SPECIMEN COLLECTION FORM for Visit 1a (L01)

CKiD Chronic Kidney Disease in Children Cohort Study (CKiD)

SECTION A: GENERAL INFORMATION

A1. PARTICIPANT ID: AFFIX ID LABEL OR ENTER NUMBER IF ID LABEL IS NOT AVAILABLE

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: 0 1 a

A3. FORM VERSION: 0 1 / 0 1 / 0 5

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY: (INITIALS) ___ ___ ___

SECTION B: PREGNANCY

B1. Is participant a female of child-bearing potential?

Yes.. 1 **(See PROMPT Below)**

No.. 2 **(Skip to C1)**

PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE GFR TESTING DATE.

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:

Positive.................................... 1 **(END; COMPLETE DISENROLLMENT FORM)**

Negative................................... 2

Encourage fluids throughout the visit.

↓

Place two IV lines (22 gauge polyethylene catheters); one in each arm
--OR---
Place one butterfly and one IV line (22 gauge polyethylene catheter); one in each arm; use tape to stabilize butterfly for Iohexol infusion

↓

Complete Time=0 (Pre-Iohexol Infusion) blood draw according to MOP instructions/flowchart on page 2.
NOTE: If patient has had a local CBC drawn within the past 30 days, those CBC results may be used instead of drawing another CBC and blood draw amounts can be decreased by 1 ml.

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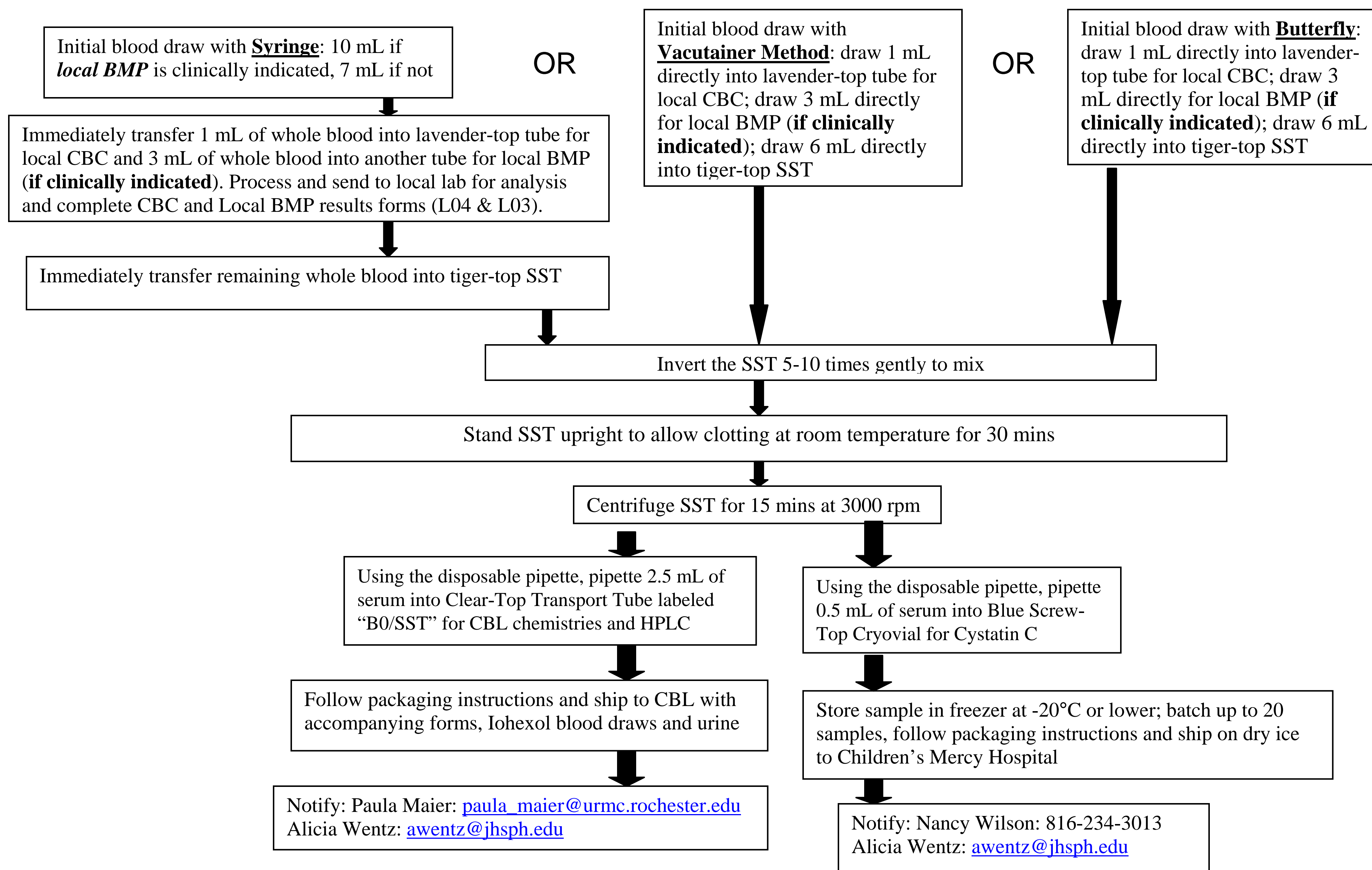
SECTION C: Visit 1A TIME = ZERO (PRE-IOHEXOL INFUSION) BLOOD DRAW



