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Correlative Laboratory Manual

STUDY TITLE:

STUDY NUMBER:

ClinicalTrials.gov NCT #: TBD

PRINCIPAL INVESTIGATOR: *Name*

*Institution*

*Addresss*

*Phone #*

*Emai*l

CO-INVESTIGATORS: *Name*

*Institution*

*Addresss*

*Phone #*

*Emai*l

STUDY COORDINATOR: *Name*

*Institution*

*Addresss*

*Phone #*

*Email*

SPONSOR:

SUPPORT/FUNDING:

**Laboratory Evaluation and Procedures**

**Laboratory Evaluation and Procedures**

**1. Laboratory Tests. [Provide details on laboratory procedures unless contained in separate documentation. If in separate documentation, note this in this section. Example language included below.]**

*[Sample Text: See Table below for list of all monitoring laboratory tests to be done monthly or every other month through out the study in all study subjects. Blood and/or urine samples will be collected after the scheduled subject assessments and/or vital signs determinations on that study day.*

*All clinical laboratory samples will be measured at [insert name] laboratory to determine if a subject meets the laboratory criteria defined in the inclusion/exclusion criteria, except for the urine pregnancy tests for subjects of childbearing potential and IgE levels. The urine pregnancy tests and IgE levels will be tested by the central CC laboratory. The laboratory will supply a list of reference ranges and units of the laboratory parameters. All abnormal laboratory results that are considered clinically significant by the investigator will be followed to a satisfactory resolution. (Please see below for details regarding procedures for abnormal laboratory results). The laboratory chosen for this study will provide instructions regarding the collection, processing and shipping of these samples. The amount of blood to be collected is described in detail in the Informed Consent Document.]*

**Clinical Laboratory Tests**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Hematology*** | ***Clinical Chemistry*** | ***Urinalysis¹*** | ***Miscellaneous*** |
|  |  |  |  |
|  |  |  |  |

¹ Pregnancy test will be performed for those patients of child bearing potential.

**1.1 Summary of collection from study subjects**

[*Sample Text: Collection of samples from study subjects will include serum and gene expresion tubes at 5 timepoints. These timepoints are baseline, months 3, 6, 9, and 12 (at the beginning and end of every treatment course). Serum will be separated at the clinical sites and the aliquots will be stored at -80oC onsite. The tube will also be stored onsite, at -80oC. The batched samples from the clinical sites will be shipped on dry ice to XXX at the end of the study.*]

* 1. **Onsite supply and equipment responsibilities**

 The following items are the responsibility the laboratory:

* *[Centrifuge*
* *Mailing Tape*
* *Phlebotomy supplies (except vacutainer tubes)*
* *Personal protective equipment (gloves, goggles, lab coats)*
* *Dry Ice*
* *-80oC Freezer*
* *Styrofoam shipping package (IATA approved) for final batched shipment*
* *Sterile transfer pipettes for transfer of serum to cryovials]*

* 1. **Methods**
	2. [*Provide details on methods used for specialized tests*.]

**2. Review and Reporting of Clinical Laboratory Abnormal Results**

[*Sample Text: 100% of all laboratory tests that are obtained on study subjects will be reviewed by the study coordinator. If the laboratory results are out of normal range, the coordinator will have the PI review the laboratory results and sign the laboratory sheet. In addition, the PI will sign off on each abnormal as either clinically significant (CS) or non-clinically significant (NCS) and instruct the coordinator on how to proceed.*

*If the laboratory results are clinically significant, the PI will either make changes to the subject’s medication or regimen, have the subject continue with the same regimen, or instruct the coordinator to have the laboratory tests repeated. If laboratory tests are to be repeated, then the coordinator will help the subject decide for the repeat draw.*

*The coordinator will follow up with the results of the repeat laboratory tests and inform the PI of the results. The coordinator will proceed with reporting the laboratory abnormal results to the appropriate personnel or agencies*.]