

## Lab Examination

### Lab Tests Performed per Protocol

Quintiles will analyze only those samples that are listed in the COMBINE protocol and the Quintiles lab manual. If there is a need for additional tests/analysis, they should be done locally.

### Lab Schedule

Week	BL	1	2	4	6	8	10	12	16	26	52	68
Electrolytes, BUN & Glucose	X					X			X			
CBC	X								X			
Liver Function Tests -- (AST, GGT, Bili T & D)	X			X		X		X	X	X	X	
CDT	X					X			X			
beta-HCG	X	Repeated only if menses is 10 or more days overdue										
Urinalysis	X								X			
ECG	Only as clinically indicated											
BAC (breathalyzer)	X	X	X	X	X	X	X	X	X	X	X	X
Urine toxicology screen	X											
beta-naltrexol levels				X*				X*				
Acamprosate levels				X*				X*				

\*not for participants in CBI-only

### Baseline

Forward the necessary lab information to the MM clinician for the Clinician Report Form and/or CBI therapist for the Personal Feedback Report prior to the initial session.

### Lab Reports

Quintiles Laboratories will supply the lab report in hard copy. Keep the copies of all lab records in the participant file. The PI or the designated staff member (i.e., MD) must sign lab results. All significant results should be initialed, and action taken or reason for no action should be indicated on the lab report itself or in the chart note for the session.

If your site requires that the birth date be deleted from the lab report before it is inserted into the participant binder, staff can black out the date (i.e., tape or marker). A written explanation for deleting the date should be inserted into the regulatory binder.

### Documenting Significant Lab Abnormalities

If the lab report notes a panic high (PH) or panic low (PL) this constitutes a significant lab abnormality. The information should be recorded on the SAFTEE (SGI).

### Lab Values that could Result in Discontinuation of Study Medication

#### ◆ **Pregnancy**

Subjects who become pregnant during the course of the treatment will be discontinued from the study medication.

#### ◆ **Elevated liver enzymes**

Individuals whose ALT/AST is greater than 5X normal will need to have ALT/AST repeated within 1-2 weeks and if still greater than 5X normal the subject's medication will be stopped. Clinical judgment should be used to determine if the patient should be discontinued from study medication immediately. If the repeat values are less than 5X normal but still elevated, the subject should be monitored using clinical judgment. Individuals whose total bilirubin is above 50% baseline level but within the normal range will be evaluated by a study physician to determine whether study medication should be discontinued. Procedures for reducing the dosage is outlined in Appendix A2. Individuals whose total bilirubin is greater than 10% above ULN will be taken off the study medication immediately.

Complete a **Liver Function Alert Form** whenever a study participant's LFTs increase by 5X normal or if bilirubin is greater than 10% above ULN. **FAX** this form to the Coordinating Center (919-962-3265) within 24 hours of being notified of the lab results. A follow-up alert form and lab report should be completed and faxed to the Coordinating Center as the site receives additional information.

#### ◆ **Renal insufficiency**

Individuals whose serum creatinine level is 1.3 or 1.4 will be evaluated by study physician to ascertain whether study medication should be discontinued. However, a creatinine cut-off of 1.5 should be cause for removal from the study medication.

**Refer to the Clinical Care Guidelines, which are located in the Protocol and Medical Management Manual, for additional information.**

#### **Hepatitis Testing**

A participant should be screened for hepatitis if LFTs are greater than 5X ULN. The hepatitis test should be done locally. Once the data services agreement between the Coordinating Center and Quintiles is modified, Quintiles will automatically test for hepatitis if LFTs are greater than 5X ULN.

#### **Missed Visits**

If the participant does not attend a visit that includes the collection of lab samples, staff should collect the samples at the next possible visit. This is applicable to those that are assigned to MM as well as those assigned to CBI.

#### **Sample Labeling Errors**

If, after sending a sample, a staff person realizes that the sample was labeled with incorrect identifiers (i.e., an incorrect screening ID number), the site should call the Quintiles Investigator Services Department (1-800-676-8452). Staff should report the scenario and the correct information for the participant(s) involved. Once the report is given to the QLAB, the database will be corrected and a revised report will be sent to the site showing the correct information. The report is a header report and not a full lab report. It will consist of the investigator and participant information. A description of the modification will also be noted (i.e., change participant screening ID number from \_\_\_ to \_\_\_).

Quintiles Laboratories will supply the Laboratory Report in hardcopy. Keep the copies of all lab records in the participant file. At the end of the study, Quintiles will transfer the lab data electronically to the Coordinating Center. All results, from the first results of the toxicology screen for drugs, and in the case of females, pregnancy test results, and standard clinical chemistries will be reported.

### **Lab Supplies**

If you discover that some lab supplies have expired, replace that individual from the bulk supply of similar sample tubes that is supplied in addition to the lab kits. If a replacement tube is selected, note that it is important to re-label that tube with the same Accession Number as the rest of the kit being used. Order a replacement sample kit from Quintiles. Use methods outlined in the Quintiles Manual.

Refer to the Laboratory Specimen and Procedures manual from Quintiles, Inc. for more details (Quintiles manual should be placed in this COMBINE Manual of Operations).