



(affix label here)

|                   |                      |                      |                      |                      |                      |                      |                      |
|-------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Patient ID Number | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|                   | Site                 | Sub-site             | Sequential ID        |                      |                      |                      |                      |

## SEARCH Specimen Collection Form

### Before drawing blood or collecting urine specimens:

- Have you had DKA in the last 4 weeks that resulted in hospitalization or had to be treated by IV fluids?
  - No
  - Yes (**if YES, then do NOT draw blood AND do not collect urine specimens**)
- For females only:** Are you currently pregnant?
  - No
  - Yes (**if YES, do NOT draw blood AND do not collect urine specimens**)
  - Unsure (**if UNSURE, do NOT draw blood AND do not collect urine specimens**)
- For females only:** Are you currently menstruating/having your period?
  - No
  - Yes (**if YES, do NOT collect urine**)
- For Cohort Visits and females only:** Were you menstruating when you did your overnight urine collection?
  - No
  - Yes (**if YES, do NOT send overnight urine sample and repeat overnight urine collection when patient is not menstruating**)

- Have you taken any insulin in the last 4 hours? (This does **NOT** include basal insulin per insulin pump.)
  - Yes (**if YES, ask which insulins were taken; mark by the appropriate list of insulins below**)
  - No (**if NO, go to question 6**)

|                          |  |   |  |   |
|--------------------------|--|---|--|---|
| <input type="checkbox"/> | Detemir<br>Glargine<br>Humulin N<br>Lantus<br>Levemir<br>Novolin N<br>NPH  | Acceptable  |  |   |
| <input type="checkbox"/> | Humulin R<br>Humulin 50/50<br>Humulin 70/30<br>Novolin R<br>Novolin 70/30<br>Regular   | Time: <input type="text"/> <input type="text"/> Hour <input type="text"/> <input type="text"/> Minute | <input type="checkbox"/> AM<br><input type="checkbox"/> PM | <b>NOT acceptable</b> if taken within 4 hours prior to fasting blood sample – Proceed with blood draw and try to re-schedule a fasting re-draw visit. |
| <input type="checkbox"/> | Apidra<br>Glulisine<br>Humalog<br>Humalog mix 50/50<br>Humalog mix 75/25<br>Novolog<br>Novolog mix 70/30<br>(by injection or bolus per pump) | Time: <input type="text"/> <input type="text"/> Hour <input type="text"/> <input type="text"/> Minute | <input type="checkbox"/> AM<br><input type="checkbox"/> PM | <b>NOT acceptable</b> if taken within 2 hours prior to fasting blood sample – Proceed with blood draw and try to re-schedule a fasting re-draw visit. |

6. Have you taken any other diabetes medications in the last 8 hours?

- 1  Yes (if YES, ask which medications were taken and mark by the appropriate list of medications below; then answer question 6a at the bottom of the page)  
2  No

**Other diabetes medications:**

|                          |   |                               |
|--------------------------|---|-------------------------------|
| <input type="checkbox"/> | Acarbose<br>Actos<br>Avandament<br>Avandia<br>Glucophage<br>Glyset<br>Metformin<br>Miglitol<br>Precose<br>Pioglitazone<br>Rosiglitazone | <b>Acceptable medications</b> |
|--------------------------|---|-------------------------------|

|                          |   |   |  |  |      |        |   |
|--------------------------|---|---|--|--|------|--------|---|
| <input type="checkbox"/> | Amaryl<br>Byetta<br>Chlorpropamide<br>DiaBeta<br>Diabinese<br>Exenatide<br>Glimepiride<br>Glipizide<br>Glucotrol<br>Glucovance<br>Glyburide<br>Glynase<br>Januvia<br>Liraglutide<br>Micronase<br>Nateglinide<br>Prandin<br>Pramlintide<br>Repaglinide<br>Sitagliptin<br>Starlix<br>Symlin<br>Tolazamide<br>Tolbutamide<br>Victoza | Time: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr><tr><td style="text-align: center; font-size: 8px;">Hour</td><td style="text-align: center; font-size: 8px;">Minute</td></tr></table><br><input type="checkbox"/> AM<br><input type="checkbox"/> PM |  |  | Hour | Minute | <p><b><u>NOT acceptable if taken within 8 hours prior to fasting blood sample</u></b></p> <p><i>Proceed with blood draw and try to re-schedule a fasting re-draw visit.</i></p> |
|                          |   |   |  |  |      |        |   |
| Hour                     | Minute  |   |  |  |      |        |   |

