



(affix label here)

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

## SEARCH 4 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 1<sup>st</sup> morning void specimen 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)? [sevLowBS24hr\\_SPEC](#)  
1  No  
2  Yes *(if YES, then do not collect/send 1<sup>st</sup> morning void specimen and re-schedule urine)*
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 1<sup>st</sup> morning void specimen and re-schedule urine)*
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 1<sup>st</sup> morning void specimen and re-schedule urine)*

### 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 1<sup>st</sup> morning void specimen and do not complete this form)*  
3  Unsure *(if UNSURE, draw blood AND collect/send 1<sup>st</sup> morning void specimen) (Script for Coordinator: "If you find out later that you were pregnant today, please let us know.")*
6. Were you menstruating when you did your 1<sup>st</sup> morning void urine collection? [period\\_spec](#)  
1  No  
2  Yes *(if YES, do NOT send 1<sup>st</sup> morning void urine sample and re-schedule urine)*

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).

7. 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)

<a href="#">ins4hraccept_spec</a> 1 <input type="checkbox"/>	Degludec (Tresiba) Detemir (Levemir) Glargine (Lantus) Humulin N Novolin N NPH	<b>Acceptable</b>		
<a href="#">ins4hrfast4hr_spec</a> 2 <input type="checkbox"/>	Humulin R Humulin 50/50 Humulin 70/30 Novolin R Novolin 70/30 Regular	Time: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Hour      Minute <a href="#">ins4hrfast4hrHour_spec</a> <a href="#">ins4hrfast4hrMin_spec</a>	<a href="#">ins4hrfast4hrampm_spec</a> <input type="checkbox"/> AM <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.
<a href="#">ins4hrfast2hr_spec</a> 3 <input type="checkbox"/>	Apidra Glulisine Humalog Humalog mix 50/50 Humalog mix 75/25 Novolog 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 <a href="#">ins4hrfast2hrHour_spec</a> <a href="#">ins4hrfast2hrMin_spec</a>	<a href="#">ins4hrfast2hrampm_spec</a> <input type="checkbox"/> AM <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.

8. 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:**

<a href="#">oral8hraccept_spec</a> 1 <input type="checkbox"/>	<b>Acceptable medications</b>
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Acarbose (*Precose*)  
 Actos  
 Avandamet  
 Avandia  
 Canagliflozin (*Invokana*)  
 Dapagliflozin (*Forxiga*)  
 Empagliflozin (*Jardiance*)  
 Glucophage  
 Glyset  
 Metformin (*metformin extended release [metformin ER], [Glucophage, Riomet, Fortamet, Fortamet ER, Glumetza]*)  
 Miglitol  
 Orlistat (*Xenical, Alli*)  
 Precose  
 Pioglitazone (*Actos*)  
 Rosiglitazone

Albiglutide ( <i>Tanzeum</i> )	<a href="#">oral8hrfast8hrHour_spec</a>	<a href="#">oral8hrfast8hrMin_spec</a>
Amaryl	Time: <input type="text"/> <input type="text"/>	
Byetta	Hour	Minute
Chlorpropamide		
Delaglutide ( <i>Trulicity</i> )		
DiaBeta		
Diabinese	<input type="checkbox"/> AM	<a href="#">oral8hrfast8hrampm_spec</a>
Empagliflozin ( <i>Jardiance</i> )	<input type="checkbox"/> PM	
Exenatide ( <i>Byetta, Bydureon</i> )		
Glimepiride ( <i>Amaryl</i> )		
Glipizide, Glipizide ER ( <i>Glucotrol, Glucotrol XL</i> )		
Glucotrol		
Glucovance		
Glyburide ( <i>Diabeta, Micronase</i> )		
Glynase		
Januvia		
<input type="checkbox"/> <a href="#">oral8hrfast8hr_spec</a>		
Liraglutide ( <i>Victoza</i> )		
Micronase		
Metformin + Sitagliptin ( <i>Janumet</i> )		
Metformin + Saxagliptin ( <i>Kombiglyze XR</i> )		
Metformin + Linagliptin ( <i>Jentadueto</i> )		
Nateglinide		
Prandin		
Pramlintide ( <i>Symlin</i> )		
Repaglinide		
Saxagliptin ( <i>Onglyza</i> )		
Sitagliptin ( <i>Januvia</i> )		
Starlix		
Symlin		
Tolazamide		
Tolbutamide		
Victoza		

**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.*

**Other diabetes medications: (specify)**

[othermeds\\_spec](#)

[othermedsText\\_spec](#)

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

★ 8a. *If a re-draw visit is necessary, has Participant agreed?* [redrawagree\\_spec](#)  Yes  No

9. Have you had anything to eat or drink in the last 8 hours? [eat8hrs\\_spec](#)

Yes 9a. *If YES, ask the Participant what they had to eat or drink. Describe what they had to eat or drink.*

[eatwhat\\_spec](#)

9b. *If Participant consumed non-allowable food or drink, record most recent time*

[eattimeHour\\_spec](#) [eattimeMin\\_spec](#)

Time:

Hour Minute  AM  PM

[eatampm\\_spec](#)

★ 9c. *If a re-draw visit is necessary, has Participant agreed?*  Yes  No fastredrawagree\_spec

2  No

10. Glucose meter reading:    glucread\_spec (May use drop from blood collected with venipuncture samples)

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

10a. Urine ketones: 1  Negative 2  Trace/small 3  Moderate 4  Large 5  Unable to obtain gluckeyt\_spec

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

- sympabdomin\_spec 1  Abdominal pain
- sympdiaph\_spec 1  Diaphoresis (excessive sweating)
- sympflight\_spec 1  Lightheadedness
- sympnausea\_spec 1  Nausea and or vomiting
- sympseizure\_spec 1  Seizure
- symptremor\_spec 1  Tremors or trembling
- sympconsgluc\_spec 1  Loss of consciousness due to low blood glucose
- sympconsphele\_spec 1  Loss of consciousness due to phlebotomy (fainting)
- sympgluc45\_spec 1  Blood glucose is < 45 mg./dl.
- sympgluc300\_spec 1  Blood glucose is > 300 mg./dl. with moderate or large ketones
- sympgluc500\_spec 1  Blood glucose is > 500 mg./dl. with or without ketones
- sympother\_spec 1  Other (specify):



sympotherspec\_spec

12. 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

13. Specimen obtained by:    (code) drawby\_spec

14. Date specimen obtained:       drawdate\_spec  
Month Day Year

15. Time specimen collected:      AM /  PM (check one) drawtimeHour\_spec  
drawtimeMin\_spec  
drawampm\_spec  
Hour 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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Completed by	<input type="text"/>
	Month	Day	Year			
Date Reviewed	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Reviewer Code	<input type="text"/>
	Month	Day	Year			
Date Entered	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Data Entry Code	<input type="text"/>
	Month	Day	Year			