BECKMAN COULTER CE

# SYNCHRON System(s)

# Chemistry Information Sheet



**CREm**
**Creatinine**
REF 472525

**For *In Vitro* Diagnostic Use**

**Rx Only**

**ANNUAL REVIEW**

| Reviewed by | Date | Reviewed by | Date |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

# PRINCIPLE

## INTENDED USE

CREm reagent, when used in conjunction with UniCel® DxC 800 System and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of creatinine concentration in human serum, plasma or urine.

## CLINICAL SIGNIFICANCE

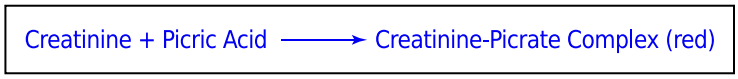
Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

## METHODOLOGY

The SYNCHRON System(s) determine creatinine concentration by means of the Jaffe rate method.[1]

A precise volume of sample (16.5 microliters serum or 5.5 microliters urine) is injected in a reaction cup containing an alkaline picrate solution. The ratio used is one part sample to 35 parts reagent for serum and one part sample to 105 parts reagent for urine. Creatinine from the sample combines with the reagent to produce a red color complex. Absorbance readings are taken at 520 nanometers between 19 and 25 seconds after sample injection. The absorbance rate has been shown to be a direct measure of the concentration of creatinine in the sample.[2,3,4]

## CHEMICAL REACTION SCHEME




E015216L.EPS

# SPECIMEN

## TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[5] Freshly drawn serum, plasma or properly collected urine (random/timed) are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

## SPECIMEN STORAGE AND STABILITY

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.[6]
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.[6]
3. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. No preservative is required.[7]

**Additional specimen storage and stability conditions as designated by this laboratory:**

## SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

## CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

**Criteria for sample rejection as designated by this laboratory:**

### PATIENT PREPARATION

**Special instructions for patient preparation as designated by this laboratory:**

### SPECIMEN HANDLING

**Special instructions for specimen handling as designated by this laboratory:**

## REAGENTS

### CONTENTS

Each kit contains the following items:

Two Alkaline Buffer Bottles (1600 mL)
Two Picric Acid Solution Bottles (400 mL)

### VOLUMES PER TEST

| | |
|---|---|
| Sample Volume | Serum 16.5 µL |
| | Urine 5.5 µL |
| Total Reagent Volume | 570 µL |

### REACTIVE INGREDIENTS

#### REAGENT CONSTITUENTS

| | |
|---|---|
| ALKALINE BUFFER: | |
| Sodium Hydroxide | 0.188 mol/L |
| PICRIC ACID SOLUTION: | |
| Picric Acid | 0.05 mol/L |

Also non-reactive chemicals necessary for optimal system performance.

### GHS HAZARD CLASSIFICATION

| | |
|---|---|
| Creatinine Alkaline Buffer | DANGER |

| | |
|---|---|
| H314 | Causes severe skin burns and eye damage. |
| H360 | May damage fertility or the unborn child. |
| P201 | Obtain special instructions before use. |
| P280 | Wear protective gloves, protective clothing and eye/face protection. |
| P303+P361+P353 | IF ON SKIN (or hair): Rinse skin with water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P310 | Immediately call a POISON CENTER or doctor/physician. |
| | Sodium Lauryl Sulfate 1 - 10% |
| | Sodium Hydroxide 0.1 - 1% |
| | Sodium Borate Decahydrate 0.1 - 1% |
| | Trisodium Phosphate, Dodecahydrate 1 - 10% |

Picric Acid Solution

DANGER

| | |
|---|---|
| H314 | Causes severe skin burns and eye damage. |
| P280 | Wear protective gloves, protective clothing and eye/face protection. |
| P303+P361+P353 | IF ON SKIN (or hair): Rinse skin with water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P310 | Immediately call a POISON CENTER or doctor/physician. |
| P501 | Dispose of contents/container in accordance with local/national regulations |
| | Picric Acid 1 - 10% |

SDS Safety Data Sheet is available at techdocs.beckmancoulter.com.