|                          |  |
|--------------------------|--|
| <input type="checkbox"/> | <b>Other diabetes medications:</b> (specify) ↓<br><div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div> |
|--------------------------|--|

**IF UNACCEPTABLE INSULIN OR ORAL MEDICATION TAKEN, PROCEED WITH BLOOD DRAW AND TRY TO SCHEDULE A FASTING RE-DRAW VISIT.**



6a. *If a re-draw visit is necessary, has Patient agreed?* 1  Yes 2  No

7. Have you had anything to eat or drink in the last 8 hours?

1  Yes 7a. if YES, ask the Patient what they had to eat or drink. Describe what they had to eat or drink.



7b. if Patient consumed non-allowable food or drink, record most recent time



Time:      AM  PM  
Hour Minute

**IF FASTING LESS THAN 8 HOURS, PROCEED WITH BLOOD DRAW AND TRY TO SCHEDULE A FASTING RE-DRAW VISIT.**



7c. **If a re-draw visit is necessary, has Patient agreed?** 1  Yes 2  No

2  No

8. Glucose meter reading:    (May use drop from blood collected with venipuncture samples)

**If glucose is > 300 mg/dl, perform urinary ketone check and record.**

8a. Urine ketones: 1  Negative 2  Trace/small 3  Moderate 4  Large 5  Unable to obtain

9. Were any of the following symptoms observed or reported by the Patient? 1  Yes 2  No

**(If YES, check all that apply):**

- 1  Abdominal pain
- 1  Diaphoresis (excessive sweating)
- 1  Lightheadedness
- 1  Nausea and or vomiting
- 1  Seizure
- 1  Tremors or trembling
- 1  Loss of consciousness due to low blood glucose
- 1  Loss of consciousness due to phlebotomy (fainting)
- 1  Blood glucose is < 45 mg./dl.
- 1  Blood glucose is > 300 mg./dl. with moderate or large ketones
- 1  Blood glucose is > 500 mg./dl. with or without ketones
- 1  Other (specify):



10. Comments?

1  Yes (if YES, describe):



2  No comments

**NOTE: Complete SEARCH Unanticipated Occurrence/Condition Reporting Form if any of the below presents:**

- seizure
- loss of consciousness due to low blood glucose

|                              |  |   |   |
|------------------------------|--|---|---|
| 11. Specimen obtained by:    | <input type="text"/> <input type="text"/> <input type="text"/> | (code)                                    |   |
| 12. Date specimen obtained:  | <input type="text"/> <input type="text"/>                      | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
|                              | Month  | Day                                       | Year  |
| 13. Time specimen collected: | <input type="text"/> <input type="text"/>                      | <input type="text"/> <input type="text"/> | <input type="checkbox"/> AM / <input type="checkbox"/> PM (check one)               |
|                              | Hour   | Minute                                    |   |

**Please instruct the Patient to take medication/insulin and provide a breakfast to the Patient.**

| FOR STUDY USE ONLY |   |   |   |                 |  |
|--------------------|---|---|---|-----------------|--|
| Date Completed     | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Completed by    | <input type="text"/> <input type="text"/> <input type="text"/> |
|                    | Month                                     | Day                                       | Year  |                 |  |
| Date Reviewed      | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Reviewer Code   | <input type="text"/> <input type="text"/> <input type="text"/> |
|                    | Month                                     | Day                                       | Year  |                 |  |
| Date Entered       | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Data Entry Code | <input type="text"/> <input type="text"/> <input type="text"/> |
|                    | Month                                     | Day                                       | Year  |                 |  |