CK – CREATINE KINASE

Intended Use

CK reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s), is intended for the quantitative determination of creatine kinase activity in human serum or plasma.

Clinical Significance

Measurements of creatine kinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Methodology

CK reagent is used to measure the CK activity by an enzymatic rate method. In the reaction creatine kinase catalyzes the transfer of a phosphate group from the creatine phosphate substrate to adenosine diphosphate (ADP). The subsequent formation of adenosine triphosphate (ATP) is measured through the use of two coupled reactions catalyzed by hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6PDH) which results in the production of reduced β-nicotinamide adenine dinucleotide phosphate (NADPH) from β-nicotinamide adenine dinucleotide phosphate (NADP). The CK assay contains the activator monothioglycerol.

The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 20 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of CK in the sample and is used by the System to calculate and express CK activity.

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Specimen

Type of Specimen

PST (Lithium Heparin) is the specimen of choice.

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.
2. Stability of CK activity in sera is not well defined, but is generally poor. Specimens should be assayed as soon after collection as possible since activity loss may occur after specimens have been stored for 4 hours at room temperature, 8 to 12 hours refrigerated or 2 to 3 days when frozen.

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 for your system.

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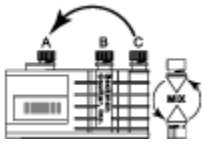
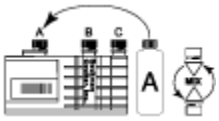
Reagents

Reagent Preparation



For P/N 442635 (2 x 200 tests): Transfer the entire contents of the smallest reagent compartment (C) into the largest reagent compartment (A).



For P/N 476836 (2 x 400 tests): Transfer all the contents of one bottle CK (A-reagent) into the largest reagent compartment (A).

Replace cartridge caps and gently invert the cartridge several times to ensure adequate mixing.

Reagent Storage and Stability

CK reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once prepared, the reagent cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

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Calibration

Calibration Required

Calibration is not required.

Quality Control

See Beckman Policy QC LCHS-5020

Sample Processing

See Beckman Policy QC LCHS-5020

Reference Range

Male: 15 – 190 IU/L
Female: 15 – 170 IU/L

Analytic Range

Sample Type	Conventional Units
Serum or Plasma	5 - 120000 IU/L
Serum or Plasma (ORDAC)	860–4100 IU/L

Author

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Distributions

Kaiser Permanente Riverside Medical Center Laboratory

End

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Reviewed and approved by:

SIGNATURE	DATE
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Mark Taira, M.D. **Medical Director, Clinical Laboratory – Riverside Medical Center**	

CK – CREATINE KINASE

HISTORY PAGE

Effective Date**:** __12/17/13__

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Medical Director review/date	Laboratory Director review/date	Date change implemented
New	New Format	B. Salas 11/07/13	D. Quach 12/16/13	D. Topliff 11/07/13	12/17/13
Minor	New Directorship	B. Salas 02/24/14	M. Taira 02/24/14	D. Topliff 03/14/14	03/14/14