## EUROPEAN HAZARD CLASSIFICATION

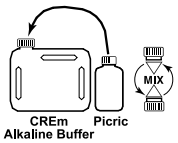
| | | |
|---|---|---|
| Creatinine Alkaline Buffer | C;R35 | |
| | R35 | Causes severe burns. |
| | S26 | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. |

| | | |
|---|---|---|
| | S37/39 | Wear suitable gloves and eye/face protection. |
| | S45 | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). |
| Picric Acid Solution | C;R1-35 | |
| | R1 | Explosive when dry. |
| | R35 | Causes severe burns. |
| | S28 | After contact with skin, wash immediately with plenty of water. |
| | S35 | This material and its container must be disposed of in a safe way. |
| | S37/39 | Wear suitable gloves and eye/face protection. |

## MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

SYNCHRON® Systems AQUA CAL 1 and 2
At least two levels of control material
Saline

## REAGENT PREPARATION




Carefully pour 400 mL of Picric Acid Solution into the 1600 mL Alkaline Buffer bottle. Replace cap and mix at least 10 times by gentle inversion.

1. Carefully pour 400 mL of Picric Acid Solution into the 1600 mL Alkaline Buffer bottle.
2. Replace cap and mix at least 10 times by gentle inversion.
3. Record preparation date on the end label.
4. If excessive foam is produced when mixing, allow foam to dissipate before loading.
5. Freshly prepared creatinine reagent may contain micro air bubbles that may result in calibration failure or calibration with low span. To prevent this phenomenon, allow the prepared reagent to sit with the cap loosened for a minimum of 30 minutes (or over night) before loading onto the instrument.

| NOTICE |
|---|
| Do not reuse old reagent containers or mix fresh reagent with old reagent. |

## ACCEPTABLE REAGENT PERFORMANCE

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria.

## REAGENT STORAGE AND STABILITY

Alkaline Buffer and Picric Acid Solution stored unopened and unmixed at room temperature are stable until the expiration dates indicated on each bottle. The combined Creatinine Reagent is stable on-instrument for 30 days from the date of preparation, or by expiration date of either component, if sooner. Do not freeze or refrigerate.

If reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting bottle a least 10 times.

NOTICE

At reduced temperature, a precipitate may form in the Alkaline Buffer or combined Creatinine Reagent. Do not filter the precipitate. DO NOT USE combined Creatinine Reagent until all precipitate is completely redissolved. It will redissolve upon warming to +21°C to +25°C without any loss of reactivity. A +25°C water bath may be used to warm reagent. Mix after redissolving precipitate by inverting bottle 10 times.

**Reagent storage location:**

# CALIBRATION

### CALIBRATOR REQUIRED

SYNCHRON® Systems AQUA CAL 1 and 2

### CALIBRATOR PREPARATION

No preparation is required.

### CALIBRATOR STORAGE AND STABILITY

1. If unopened, the calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.
2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

**Calibrator storage location:**

### CALIBRATION INFORMATION

1. The system must have a valid calibration in memory before controls or patient samples can be run.
2. Under typical operating conditions the CREm assay must be calibrated every 72 hours or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions for Use* (IFU) manual.
3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

**TRACEABILITY**

For Traceability information refer to the Calibrator instructions for use.

