

-
Participant ID

Nickname

RISE **LOCLAB.2**

February 2016

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Restoring Insulin Secretion Study
LOCLAB: Local Lab Results

1. Study visit number VISIT	<table border="1"> <tr> <td>BAS</td> <td>M03</td> <td>M06</td> <td>M09</td> <td>M12</td> </tr> <tr> <td>M15</td> <td>M18</td> <td>M21</td> <td>UNS</td> <td></td> </tr> </table>	BAS	M03	M06	M09	M12	M15	M18	M21	UNS	
BAS	M03	M06	M09	M12							
M15	M18	M21	UNS								
2. Visit date (mm/dd/yy) Replaced by DAYSRAND	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>										
3. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>										

Instructions: Complete this form any time a local laboratory measurement is requested on or following the Baseline visit. Complete only labs collected at this visit.

Note: Hemoglobin and/or hematocrit are collected at M06 big visit for safety and at M12 and M15 clamp visits prior to the clamp for safety. Serum creatinine and ALT are collected at M06 for safety. HbA1c is not routinely measured outside of the CBL. Enter a locally-obtained HbA1c when measured offsite for safety reasons or if the patient is unable to attend a scheduled clinic visit.

Local Lab Results

4. Hemoglobin* LOHEMOG	<input type="text"/> <input type="text"/> . <input type="text"/> g/dl
5. Hematocrit* LOHEMAT	<input type="text"/> <input type="text"/> . <input type="text"/> %
6. Serum creatinine* LOSERCRT	<input type="text"/> . <input type="text"/> mg/dl
7. ALT LOALT	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> U/L
8. HbA1c (if processed locally, see note above) LOHBA1C	<input type="text"/> <input type="text"/> . <input type="text"/> %

***Notes:**

- Following the M06, M12, and M15 visits assess anemia based on protocol definitions: hematocrit <30.0%, hemoglobin <10 gm/dl, a decline in hematocrit by 4% from study entry (screening), or a decline in hemoglobin by 2 gm/dl from study entry (screening). If anemia persists for more than six months despite appropriate therapy, consideration will be given to discontinuing study medication or participation.
- Following the M06 visit, assess renal insufficiency. Serum creatinine will be determined after 6 months on therapy and metformin will be discontinued if the levels exceed 1.2 mg/dl.