

# BioSystems

## Quality Standard Procedures

### ***CHOLESTEROL HDL DIRECT***

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 < 0.050 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 1.90 – 2.60 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 0.75 - 1.25.



BioSystems S.A.

June 2021