

Local Lab Worksheet

Renal insufficiency eligibility: follow the steps below. When you reach an outcome of ELIGIBLE or INELIGIBLE in one of the steps **circle it** and then check the appropriate box below.

<u>Males</u>	<u>Females</u>
1. If serum creatinine ≤ 1.5 mg/dl then ELIGIBLE , Otherwise go to step 2	1. If serum creatinine ≤ 1.2 mg/dl then ELIGIBLE , Otherwise go to step 2
2. If clinician chooses to reject participant at this point, then INELIGIBLE , Otherwise go to step 3	2. If clinician chooses to reject participant at this point, then INELIGIBLE , Otherwise go to step 3
3. Compute GFR Weight in kg = _____ A 140 - age in years = _____ B 72 * serum creatinine mg/dl = _____ C GFR = $(A * B) / C$ = _____	3. Compute GFR Weight in kg = _____ A 140 - age in years = _____ B 72 * serum creatinine mg/dl = _____ C GFR = $((A * B) / C) * 0.85$ = _____
If GFR < 60, then participant is INELIGIBLE Otherwise participant is ELIGIBLE	If GFR < 60, then participant is INELIGIBLE Otherwise participant is ELIGIBLE

eligible ineligible

4. Renal insufficiency eligibility 1 2

Blood sugar eligibility: check the appropriate boxes for initial and repeat results. Check the overall outcome below. If a repeat is done, use the repeat result for the overall outcome.

	Non-fasting	Fasting
Initial	<input type="checkbox"/> <160 = eligible	<input type="checkbox"/> <126 = eligible
	<input type="checkbox"/> ≥ 160 = ineligible	<input type="checkbox"/> ≥ 126 = ineligible
Repeat	<input type="checkbox"/> <160 = eligible	<input type="checkbox"/> <126 = eligible
	<input type="checkbox"/> ≥ 160 = ineligible	<input type="checkbox"/> ≥ 126 = ineligible

eligible ineligible

Blood sugar eligibility..... 1 2

Reviewed by (staff ID): _____
 Entered by (staff ID): _____

Local Lab Worksheet

Overview

The Local Lab Worksheet is filled out by clinic staff and is used for renal insufficiency and blood sugar screening to determine eligibility of potential participants.

The Local Lab Worksheet must be filled out during each SV2 visit.

If some data collected on this form indicates immediate exclusion, “ineligible” should be checked on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome. If data requires that participants be referred to a physician for consultation, make sure the Participant Information Sheet (form #100) gives you permission to contact their physician.

Administration/Coding Instructions

Place ID label on Page 1.

This form should be completed by clinic staff after the local lab results have been received.

Local lab tests may be repeated once. If a test was repeated, make a note of this on the form. If a test is repeated, the repeat result must be used.

When an outcome is reached in one of the steps for Renal Insufficiency, be sure to **CIRCLE IT** and then check the appropriate box towards the bottom of page 1.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
1	1-3	<p>Using the participants lab results follow steps 1-3 listed on the form to determine whether or not the data indicate renal insufficiency. Be certain to use the appropriate gender (male, female).</p> <p>Renal insufficiency eligibility: Refer to steps 1-3 above. If ELIGIBLE is circled in steps 1 or 3, mark the “eligible” box. If INELIGIBLE is circled in steps 2 or 3, mark the “ineligible” box.</p> <p>Blood sugar eligibility: Refer to ‘non-fasting’ and ‘fasting’ eligibility criteria at the bottom of page 1. If only an initial test is done, use the outcome of that test to check the overall blood sugar outcome at the bottom of the page. If a repeat test is done, use the outcome of the repeat test to check the overall blood sugar outcome at the bottom of the page. Once a repeat test is done, the initial outcome may not be used.</p>

Review Instructions

If the participant is INELIGIBLE (Renal insufficiency eligibility **and/or** Blood sugar eligibility is marked “ineligible”), enter “ineligible” on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome.

If the participant is ELIGIBLE (Renal insufficiency eligibility **and** Blood sugar eligibility is marked “eligible”), check the following items:

- Page 1 should have correct ID# labels.
- Make sure one outcome is **circled** in steps 1-3. If step 3 is filled in, check the calculations for accuracy.
- Renal insufficiency eligibility outcome = “eligible” and “eligible” is circled in steps 1 or 3.
- Make sure one box is marked in either the non-fasting or fasting criteria.
- Blood sugar eligibility outcome = “eligible” and one “eligible” box is checked in either the non-fasting or fasting criteria.
- If all of the above items look acceptable, enter your Staff ID in the “reviewed by” section at the bottom of page 1, and enter “eligible” on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome.

All corrections should be explained, initialed, and dated.

When filling out the “Reviewed by” box, be sure to use the correct staff ID number.

Additional instructions:

This form is not entered. The outcome is reported and entered on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome.

If participant is ineligible due to high blood sugar, and they do not know they are diabetic, refer them to their physician. If any lab value requires immediate medical attention or the study clinician decides for any reason that the participant’s physician must be informed of an abnormal lab value, first refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Tests can be repeated once at local discretion. Sites can do any of the following combination of blood draws: two non-fasting blood draws, two fasting blood draws, or one non-fasting and one fasting blood draw. Eligibility is based on the repeat specimen.