DXC (CK) CREATINE KINASE

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PURPOSE

To provide instructions for the quantitative determination of creatine kinase on the DXC 600/800.

PRINCIPLE

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

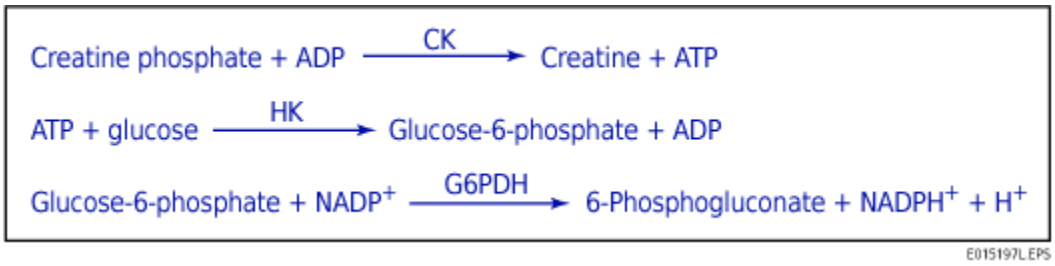
BACKGROUND

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.



RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls

M-F-CH0820	Chemistry Controls
J-F-CH0826	DXC 800 Calibrators
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH1940	DXC 800 (AMR) Analytical Measurement Range
R-W-CH0815	DXC Reagent Lot to Lot Correlations
R-F-CH0814	Lot-to-Lot Correlation

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are 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.

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 Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • Room Temp 4 hours • Refrigerated 8-12 hours • Frozen 2-3 days

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

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.

REAGENTS

Contents

Each kit contains the following items:
Two Creatine Kinase Reagent Cartridges (2 x 200 tests) or (2 x 400 tests and two bottles of CK (A-reagent)

Volume per Test	
Sample Volume	13 µL
Ordac Sample Volume	3 µL
Total Reagent Volume	260 µL
Cartridge Volumes	A 238 µL B 22 µL C – –

Reactive Ingredients	
Creatine phosphate	53 mmol/L
Glucose	18 mmol/L
ADP	2.9 mmol/L
NAD+	2.4 mmol/L
Hexokinase	>11 KIU/L
Glucose-6-phosphate dehydrogenase	>3.8 KIU/L

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

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

For P/N 476836 (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.

Acceptable Reagent Performance

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

NOTE: New lots of reagent require lot to lot correlation studies. Refer to Related Documents section for related work instructions/forms.

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 opened, the reagent cartridge is stable for 30 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

Calibration is not required.

Traceability

This measurand (analyte) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

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. Program controls for analysis.

3. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform 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.

ANTICOAGULANT TEST RESULTS

1. 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:

Anticoagulant	Level Tested for In Vitro Interference
Ammonium Heparin	29 Units/mL
Lithium Heparin	29 Units/mL
Sodium Heparin	29 Units/mL

2. The following anticoagulants were found to be incompatible with this method:

Anticoagulant	Level Tested for In Vitro Interference
Potassium Oxalate	4.0 mg/mL
Sodium Fluoride	5.0 mg/mL
Sodium Citrate	6.6 mg/mL

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Gender	Range
Serum/ Plasma	Male	55-400 U/L
Serum/ Plasma	Female	30-240 U/L

Analytic Range

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

Sample Type	Conventional Units
Serum or Plasma	5 – 1200 IU/L
Serum or Plasma (Ordac)	860-4100 IU/L

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

Reporting results outside of analytical range

Lower limit of detection	5 IU/L	Results <5; Report as <5
Upper limit of range	4100 IU/L	Result >4100 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X5. Results >20,500 are reported as >20,500 IU/L.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for CK determination is 5 IU/L (0.08 µkat/L).

LIMITATIONS

None identified.

Interferences

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

Substance	Source	Level Tested	Observed Effect
Hemoglobin	RBC hemolysate	50 mg/dL INDEX of 2	+12 IU/L
Bilirubin	Bovine	30 mg/dL INDEX of 20	No significant interference (within ± 10 IU/L or 7%)
Lipemia	Human	320 mg/dL INDEX of 8 Airfuge recommended	No significant interference (within ± 10 IU/L or 7%)
Adenylate Kinase	NA	100 U/L	+8 IU/L

2. Refer to References (11,12,13) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

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

REFERENCES

1. Oliver, J. T., *Biochem. J.*, 61:116 (1955).
2. Neilsen, L., Ludvigsen, B, *J. Lab. Clin. Med.*, 62:159 (1963).
3. Rosalki, S. B., *J. Lab. Clin. Med.*, 69:696 (1967).
4. Stow, R. W., Randall, B. F., *Am. J. Physiol.*, 179:678 (1954).

5. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).
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. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
8. 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 (1994).
9. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).
10. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).
11. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D. C. (1995).
12. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1997).
13. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D. C. (1997).
14. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).
15. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).

DOCUMENT APPROVAL Purpose of Document / Reason for Change:			
Committee Approval Date	☒ Date: 8/26/14 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 8/26/14