

TECHNICAL BULLETIN



Roche Support Network | Roche Care Center
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Date	July 2020	IM-2020-913upd
Subject	Update - Additional Information on the commonly used pharmaceuticals stated in the method sheet for certain Elecsys assays	
Systems	cobas e 411, cobas e 601, cobas e 602, cobas e 801	
Attachment	Commonly used pharmaceuticals – V1 – 2020-04	

Product names	Product no.
NSE Elecsys cobas e 100 – cobas e 411/601/602	12133113122
NSE Elecsys E2G 300 – cobas e 801	07299982190
GDF-15 Elecsys cobas e 100 – cobas e 411/601/602	07125933190
GDF-15 Elecsys E2G 100 – cobas e 801	07028172190
SCC Elecsys cobas e 100 – cobas e 411/601/602	07028253190
SCC Elecsys E2G 100 – cobas e 801	07126972190
S100 Elecsys cobas e 100 – cobas e 411/601/602	03175243190
S100 Elecsys E2G 100 – cobas e 801	07027800190
Elecsys CYFRA 21-1 – cobas e 100 - cobas e 411/601/602	11820966122
Elecsys CYFRA 21-1 – E2G – 300 – cobas e 801	07299966190
Elecsys CA 72-4 – cobas e 100 - cobas e 411/601/602	11776258122
Elecsys CA 72-4 – E2G – 300 – cobas e 801	07324910190
Elecsys Chagas – cobas e 100 - cobas e 411/601/602	07092563190
Elecsys Chagas – E2G – 300 – cobas e 801	07028164190

Subject

This is an update of the original bulletin, changes are shown in blue.

This technical bulletin is providing additional information regarding the commonly used pharmaceuticals referenced in the **Limitations – Interference** section of Elecsys assays method sheet.

Limitations - interference
The assay is unaffected by icterus (bilirubin < 1231 µmol/L or < 72 mg/dL), lipemia (triglycerides < 22.8 mmol/L or < 2000 mg/dL) and biotin (< 409 nmol/L or < 100 ng/mL). Criterion: Recovery within ± 10 % of initial value. Hemolysis interferes because erythrocytes contain NSE. Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration. No interference was observed from rheumatoid factors up to a concentration of 1500 IU/mL. There is no high-dose hook effect at NSE concentrations up to 100000 ng/mL. In vitro tests were performed on 21 commonly used pharmaceuticals. No interference with the assay was found.

The attached document “*Commonly used pharmaceuticals – V. 1 , 2020-04*” provides the list of the pharmaceuticals that are used during internal interferences testing with their concentrations for the Elecsys assays listed above.

This information can also be found on the Roche Canada website (www.rochecanada.com). Please look for the documentation section via the search engine on the website, or use this direct link: <https://www.rochecanada.com/en/products/diagnostics-products/documentation/canadian-package-inserts.html>

This technical bulletin will be update as additional information becomes available from the manufacturer.



Action required

- Use the information stated in this Technical Bulletin to update your documentation.
- Keep this document for future reference.

Questions

Should you need more information, please do not hesitate to contact the Roche Care Center at 1-877-273-3433 or (450) 686-7111 and also by e-mail at laVal.techinfo@roche.com.

Thank you for your continued support of Roche Diagnostics.

Assay: **Elecsys SCC**
Cat.-No. 07126972190
Cat.-No. 07028253190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
0.2 - 1 ng/mL	≤ 0.2 ng/mL
> 1 ng/mL	± 10 %

Pharmaceutical	Concentration tested
Acetylcystein	1660 µg/mL
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methyldopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL

No interference was found for the above mentioned specified drug concentrations.

Assay: **Elecsys NSE**
Cat.-No. 12133113122
Cat.-No. 07299982190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
0.075 - 15 ng/mL	≤ 1.5 ng/mL
> 15 ng/mL	± 10 %

Pharmaceutical	Concentration tested
Acetylcystein	1660 µg/mL *
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methylidopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL
Cyclophosphamide	150 µg/mL
Etoposid	400 µg/mL
Doxorubicine	50 µg/mL
Cisplatin	250 µg/mL
Vincristine	2500 µg/mL

* Tested concentration for Cat.-No.07299982190: 553 µg/mL

No interference was found for the above mentioned specified drug concentrations.

