3300 IU/L
Levodopa	7.5 mg/L
Methyldopa	22.5 mg/L
Metronidazole	123 mg/L
Rifampicin	48 mg/L
Acetaminophen	156 mg/L
Cyclosporine	1.8 mg/L
Ibuprofen	219 mg/L
Theophylline	60 mg/L
Phenylbutazone	321 mg/L
Itraconazole	30 mg/L
Ganciclovir	800 mg/L
Valganciclovir	900 mg/L

4.3.3. High Dose Hook Effect

A study was conducted to evaluate whether high dose hook effect can result in false non-reactive results using Elecsys Anti-CMV. Three high titer reactive samples were diluted in non-reactive serum in 12 dilution steps to generate a dilution series that covers the range from low-reactive to high reactive COI values. The diluted samples were measured on one **cobas e** 801 analytical unit in three-fold determination with one lot of Elecsys Anti-CMV. No false non-reactive result due to high dose hook effect was found with the Elecsys Anti-CMV assay.

4.4. Cross-Reactivity

A total of 112 samples containing potentially interfering factors were tested with the Elecsys Anti-CMV assay on the **cobas e** 801 analytical unit comprising specimens:

- containing antibodies against EBV, HAV, HBV, HCV, HTLV, HSV, and Rubella,

- containing antibodies against *Toxoplasma gondii, Treponema pallidum*
- after vaccination against influenza

One discrepant reactive result was observed for the *Treponema pallidum* cohort (1/11 tested samples) and one for the vaccination against influenza cohort (1/21 tested samples).

4.5. Matrix Equivalency

Serum/Plasma Comparison: Serum/plasma comparison studies were conducted to examine the suitability of the following anti-coagulants for use with the Elecsys Anti-CMV assay: K_2-EDTA plasma, K_3-EDTA plasma, Li-heparin plasma, Na-citrate plasma (39 sample pairs each including 23 reactive / non-reactive native specimens and 16 reactive / non-reactive spiked samples), and CPD plasma (38 sample pairs each including 16 reactive / non-reactive native specimens and 22 reactive / non-reactive spiked samples). Samples were collected into serum and plasma collection tubes and measured in single determination using the Elecsys Anti-CMV assay.

Recovery of each plasma sample compared to the matching serum sample (reference) was calculated on individual pairs. Serum, and Li-heparin, K_2-EDTA, K_3-EDTA, CPD and Na-citrate plasma collected using standard sampling tubes can be used with the Elecsys Anti-CMV assay. Sampling devices containing liquid anticoagulants may have a dilution effect resulting in lower COI values for individual specimens.

Serum/Plasma Comparison Study for Separation Tubes: The suitability of serum separation tubes and plasma tubes, K_2-EDTA/Li-heparin, with separating gel was tested by comparing them to tubes without separating gel (reference). Six sample pairs per tube types were measured in duplicate with one reagent lot using the Elecsys Anti-CMV assay. Recovery was calculated on individual pairs and compared to the reference. Serum and Li-heparin, K_2-EDTA, K_3-EDTA, CPD and Na-citrate plasma collected using standard sampling tubes can be used with the Elecsys Anti-CMV assay.

4.6. Stability

Kit stability (unopened): Kit stability/shelf-life was determined using three production lots of the Elecsys Anti-CMV **cobas e** pack stored refrigerated at 2-8°C, using nine samples (non-reactive

and reactive samples) and the PreciControls (PC CMVG0 B and PC CMVG3 B) in duplicate on the **cobas e** 801 analytical unit. The stability data support real-time (shelf-life) kit stability of 15 months at 2-8°C.

On-board (In-use) stability: An on-board stability study was performed for the Elecsys Anti-CMV **cobas e** pack to determine the time the reagent kit can be kept on-board the **cobas e** 801 analytical unit once opened. The study was performed with three non-reactive specimen, six Anti-CMV reactive specimens (COI ranged from 1.05 to 637) and the PreciControls (PC CMVG0 B and PC CMVG3 B). Samples were tested in duplicate after storage on-board for the specified time. Percent recovery for each sample was calculated compared to the unstressed Elecsys Anti-CMV **cobas e** pack. The stability data support on-board stability up to 16 weeks.

PreciControl Stability (Shelf-life): Kit stability/shelf-life was determined using three production lots of the PreciControl Anti-CMV stored refrigerated at 2-8°C. PreciControls (PC CMVG0 B and PC CMVG3 B) were tested in triplicate on the **cobas e** 801 analytical unit. The stability data support real-time (shelf-life) stability of 15 months at 2-8°C.

