

**Multi-site Study
Advance Reporting Script for Clinical Tests**

FOR OFFICE USE ONLY
Adult Study ID No. | _____ |
Parent Study ID No. | _____ |
Child Study ID No. | _____ |

HELLO,

My name is | _____ |. I am calling on behalf of the [institution name]. We are calling about the Multi-site Study. Am I speaking with | NAME OF ADULT OR PARENT OF CHILD WHOSE RESULTS ARE CRITICAL | ?

[IF NOT CORRECT PERSON] Please let me know the best time we can reach [him/her].

| _____ | (day of the week)

|__|_|/|__|_|/|__|_| (date);

|__|_|:|__|_| AM PM (time).

I will call back then. Thank you.

[IF CORRECT PERSON] We are contacting you about [your/your child's] lab results. [Your/Your child's] [glucose/triglyceride/albumin/total bilirubin] test was significantly outside of the normal range. You should call [your/your child's] doctor today to discuss this. We will be sending you a letter with the details of [your/your child's] clinical tests.

Specifically, the results of [your/your child's] test have shown the following [read those that apply.]

Do you have a pen or pencil to write this down?

1. I am calling to report critical test results for | NAME OF ADULT OR CHILD |.
2. Select the appropriate critical test and reporting value from below:

[Your/Your child's] **glucose level** was | _____ | mg/dL. The test was performed on | ____|_|/|__|_|/|__|_| (date).

If below 40 mg/dl read the following: This is below the critical value of 40 mg/dL. [Your/Your child's] diabetes was poorly controlled or [your/his/her] medications might need to be adjusted. If this problem has not been addressed, we recommend that [you/your child] see the doctor immediately.

If above 400 mg/dL read the following: This is above the critical value of 400 mg/dL. [Your/Your child's] blood sugar was very high.

[Your/Your child's] **triglyceride level** was |_____| mg/dL. This is above the critical value of 1,000 mg/dL. The test was performed on |__|_|_|/|__|_|_|/|__|_|_| (date).

[You have/Your child has] a problem with lipid metabolism and have very high risk of heart disease.

[Your/Your child's] **albumin level** was |_____| g/dL. The test was performed on |__|_|_|/|__|_|_|/|__|_|_| (date).

[If below 1.5 g/dL read the following:] This is below the critical value of 1.5 g/dL. You may have a liver or kidney problem.

[If above 7.9 g/dL read the following:] This is above the critical level of 7.9 g/dL. You may be severely or chronically dehydrated.

[Your/Your child's] **total bilirubin** was |_____| mg/dL. This is above the critical value of >12.9 mg/Dl. The test was performed on |__|_|_|/|__|_|_|/|__|_|_| (date).

[You/Your child] may have a liver problem or a bile duct problem.

3. As a check, please read back the participant name and [his/her] critical lab result to me. > *Verbally correct any errors and repeat the request for a "read-back" to verify accurate reporting and message received.*
4. You should call [your/your child's] doctor today to discuss this information. As it is now more than |__|_|_| months since we collected [your/your child's] blood, this result may not be important today. You and [your/your child's] doctor may have already taken steps to correct the problem. We will be sending you a letter with the details of [your/your child's] clinical tests. If you or your doctor has a question about the results of these tests, you or he/she can contact us at [institution name] at [insert telephone number]. Thank you for [your/your child's] participation in the study.
5. [CONCLUSION] Document the date, time, test results, and person to whom the test results were reported. Prepare **Attachment 20a - Report of Critical Values Tracking Form** and **Attachment 20b - Letter Report of Critical Values** for mailout.