KID#: ___ - ___ ___ - ___ ___ ___

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C1. ACTUAL TIME OF TIME=ZERO (PRE-IOHEXOL INFUSION) BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

Reasons Code List*:	1= Not required	3 = Participant Refused	5 = Inadvertently Destroyed
	2 = Difficult Blood Draw/Urine Collection	4 = Red Blood Cell Contamination	6 = Oversight

Sample Type (Required Volume in Top Color Tube Type):	**(a) Sample Obtained:** Yes	No	**(b) If No, specify reason** *SEE CODE LIST ABOVE	**(c) Volume Distributed into Tubes:**	**(d) Required Volume Collected:** Yes	No	**(e) Centrifuged at Clinical Site:** Yes	No	**(f) Additional Requirements:**
C2. 1st Morning Urine (Urine Creatinine, Urine Protein) (5.0 mL–14.5 mL in Blue Top tube)	1 **(skip to c→)**	2	___ ___ **(skip to C3)**	___ ___ . ___ mL	1	2	**N/A**		i. Was urine collected at home? Yes.........................1 No...........................2 ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm
C3. Renal Chemistries and HPLC (5.0 mL in Tiger Top SST)	1 **(skip to c→)**	2	___ ___ **(skip to C4)**	___ . ___ mL	1	2	1	2	**N/A**
C4. Cystatin C (1.0 mL in Tiger Top SST)	1 **(skip to c→)**	2	___ ___ **(skip to C5)**	___ . ___ mL	1	2	1	2	Frozen Date: __ __ / __ __ / __ __ (m m d d y y)
C5. Local CBC (1.0 mL in Lavender Top tube)	1 **(skip to c→)**	2	___ ___ **(skip to D1)**	___ . ___ mL	1	2	**N/A**		**N/A**

C6. Please indicate:

a. The fax number to which the Central Biochemistry Lab should fax lab results Fax number: ______________________________

b. The recipient's name who will be receiving the results Recipient's name: _________________________

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SECTION D: OPTIONAL LOCAL LAB TESTS (IF CLINICALLY INDICATED)

D1. Was a basic metabolic panel (BMP) assay performed at the clinical site's local laboratory?