PreciControl On-board (In-use) Stability: On-board (In-use) stability was determined using one production lot of the PreciControl Anti-CMV. PreciControls (PC CMVG0 B and PC CMVG3 B) were tested in duplicate on the **cobas e** 801 analytical unit. Controls were stored at 20-25 °C and retested in duplicate at 5 hours and 6 hours. The stability data support on-board stability up to 5 hours.

5. PRECISION

Precision was determined using Elecsys reagents, pooled human sera, and controls in a protocol based on CLSI EP05-A3 - Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition: 2 runs per day in duplicate each for 21 days (n = 84). Precision of the Elecsys Anti-CMV assay demonstrated minor variability from run to run, day to day and between reagent lots. The following results were obtained.

Table 4: Repeatability and between run precision for Elecsys Anti-CMV

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Between run SD (COI)	Between run % CV
HSP 01[c)]	0.304	0.00470	1.5	0.00341	1.1
HSP 02	0.919	0.0209	2.3	0.0126	1.4
HSP 03	1.04	0.0214	2.1	0.00000	0.0
HSP 04	1.25	0.0361	2.9	0.00000	0.0
HSP 05	1.69	0.410	2.4	0.0197	1.2
HSP 06	15.1	0.293	1.9	0.133	0.9
HSP 07	416	5.36	1.3	4.48	1.1
HSP 08	616	5.15	0.8	6.93	1.1
HSP 09	0.56	0.0228	2.7	0.0136	1.6
PC ACMV0 B[d)]	0.113	0.00340	3.0	0.00000	0.0
PC ACMV3 B	3.60	0.329	0.9	0.0483	1.3

c) HSP = human specimens
d) PC = PreciControl

Table 5: Between day and intermediate precision for Elecsys Anti-CMV

Sample	Mean (COI)	Between day SD (COI)	Between day % CV	Intermediate precision SD (COI)	Intermediate precision % CV
HSP 01[c)]	0.304	0.00261	0.9	0.00636	2.1
HSP 02	0.919	0.0134	1.5	0.0278	3.0
HSP 03	1.04	0.0137	1.3	0.0254	2.4
HSP 04	1.25	0.0226	1.8	0.0426	3.4
HSP 05	1.69	0.0143	0.8	0.0477	2.8
HSP 06	15.1	0.245	1.6	0.404	2.7
HSP 07	416	0.00	0.0	6.98	1.7
HSP 08	616	5.58	0.9	10.3	1.7
HSP 09	0.56	0.0106	1.2	0.0286	3.3
PC ACMV0 B[d)]	0.113	0.00174	1.5	0.00382	3.4
PC ACMV3 B	3.60	0.0481	1.3	0.0757	2.1

c) HSP = human specimens
d) PC = PreciControl

6. EXTERNAL (CLINICAL) TESTING

6.1. Reproducibility

A study was performed based on guidance from CLSI EP05-A3 -Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition . Testing was conducted at three external sites using three lots of the Elecsys Anti-CMV reagent kit and one lot each of PreciControl Anti-CMV and of PreciControl Release Anti-CMV. Panel members andA study was performed based on guidance from CLSI EP05-A3 -Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition . Testing was conducted at three external sites using three lots of the Elecsys Anti-CMV reagent kit and one lot each of PreciControl Anti-CMV and of PreciControl Release Anti-CMV. Panel members and PreciControl Anti-CMV were tested in two runs per day for 5 days with three replicates per run. There were a total of 270 data points acquired. The reproducibility of the Elecsys Anti-CMV assay demonstrated minor variability from run to run, day to day, and between reagent lots. The results for the Elecsys Anti-CMV assay are presented in the following tables.

Table 6: Overall repeatability and reproducibility for Elecsys Anti-CMV

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Between run SD (COI)	Between run % CV
HSP 01[c)]	1.59	0.020	1.29	0.020	1.26
HSP 02	11.3	0.405	3.59	0.100	0.882
PC ACMV0 B[d)]	0.117	0.004	3.67	0.002	1.44
PC ACMV3 B	3.53	0.042	1.20	0.043	1.20

c) HSP = human specimens
d) PC = PreciControl

Table 7: Repeatability and between run precision for Elecsys Anti-CMV

Sample	Mean (COI)	Between day SD (COI)	Between day % CV	Intermediate precisionSD (COI)	Intermediate precision % CV
HSP 01[c)]	1.59	0.024	1.50	0.037	2.35
HSP 02	11.3	0.275	2.43	0.500	4.42
PC ACMV0 B[d)]	0.117	0.004	3.61	0.006	5.34
PC ACMV3 B	3.53	0.052	1.47	0.079	2.25