Assay: **Elecsys CYFRA 21-1**
 Cat.-No. 11820966122
 Cat.-No. 07299966190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
0.1 3.3 ng/mL	± 0.5 ng/mL
> 3.3 ng/mL	± 10 %

Pharmaceutical	Concentration tested
Acetylcystein	1660 µg/mL
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methyldopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL
additionally tested for Cat.-No. 11820966122:	
Ca-Dobesilate	200 µg/mL
Doxorubicin	75 µg/mL
Cyclophosphamid	1000 µg/mL
Cisplatin	225 µg/mL
5-Flourouracil	500 µg/mL
Methotrexat	50 µg/mL
Tamoxifen	50 µg/mL
Mitomycin	25 µg/mL
Carboplatin	1000 µg/mL
Etoposid	400 µg/mL
Flutamid	1000 µg/mL
Taxol	5.5 µg/mL

No interference was found for the above mentioned specified drug concentrations.

Assay: **Elecsys CA 72-4**
Cat.-No. 11776258122
Cat.-No. 07324910190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
0.75 4 U/mL	± 0.4 U/mL
> 4 to 100 U/mL	± 10 %
>100 U/mL	± 12 %

Pharmaceutical	Concentration tested
Acetylcystein	1660 µg/mL*
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methyldopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL
Doxorubicin	75 µg/mL
Cyclophosphamid	1000 µg/mL
Cisplatin	225 µg/mL
5-Flourouracil	500 µg/mL
Methotrexat	1000 µg/mL**
Tamoxifen	50 µg/mL
Mitomycin	25 µg/mL***
Carboplatin	1000 µg/mL
Etoposid	400 µg/mL
Flutamid	1000 µg/mL
Taxol	5.5 µg/mL

* Tested concentration for Cat.-No.11776258122: 150 µg/mL

** Tested concentration for Cat.-No.11776258122: 50 µg/mL

*** Tested concentration for Cat.-No.11776258122: 5000 U

No interference was found for the above mentioned specified drug concentrations.

Assay: **Elecsys S100**
Cat.-No. 03175243190
Cat.-No. 07027800190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
≤ 0.05 µg/L	≤ 0.005 µg/L
> 0.05 µg/L	± 10 %

Pharmaceutical	Concentration tested
Acetylcystein	553 µg/mL *
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methyldopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL
additionally tested for Cat.-No. 03175243190:	
Ca-Dobesilate	200 µg/mL

* Tested concentration for Cat.-No. 03175243190: 150 µg/mL

No interference was found for the above mentioned specified drug concentrations.

Assay: **Elecsys GDF-15**
Cat.-No. 07125933190
Cat.-No. 07028172190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
≤ 800 pg/mL	± 80 pg/mL
> 800 to 2000 pg/mL	± 10 %
> 2000 pg/mL	± 14 %

Pharmaceutical	Concentration tested
Acetylcystein	553 µg/mL
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methyldopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL

No interference was found for the above mentioned specified drug concentrations.

Assay: **Elecsys Chagas**
Cat.-No. 07092563190
Cat.-No. 07028164190

Test: **Drug Interferences**

Acceptance criterion:

Concentration	Deviation
negative samples	± 0.10 COI
positive samples	± 10 %

Pharmaceutical	Concentration tested
Acetylcystein	1660 µg/mL
Ampicillin-Na	1000 µg/mL
Ascorbic acid	300 µg/mL
Cyclosporine	5 µg/mL
Cefoxitin	2500 µg/mL
Heparin	5000 IU/L
Levodopa	20 µg/mL
Methyldopa	20 µg/mL
Metronidazole	200 µg/mL
Phenylbutazone	400 µg/mL
Doxycyclin	50 µg/mL
Acetylsalicylic Acid	1000 µg/mL
Rifampicin	60 µg/mL
Acetaminophen	200 µg/mL
Ibuprofen	500 µg/mL
Theophyllin	100 µg/mL

No interference was found for the above mentioned specified drug concentrations.