## QUALITY CONTROL

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new bottle of reagent, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

**Table 1.0 Quality Control Material**

| CONTROL NAME | SAMPLE TYPE | STORAGE |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## TESTING PROCEDURE(S)

1. If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operations.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

## CALCULATIONS

The SYNCHRON System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

## REPORTING RESULTS

Equivalency between the SYNCHRON LX and UniCel DxC 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

### REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.[8]

**Table 2.0 Reference intervals**

| INTERVALS | SAMPLE TYPE | CONVENTIONAL UNITS | S.I. UNITS |
|---|---|---|---|
| Literature | Serum or Plasma (Male) | 0.9 – 1.3 mg/dL | 80 – 115 µmol/L |
| | Serum or Plasma (Female) | 0.6 – 1.1 mg/dL | 53 – 97 µmol/L |
| | Urine (Male) | 800 – 2000 mg/24 hrs | 7.1 – 17.7 mmol/24 hrs |
| | Urine (Female) | 600 – 1800 mg/24 hrs | 5.3 – 15.9 mmol/24 hrs |
| SYNCHRON | Serum or Plasma (Male) | 0.64 –1.27 mg/dL | 57 – 113 µmol/L |
| | Serum or Plasma (Female) | 0.44 – 1.03 mg/dL | 39 – 91 µmol/L |

| INTERVALS | SAMPLE TYPE | CONVENTIONAL UNITS | S.I. UNITS |
|---|---|---|---|
| Laboratory | | | |
| | | | |

Refer to References (9, 10, 11) for guidelines on establishing laboratory-specific reference intervals.

**Additional reporting information as designated by this laboratory:**

## PROCEDURAL NOTES

### ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

**Table 3.0 Compatible Anticoagulants**

| ANTICOAGULANT | LEVEL TESTED FOR IN VITRO INTERFERENCE | AVERAGE PLASMA-SERUM BIAS (mg/dL)[a] |
|---|---|---|
| Ammonium Heparin | 14 Units/mL | NSI |
| Lithium Heparin | 14 Units/mL | NSI |
| Sodium Heparin | 14 Units/mL | NSI |
| Potassium Oxalate/Sodium Fluoride | 2.0 / 2.5 mg/mL | NSI |

a NSI = No Significant Interference (within ± 0.2 mg/dL or 6%).

### LIMITATIONS

If urine samples are cloudy or turbid, it is recommended that they be centrifuged before transfer to a sample cup.

### INTERFERENCES

1. The following substances were tested for interference with this methodology:

**Table 4.0 Interferences**

| SUBSTANCE | SOURCE | LEVEL TESTED | OBSERVED EFFECT[a] |
|---|---|---|---|
| Acetoacetic Acid | Acetoacetic Lithium Salt | 5 mg/dL | + 0.04 mg/dL[b] |
| | | 50 mg/dL | + 0.4 mg/dL[b] |
| | | 125 mg/dL | + 0.9 mg/dL |
| | | 500 mg/dL | + 3.5 mg/dL |
| Bilirubin (unconjugated) | Bovine | 20 mg/dL | - 0.2 mg/dL |
| Cefaclor | NA[c] | 100 µg/dL | + 0.2 mg/dL |
| Cefoxitin | Cefoxitin sodium salt | 50 µg/mL | + 0.2 mg/dL |
| Cephalothin | NA | 50 µg/mL | + 0.2 mg/dL |
| α-D-Glucose | NA | 1000 mg/dL | + 0.2 mg/dL |
| Fluorescein | Fluorescein Disodium Salt | 220 mg/dL | Results suppressed |
| Glutathione | NA | 1.5 mmol/L | + 0.2 mg/dL |
| Hemoglobin | RBC hemolysate | 500 mg/dL | NSI[d] |
| L-Dopa | NA | 160 mg/dL | - 0.2 mg/dL |
| Lipemia | Intralipid[e] | 500 mg/dL | NSI |
| | Human | Serum Index 8 | NSI |
| Methyl dopa | NA | 10 mg/dL | - 0.2 mg/dL |
| Pyruvic acid | NA | 5 mg/dL | + 0.2 mg/dL |
| Sulfasalazine | NA | 60 mg/dL | NSI |
| Sulfobromophthalein | Sulfobromophthalein sodium salt | 2.0 mg/dL | NSI |

a Plus (+) or minus (-) signs in this column signify positive or negative interference.
b The observed effect at 5 and 50 mg/dL levels of acetoacetic acid are calculated based on the extrapolation of the interference data collected with 0, 125, 250, 375, and 500 mg/dL of acetoacetic acid.
c NA = Not applicable.
d NSI = No Significant Interference (within ±0.2 mg/dL or 6%).
e Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

2. Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >8, should be ultracentrifuged and the analysis performed on the infranate.
3. Refer to References (12,13,14,15) for other interferences caused by drugs, disease and preanalytical variables.