c) HSP = human specimens
d) PC = PreciControl

Table 8: Between site and between lot reproducibility for Elecsys Anti-CMV

Sample	Mean (COI)	Between site SD (COI)	Between site % CV	Between lot SD (COI)	Between lot % CV
HSP 01[c)]	1.59	0.015	0.975	0.048	3.02
HSP 02	11.3	0.152	1.35	0.646	5.72
PC ACMV0 B[d)]	0.117	0.002	1.52	0.010	8.90
PC ACMV3 B	3.53	0.046	1.31	0.050	1.43

c) HSP = human specimens
d) PC = PreciControl

Table 9: Overall reproducibility for Elecsys Anti-CMV

Sample	Mean (COI)	Reproducibilty SD (COI)	Reproducibility % CV
HSP 01[c)]	1.59	0.063	3.95
HSP 02	11.3	0.830	7.35
PC ACMV0 B[d)]	0.117	0.012	10.5
PC ACMV3 B	3.53	0.105	2.97

c) HSP = human specimens
d) PC = PreciControl

6.2. Clinical Sensitivity and Specificity

Specificity and sensitivity performance was based on 4017 specimens from first-time donors (2118 serum and 1899 plasma). A total of 2214 specimens had a final specimen status of negative, and 1803 specimens had a positive final specimen status determined by algorithm testing. There were 30 total discordant samples out of 4017.

6.2.1. Clinical sensitivity

A total of 1803 (869 plasma and 934 serum) of the 4017 total specimens tested for the clinical studies were interpreted as positive and used for evaluating the sensitivity of the Elecsys Anti-CMV assay on the **cobas pro** serology solution, using 4 reagent lots distributed among 3 test sites. Sample status was defined in agreement with the FDA-cleared predicate assay and in case of discrepancy with a second FDA-cleared confirmatory assay. There were 18 Elecsys non-

reactive / predicate reactive specimens. The sensitivity was calculated to be 99.83 % (1800/1803) with a 95 % confidence interval of 99.51 % to 99.94 %.

Table 10: Sensitivity – Donor specimen status (serum and plasma) for Elecsys Anti-CMV

Assay result	Reactive	Non-reactive	Overall	Sensitivity (%) [95 % Score CI]
Volunteer blood donors – Serum	933	1	934	933/934 99.89 % [99.40 % - 99.98 %]
Volunteer blood donors – Plasma	867	2	869	867/869 99.77 % [99.16 % - 99.94 %]
Total donors	1800	3	1803	1800/1803* 99.83 % [99.51 % - 99.94 %]

*3 Elecsys non-reactive samples were non-reactive for CMV IgM and CMV NAT (1 serum and 2 plasma)

6.2.2. Clinical specificity

A total of 2214 specimens (1184 serum specimens and 1030 plasma specimens) tested for the clinical studies were interpreted as negative and used for evaluating the specificity of the Elecsys Anti-CMV assay. Specimens were collected at 3 donor centers and tested with 4 reagent lots of the Elecsys Anti-CMV assay on the **cobas pro** serology solution. Sample status was defined in agreement with the FDA-cleared predicate assay and in case of discrepancy with a second FDA-cleared assay. The overall specificity was estimated in this study to be 99.46 % (2202/2214) with a 95 % CI of 99.05 % to 99.69 %.

Table 11: Specificity – Donor specimen status (serum and plasma) for Elecsys Anti-CMV

Assay result	Reactive	Non-reactive	Overall	Specificity (%) [95 % Score CI]
Volunteer blood donors – Serum	8	1176	1184	1176/1184 99.32 % [98.67 % - 99.66 %]
Volunteer blood donors – Plasma	4	1026	1030	1026/1030 99.61 % [99.01 % - 99.85 %]
Total donors	12	2202	2214	2202/2214 99.46 % [99.05 % - 99.69 %]

Percent agreement

A method comparison of the agreement between the predicate assay and the Elecsys Anti-CMV assay was evaluated. The positive percent agreement PPA = predicate and Elecsys reactive / (predicate and Elecsys reactive + predicate reactive and Elecsys non-reactive), was 99.01 % with a 95 % confidence interval of 98.44 % to 99.37 %, and the negative percent agreement NPA = predicate and Elecsys non-reactive / (predicate and Elecsys non-reactive + predicate non-reactive and Elecsys reactive), was 99.45 % with a 95 % confidence interval of 99.05 % to 99.69 %.

7. CONCLUSIONS

The results of non-clinical analytical and clinical performance studies demonstrate that the Elecsys Anti-CMV test for use on the **cobas pro** system when equipped with the **cobas e** 801 analytical unit is as safe, as effective, and performs as well as the predicate device.