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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :LP-307 |
| **Title**  **CREATININE TESTING AND DETERMINATION OF CREATININE CLEARANCE** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

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| **Review date** | **Revision Date** | **Signature** |
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**Document History**

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| **Version number** | **Reason for change** | **Date** |
| 1.0 | Initial release | 28th March 2015 |
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**Distribution List**

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1. **Introduction**

Participants’ safety is of the greatest importance for both the individual participant and the goals of the clinical study. Investigators are required to report to the sponsor all adverse events occurring during a study. If the event is serious and unexpected, prompt reporting to pharma (the manufacturer of the investigational product) and to the IRB is mandatory. This standard operating procedure (SOP) describes the steps Nigerian PreP study follows to monitor kidney profile (creatinine and creatinine clearance) .

1. **Objectives**

This standard operating procedure (SOP) describes how serum sample are processed for electrolytes assay (ISE) especially creatinine and the determination of creatinine clearance in the study.

1. **Responsibility**

The procedure cited is and will be performed by;

* All trained laboratory personnel on the chemistry bench
* All laboratory personnel certified okay after the training exercise by the trainer and head of the lab.

1. Specimen

Serum on heparinsed bottle

1. Safety Considerations

* Be careful with the handling of the Probe
* Avoid ingestion of reagents and buffers and contact with the eyes
* Observe universal safety precautions.

1. Equipment Supplies and Reagents

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| **Equipment** | **Supplies** | **Reagents** |
| ISE Electrolyte machine or equivalent  Centrifuge | 5000ul-100ul pipette and tips  Eppendorf tubes or equivalent | ISE Reagent.  Calibrator |

1. Procedures

* Switch on power from the mains and then the UPS
* Switch on the ISE electrolyte machine
* Allow the machine to boot and auto-calibrate Confirm that the slopes are satisfactory
* Press TEST on the ISE machine
* Place serum or heparinsed plasma at the base of the probe (for aspiration) .
* Press RUN on the ISE machine
* Remove sample from the probe as the ISE machine commands
* Allow for auto-analysis
* Wait for the ISE machine to automatically display and print out the results.

1. **Quality control/Quality Assurance**

* Check for correctness of the slope
* Always run the control sample along with the test

1. **Reporting and recording of o Results**

The calculated result should be copied into the chemistry result register and lab result form. Reference range and unit of reporting should be quoted. Sign, date and stamp the result. File the original print out from the machine for reference.

1. **Determination of Creatinine clearance**

Creatinine clearance is determined using the Cockcroft Creatinine Clearance formula. Use the electronic creatinine clearance calculator that has been provided. In the case of a power outage, you may use the formula below.

**Cockcroft-Gault:**

Males: (140 – age (years)) x IBW

.815 x serum creatinine

Females: (140 – age (years)) x IBW x 0.85

.815 x serum creatinine

* **Ideal Body Weight (IBW):**

Males: 50 + 0.9(height in cm – 152)

Females: 45.5 + 0.9(height in cm – 152)

**This SOP has been read and understood by:**

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