Yes... 1 → **(Complete Local Basic Metabolic Panel Results Form L03)**

No... 2

D2. Was a 1st morning urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes... 1 → **(Complete Local Urine Assay Results Form L06)**

No... 2

SECTION E: INFUSION SYRINGE WEIGHT

E1. Infusion syringe weight: **[THE SAME SCALE MUST BE USED TO WEIGH THE SYRINGE WITHOUT ALUMINIUM FOIL COVERING]**

a. With Iohexol: ___ ___ . ___ ___ (g)

b. Post Injection of Iohexol: ___ ___ . ___ ___ (g)

SECTION F: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 7

- ***IF SYRINGE IS COVERED WITH ALUMINIUM FOIL, REMOVE ALUMINIUM FOIL.***
- ***START INFUSION AT TIME = 0 ON TIMER AND COMPLETE INFUSION BETWEEN 1 TO 2 MINUTES.***
- ***LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND POST-INFUSION BLOOD DRAWS***

F1. IOHEXOL INFUSION

a. INFUSION START TIME: ____ ____ : ____ ____ 1 = AM 2 = PM **(SET TIMER TO ZERO)**

b. INFUSION END TIME: ____ ____ : ____ ____ 1 = AM 2 = PM

- ***DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.***
- ***COLLECT 1 mL of BLOOD FOR EACH IOHEXOL BLOOD DRAW. PLACE IN THE PROVIDED 2mL RED TOP PEDIATRIC TUBE.***
- ***PROVIDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 10, 30, 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 33 MINS INSTEAD OF 30 MINS, DOCUMENT BLOOD DRAWN @ 33 MINS.***

KID#: ___ - ___ ___ - ___ ___ ___

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		(i) Actual Minutes on TIMER	(ii) Real Time using CLOCK (Same Clock MUST be used)	(iii) Difficult Blood Draw: Yes	No	(iv) Blood Volume Collected (1 mL):	(v) Required Volume Collected: Yes	No	(vi) Centrifuged at Clinical Site: Yes	No
F2a.	**B1** 10 min*:	___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1	2	1 **(Skip to F3a)**	2 **(Skip to F3a)**
b.	**B1** 2nd attempt:	___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2	1	2

INVERT TUBE 5-10 TMES AFTER EACH BLOOD DRAW
LET SST TUBE STAND 20-30 MINUTES (BUT NO LONGER THAN 1 HOUR)
CENTRIFUGE FOR AT LEAST 15 MINUTES AT 3000 RPM

***POST VITALS SHOULD BE TAKEN IMMEDIATELY AFTER THE 10 MINUTE BLOOD DRAW USING LOCAL BP Measurement (i.e. DINAMAP)**

- **If rash develops after Iohexol Infusion, consider it a reaction to Iohexol and notify PI immediately. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV).**
- **In the rare event that systolic BP decreases more than 20 mm Hg or pulse increases more than 20 beats per min, notify PI immediately to evaluate reaction. Consider the possibility of an anaphylactic reaction to Iohexol. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV). Draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV for administration as ordered by physician.**

		(i) Post Vitals:	
F3a.	Post- infusion blood pressure:	___ ___ ___ / ___ ___ ___	**N/A**
b.	Post-infusion temperature:	___ ___ . ___ (°C)	**N/A**
c.	Post-infusion number of heart beats per minute:	___ ___ ___	**N/A**
d.	Post-infusion respirations per minute:	___________	**N/A**

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		(i) Actual Minutes on TIMER	(ii) Real Time using CLOCK (Same Clock MUST be used)	(iii) Difficult Blood Draw:		(iv) Blood Volume Collected (1 mL):	(v) Required Volume Collected:		(vi) Centrifuged at Clinical Site:	
				Yes	**No**		**Yes**	**No**	**Yes**	**No**
F4a.	**B2** 30 min:	___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1	2	1 **(Skip to F5a)**	2 **(Skip to F6a)**
b.	**B2** 2nd attempt:	___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2	1	2
F5a.	**B3** 120 min (2 hrs):	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1	2	1 **(Skip to F6a)**	2 **(Skip to F6a)**
b.	**B3** 2nd attempt:	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2	1	2
F6a.	**B4** 300 min (5 hrs):	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1	2	1 **(END)**	2 **(END)**
b.	**B4** 2nd attempt:	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2	1	2