## PERFORMANCE CHARACTERISTICS

### ANALYTIC RANGE

The SYNCHRON System(s) method for the determination of this analyte provides the following analytical ranges:

**Table 5.0 Analytical Range**

| SAMPLE TYPE | CONVENTIONAL UNITS | S.I. UNITS |
|---|---|---|
| Serum or Plasma | 0.1 – 25 mg/dL | 8.84 – 2210 µmol/L |
| Urine | 10 – 400 mg/dL | 0.88 – 35.36 mmol/L |

Samples with activities exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

**REPORTABLE RANGE (AS DETERMINED ON SITE):**

**Table 6.0 Reportable Range**

| SAMPLE TYPE | CONVENTIONAL UNITS | S.I. UNITS |
|---|---|---|
| | | |
| | | |
| | | |

**SENSITIVITY**

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for this analyte determination is 0.1 mg/dL (8.84 µmol/L) for serum or plasma and 10 mg/dL (0.88 mmol/L) for urine.

**EQUIVALENCY**

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

**Serum or Plasma (in the range of 1.0 to 24.3 mg/dL):**

| | |
|---|---|
| Y (UniCel DxC Systems) | = 1.037X - 0.01 |
| N | = 137 |
| MEAN (UniCel DxC Systems) | = 2.8 |
| MEAN (SYNCHRON LX Systems) | = 2.7 |
| CORRELATION COEFFICIENT (r) | = 0.999 |

**Urine (in the range of 17.9 to 412.7 mg/dL):**

| | |
|---|---|
| Y (UniCel DxC Systems) | = 1.000X + 0.97 |
| N | = 110 |
| MEAN (UniCel DxC Systems) | = 136.1 |
| MEAN (SYNCHRON LX Systems) | = 135.2 |
| CORRELATION COEFFICIENT (r) | = 1.000 |

**Serum (in the range of 4.42 to 22.45 mg/dL):**

| | |
|---|---|
| Y (UniCel DxC Systems) | = 1.01X - 0.03 |
| N | = 39 |
| MEAN (UniCel DxC Systems) | = 4.42 |

**Serum (in the range of 4.42 to 22.45 mg/dL):**

| | |
|---|---|
| MEAN (Isotope Dilution Mass Spectroscopy reference procedure (16)) | = 4.40 |
| CORRELATION COEFFICIENT (r) | = 0.9996 |

Refer to References (17) for guidelines on performing equivalency testing.

**PRECISION**

A properly operating SYNCHRON System(s) should exhibit imprecision values less than or equal to the maximum performance limits in the table below. Maximum performance limits were derived by an examination of the imprecision of various methods, proficiency test summaries, and literature sources.

**Table 7.0 Maximum Performance Limits**

| TYPE OF PRECISION | SAMPLE TYPE | 1 SD | | CHANGEOVER VALUE[a] | | % CV |
|---|---|---|---|---|---|---|
| | | mg/dL | µmol/L | mg/dL | µmol/L | |
| Within-run | Serum/Plasma | 0.1 | 9 | 3.3 | 300 | 3.0 |
| Total | Serum/Plasma | 0.2 | 13 | 3.3 | 300 | 4.5 |
| Within-run | Urine | 2.0 | 177 | 66.7 | 5900 | 3.0 |
| Total | Urine | 3.0 | 265 | 66.7 | 5900 | 4.5 |

a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.[18] Each laboratory should characterize their own instrument performance for comparison purposes.

