



(affix label here)

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

SEARCH Specimen Collection Form

Before drawing blood or collecting urine specimens:

1. Have you had DKA in the last 4 weeks that resulted in hospitalization or had to be treated by IV fluids?
1 No dka4week_spec
2 Yes (*if YES, then do NOT draw blood AND do not collect/send 1st morning void and spot urine specimens and do not complete this form*)
2. Have you had a severe low blood sugar in the past 24 hours that required you to get help (glucagon injection, called 911, went to an emergency room or urgent care center)? sewlowBS24hr_spec
1 No
2 Yes (*if YES, then do not collect/send 1st morning void and spot urine specimens and re-schedule urines*)
3. Have you had a fever greater than 100 degrees in the past 24 hours? feverGT100_spec
1 No
2 Yes (*if YES, then do NOT collect/send 1st morning void and spot urine specimens and re-schedule urines*)
4. In the past month, have you been told by a doctor that you have a urinary tract infection? monthtoldUTI_spec
1 No
2 Yes - *if YES, are you currently taking an antibiotic for your infection?* utiantibiotic_spec

1 No (*if NO, collect urine specimens*)
2 Yes (*if YES, then do NOT collect/send 1st morning void and spot urine specimens and re-schedule urines*)

The next questions are for females only:

5. Are you currently pregnant? pregnant_spec
1 No
2 Yes (*if YES, do NOT draw blood AND do NOT collect/send 1st morning void and spot urine specimens and do not complete this form*)
3 Unsure (*if UNSURE, draw blood AND collect/send 1st morning void and spot urine specimens*) (*Script for Coordinator: "If you find out later that you were pregnant today, please let us know."*)

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0904).

6. Are you currently menstruating/having your period? period_spec

1 No

2 Yes *(if YES, do NOT collect spot urine specimen and re-schedule spot urine)*

7. Were you menstruating when you did your 1st morning void urine collection? periodcoll_spec

1 No

2 Yes *(if YES, do NOT send 1st morning void urine sample and re-schedule urine)*

8. Have you taken any insulin in the last 4 hours? (This does **NOT** include basal insulin per insulin pump.) insulin4hr_spec

1 Yes *(if YES, ask which insulins were taken; mark by the appropriate list of insulins below)*

2 No *(if NO, go to question 9)*

ins4hraccept_spec	<input type="checkbox"/> Detemir <input type="checkbox"/> Glargine <input type="checkbox"/> Humulin N <input type="checkbox"/> Lantus <input type="checkbox"/> Levemir <input type="checkbox"/> Novolin N <input type="checkbox"/> NPH	Acceptable	
ins4hrfast4hr_spec	<input type="checkbox"/> Humulin R <input type="checkbox"/> Humulin 50/50 <input type="checkbox"/> Humulin 70/30 <input type="checkbox"/> Novolin R <input type="checkbox"/> Novolin 70/30 <input type="checkbox"/> Regular	Time: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Hour Minute	<input type="checkbox"/> AM ins4hrfast4hrampm_spec <input type="checkbox"/> PM NOT acceptable if taken within 4 hours prior to fasting blood sample – Proceed with blood draw and try to re-schedule a fasting re-draw visit.
ins4hrfast2hr_spec	<input type="checkbox"/> Apidra <input type="checkbox"/> Glulisine <input type="checkbox"/> Humalog <input type="checkbox"/> Humalog mix 50/50 <input type="checkbox"/> Humalog mix 75/25 <input type="checkbox"/> Novolog <input type="checkbox"/> Novolog mix 70/30 (by injection or bolus per pump)	Time: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Hour Minute	<input type="checkbox"/> AM ins4hrfast2hrampm_spec <input type="checkbox"/> PM NOT acceptable if taken within 2 hours prior to fasting blood sample – Proceed with blood draw and try to re-schedule a fasting re-draw visit.

9. Have you taken any other diabetes medications in the last 8 hours? oralmed8hr_spec

1 Yes (if YES, ask which medications were taken and mark by the appropriate list of medications below; then answer question 9a on next page)

2 No

Other diabetes medications:

oral8hraccept_spec

1

Acarbose
Actos
Avandament
Avandia
Glucophage
Glyset
Metformin
Miglitol
Precose
Pioglitazone
Rosiglitazone

Acceptable medications

oral8hrfast8hr_spec

2

Amaryl
Byetta
Chlorpropamide
DiaBeta
Diabinese
Exenatide
Glimepiride
Glipizide
Glucotrol
Glucovance
Glyburide
Glynase
Januvia
Liraglutide
Micronase
Nateglinide
Prandin
Pramlintide
Repaglinide
Sitagliptin
Starlix
Symlin
Tolazamide
Tolbutamide
Victoza

Time:
Hour Minute

oral8hrfast8hrHour_spec oral8hrfast8hrHour_spec

AM

PM

oral8hrfast8hrampm_spec

NOT acceptable if taken within 8 hours prior to fasting blood sample

Proceed with blood draw and try to re-schedule a fasting re-draw visit.

othermeds_spec

1

Other diabetes medications: (specify) ↓

othermedstext_spec

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



9a. *If a re-draw visit is necessary, has Participant agreed?* 1 Yes 2 No

redrawagree_spec

10. Have you had anything to eat or drink in the last 8 hours? eat8hrs_spec

1 Yes 10a. *if YES, ask the Participant what they had to eat or drink. Describe what they had to eat or drink.* →

eatwhat_spec

10b. *if Participant consumed non-allowable food or drink, record most recent time* →

eattimehour_spec eattimemin_spec

Time: AM PM
Hour Minute eatampm_spec

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

★ 10c. ***If a re-draw visit is necessary, has Participant agreed?*** 1 Yes 2 No
fastredrawagree_spec

2 No

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

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

11a. Urine ketones: 1 Negative 2 Trace/small 3 Moderate 4 Large 5 Unable to obtain
gluckeyt_spec

12. Were any of the following symptoms observed or reported by the Participant? 1 Yes 2 No symptoms_spec
(If YES, check all that apply):

- 1 Abdominal pain sympabdomin_spec
- 1 Diaphoresis (excessive sweating) sympdiaph_spec
- 1 Lightheadedness symplight_spec
- 1 Nausea and or vomiting sympnausea_spec
- 1 Seizure sympseizure_spec
- 1 Tremors or trembling symptremor_spec
- 1 Loss of consciousness due to low blood glucose sympconsgluc_spec
- 1 Loss of consciousness due to phlebotomy (fainting) sympconspheleb_spec
- 1 Blood glucose is < 45 mg./dl. sympgluc45_spec
- 1 Blood glucose is > 300 mg./dl. with moderate or large ketones sympgluc300_spec
- 1 Blood glucose is > 500 mg./dl. with or without ketones sympgluc500_spec
- 1 Other (specify):

sympother_spec →

sympotherspec_spec

13. Comments? speccomm_spec

1 Yes (if YES, describe):

specnote_spec

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

14. Specimen obtained by:	<input type="text"/> <input type="text"/> <input type="text"/>	(code)	drawby_spec	
15. 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"/>	drawdate_spec
	Month	Day	Year	
16. 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)	drawampm_spec
	drawtimeHour_spec Hour	drawtimemin_spec Minute		

Please instruct the Participant to take medication/insulin and provide SphygmoCor snack (Cohort visit) or breakfast (Registry visit) to the Participant.

FOR STUDY USE ONLY					
Date Completed compldat	<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 complby	<input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year		
Date Reviewed revwdate	<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 revwby	<input type="text"/> <input type="text"/> <input type="text"/>
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	Month	Day	Year		