

ELITech Clinical Systems SAS

CREATININE JAFFE TWO REAGENT PROCEDURE

REF: CRCO-XXXX

<u>Instruction for use</u>:

Consult Instruction for Use

APPLICATION - MINDRAY BS-120 / BS-200 / BS-200E - PROPOSAL

This application is intended to serve as a guide for using the referenced ELITechGroup Reagent on this instrument system only. It is recommended that the user validate this application prior to routine use.

BS120 / BS200 / BS200E

| Test CRCO R1 180 / 180 / 180 No. *** R2 180 / 180 / 180 Full Name CREAT Sample volume 36 / 36 / 36 Standard No. 1 R1 Blank Reac. Type Fixed Time Mixed Rgt Blank Pri. Wavelength 510 nm / 510 nm / 505 nm Linearity Range * Sec. Wavelength Lincarity Limit * Direction Increase Substrate Limit * Reac Time 1 4 Factor Incuba. Time 14 Prozone check * Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two p | <u>PARAMETERS</u> | | | | |
|--|-----------------------------|-------------------------------------|-----------------|-----------------|--|
| Full Name | Test | CRCO | R1 | 180 / 180 / 180 | |
| Standard No. 1 R1 Blank Reac. Type Fixed Time Mixed Rgt Blank Pri. Wavelength 510 nm / 510 nm / 505 nm Linearity Range * Sec. Wavelength Linearese Substrate Limit * Reac Time 1 4 Factor Incuba. Time 14 Prozone check * Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | No. | ** | R2 | 180 / 180 / 180 | |
| Reac. Type Fixed Time Mixed Rgt Blank Pri. Wavelength 510 nm / 510 nm / 505 nm Linearity Range * Sec. Wavelength Linearity Limit * Direction Increase Substrate Limit * Reac Time 1 4 Factor Incuba. Time 14 Prozone check * Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Full Name | CREAT | Sample volume | 36 / 36 / 36 | |
| Pri. Wavelength Sec. Wavelength Direction Increase Reac Time Incuba. Time Units Missing Sec. Wavelength Direction Increase Substrate Limit Factor Incuba. Time Id Id Prozone check Units Missing Mis | Standard No. | 1 | R1 Blank | | |
| Sec. Wavelength Direction Increase Reac Time 1 | Reac. Type | Fixed Time | Mixed Rgt Blank | | |
| Direction Increase Substrate Limit * Reac Time 1 4 Factor Incuba. Time 14 Prozone check * Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Pri. Wavelength | 510 nm / 510 nm / 505 nm | Linearity Range | * | |
| Reac Time 1 4 Factor Incuba. Time 14 Prozone check * Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Sec. Wavelength | | Linearity Limit | * | |
| Incuba. Time 14 Prozone check Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rqt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Direction | Increase | Substrate Limit | * | |
| Units mg/dL q1 Q2 Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point / Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Reac Time | 1 4 | Factor | | |
| Precision 0.01 q3 Q4 PC Abs CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Incuba. Time | 14 | Prozone check | * | |
| Rule Linear one point / Linear two point / Linear two point / Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Units | mg/dL | q1 | Q2 | |
| CALIBRATION (Cal + Rgt Blk) Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Precision | 0.01 | q3 | Q4 | |
| Rule Linear one point / Linear two point / Linear two point Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | 0.1.155.45.01.10 | | PC | Abs | |
| Sensitivity 1 Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | CALIBRATION (Cal + Rgt Blk) | | | | |
| Replicates 2 Interval (days) 0 Difference Limit SD Blank Response Error Limit | Rule | Linear one point / Linear two point | | | |
| Interval (days) 0 Difference Limit SD Blank Response Error Limit | - | 1 | | | |
| Difference Limit SD Blank Response Error Limit | | 2 | | | |
| Blank Response Error Limit | Difference Limit | 0 | | | |
| Error Limit | | | | | |
| Correlation coefficient 1 | · | | | | |
| | Correlation coefficient | 1 | | | |

^{*}Enter by the user.