Creatinine (CREAm) – Serum, Plasma, Urine, Ascites/Peritoneal Fluids Technical Procedure 3122
Estimated Glomerular Filtration Rate (eGFR) CKD-EPI – Serum, Plasma
Beckman UniCel DxC Systems

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, urine or peritoneal fluids.

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.

The National Kidney Disease Education Program (NKDEP) suggests the use of an estimating or prediction equation to estimate glomerular filtration rate from serum creatinine for people with chronic kidney disease (CKD) and those at risk for CKD (diabetes, hypertension, cardiovascular disease, and family history of kidney disease). Primary reasons for these recommendations are:

- GFR and creatinine clearance are poorly inferred from serum creatinine alone. This is mainly because these are related inversely (non-linearly) to serum creatinine. The effects of age and gender, and to a lesser extent race, on creatinine production further inhibit effective interpretation.
- Creatinine is more often measured than urinary albumin. For patients with diabetic nephropathy, increased urinary albumin excretion often occurs before decreases in GFR. However, serum creatinine is measured frequently and may be the initial screening test for CKD.
- The normal serum creatinine reference interval does not necessarily reflect a normal GFR for an individual patient. Primary care providers and other specialists should routinely use an estimating equation to assess patients' kidney function.
- The CKD-EPI equation does not require weight or height variables. The equation yields a GFR result normalized to 1.73m^2 body surface area, which is an accepted average adult body surface area.

Methodology

The UniCel® DxC 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

Creatinine + Picric Acid ⟶ Creatinine-Picrate Complex (red)

Specimen

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers

Spot urines should be aliquoted into a 13 x 75 clear cap BD tube

24 hour urine collections are usually received in 3000 ml plastic urine collection jugs.

Ascites, peritoneal, and JP Drain Fluids from ascites/peritoneal sources should be received in a 13 x 75 Clear Cap BD tube

Unacceptable Specimens

Urine samples aspirated by the IRIS IQ are not acceptable for urine chemistry testing.

Urine collected in a BD UA Preservative Tube is not acceptable for urine chemistry testing.

Fluids other than ascites/peritoneal sources are unacceptable for testing at UCDHS.

Refer to the *Procedural Notes* section of this chemistry information sheet for information on unacceptable specimens.

Type of Specimen

Freshly drawn serum, plasma, fluids or properly collected urine (random/timed) are the preferred specimens. Whole blood is not recommended for use as a sample.

Specimen Storage and Stability

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)

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)

It is recommended that random urine assays be performed within 2 hours of collection. (7)

For timed specimens, the collection container is to be kept in the refrigerator or on ice during the collection period. No preservative is required. Upon receipt in the laboratory, the collection container must be stored refrigerated until testing is performed. Testing must be performed within 4 days (96 hours) of start of collection.(6,7,8,9)

Sample Volume

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the *Primary Tube Sample Template*.

Reagents

Contents

Each kit contains the following items: **Kit Reorder # 472525**

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

Volumes per Test

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