

TIÊU CHUẨN CHỦ SỞ HỮU TRANG THIẾT BỊ Y TẾ CÔNG BỐ ÁP DỤNG

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 14 tháng 10 năm 2022

Người đại diện hợp pháp của cơ sở

Giám đốc

Uông Tuấn Phương

BioSystems

Quality Standard Procedures

UNSATURATED IRON BINDING CAPACITY (UIBC)

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 > 0.500 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 $0.520 - 0.710$ mAug/dL 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 $0.79 - 1.21$



BioSystems S.A.
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