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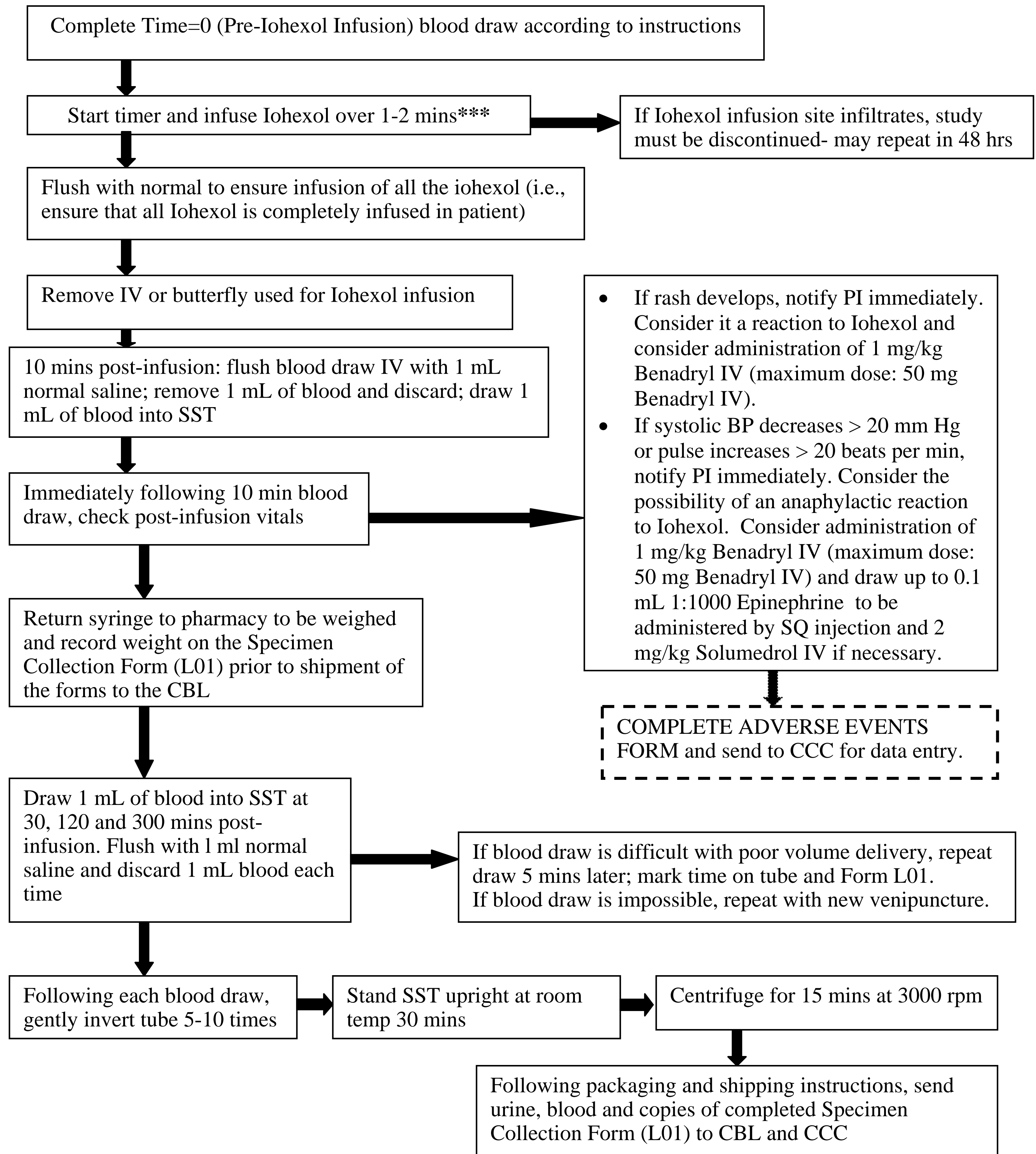
Instructions for Iohexol Infusion and GFR Blood Draws



*****Physician should be immediately available (in person or by phone) during Iohexol**

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