**Table 8.0 NCCLS EP5-T2 Precision Estimate Method**

| TYPE OF IMPRECISION | SAMPLE TYPE | | No. Systems | No. Data Points[a] | Test Mean Value (mg/dL) | EP5-T2 Calculated Point Estimates | |
|---|---|---|---|---|---|---|---|
| | | | | | | SD | % CV |
| Within-run | Serum | Control 1 | 1 | 80 | 0.57 | 0.03 | 4.8 |
| | Serum | Control 2 | 1 | 80 | 7.86 | 0.08 | 1.0 |
| | Urine | Control 1 | 1 | 80 | 90.90 | 0.71 | 0.8 |
| | Urine | Control 2 | 1 | 80 | 244.73 | 1.72 | 0.7 |
| Total | Serum | Control 1 | 1 | 80 | 0.57 | 0.05 | 8.2 |
| | Serum | Control 2 | 1 | 80 | 7.86 | 0.25 | 3.1 |
| | Urine | Control 1 | 1 | 80 | 90.90 | 2.28 | 2.5 |
| | Urine | Control 2 | 1 | 80 | 244.73 | 6.94 | 2.8 |

a The point estimate is based on the data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer‘s instructions.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX® System and are not intended to represent the performance specifications for this reagent.

# ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.



### SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

### REVISION HISTORY

**Revision AF**

Revised Reagent Preparation and the Reagent Storage and Stability section.

**Revision AG**

Updated corporate address; updated European Hazard Classification, removed EDTA Acceptable Anticoagulant claim, and removed insert reference from content description.

**Revision AH**

Added Revision History.

**Revision AJ**

Added new language requirement: Czech, and Korean.

**Revision AK**

Removed references to CX and LX systems as they are discontinued effective 12/2013.

Added Beckman Coulter trademark statement and disclaimer.

**Revision AL**

Revised Interferences section.

**Revision AM**

Added GHS Classification information

**Revision AN**

Added Reagent Preparation visual aid to the Reagent Preparation section.

**Revision AP**

Added new language requirement: Romanian

## REFERENCES


1. Jaffe, M. Z., *Physiol. Chem.*, 10:391 (1886).
2. Bartels, E., Cikes, M., *Clin. Chem. Acta*, 26:1 10 (1969).
3. Fabiny, D. L., Ertingshausen, G., *Clin. Chem.*, 17:8 696 (1971).
4. Heinegard, D., Tiderstrom, G., *Clin. Chem. Acta*, 43:305 310 (1973).
5. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 5th Edition, W. B. Saunders, Philadelphia, PA (2005).
6. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens* Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
7. National Committee for Clinical Laboratory Standards, *Routine Urinalysis and Collection, Transportation and Preservation of Urine Specimens* Tentative Guideline, NCCLS publication GP16-T, Villanova, PA (1992).
8. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders Company, Philadelphia, PA (1995).
9. National Committee for Clinical Laboratory Standards, *How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory* Approved Guideline, NCCLS publication C28-A, Villanova, PA (1995).
10. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 6th Edition, W. B. Saunders, Philadelphia, PA (2007).
11. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 22nd Edition, W. B. Saunders Company, Philadelphia, PA (2006).
12. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 5th Edition, AACC Press, Washington, D. C. (2000).
13. Friedman, R. B., Young, D. S.,*Effects of Disease on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D.C. (2001).
14. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D. C. (2007).
15. De Leacy E. A., Brown N. N., Clague A. E., *Clin Chem* 35:1772-1774 (1989).
16. Stockl D, Reinauer H., *Clin Chem* 39:993-1000 (1993).
17. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples* Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).
18. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices* Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).



EC REP Beckman Coulter Eurocenter S.A., 22, rue Juste-Olivier. Case Postale 1044, CH - 1260 Nyon 1, Switzerland
Tel: +41 (0)22 365 36 11

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.