

BioSystems

Quality Standard Procedures

CREATINE KINASE (CPK)

All test procedures are carried out in BioSystems Clinical Chemistry Analyzer **A25** as a Quality Control Department routine.

REAGENT ABSORBANCE

Read in triplicate working reagent & water absorbance against water.

Result is stated as the mean value of the measured absorbances values.

BRC: *REAGENT ABSORBANCE*

Acceptable range is between 0.000 – 0.300 and is specific per product and the same for each lot.

ANALYTICAL SENSITIVITY

Read in triplicate the working reagent absorbance with Calibrator Serum or equivalent.

Result is showed as mA / calibrator concentration mean value.

BRC: *SENSITIVITY*

Acceptable range is between 0.240 – 0.360 mA/mg/dL and is specific per product and the same for each lot.

LINEARITY

Measurement in triplicate of an elevated internal control or standard concentration.

Result is stated as the ratio between obtained concentration / assigned concentration

BRC: *LINEARITY LIMIT*. Indicate "Correct"

Acceptable range is between 0.90 - 1.10.

ACCURACY

Measurement in triplicate up to four (4) reference material concentrations (control serum or equivalent). Result is stated as obtained concentration or ratio with Reference Value.

Tolerance: Tolerance ranges assigned to every material or acceptable ratio with reference value.

BRC: *ACCURACY*. Indicate "Correct"

Acceptable range is between 0.80 – 1.20.



BioSystems S.A.

June 2021