

# BioSystems

## Quality Standard Procedures

### **COMPLEMENT COMPONENT C4**

All test procedures are carried out in BioSystems Clinical Chemistry Analyzer 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  $< 0.300$  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  $11.700 - 17.600$  mA.dL/mg and is specific per product and the same for each lot.

#### 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  $0.65 - 1.35$ .



BioSystems S.A.

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