

AFRICAN AMERICAN STUDY OF KIDNEY DISEASE AND HYPERTENSION
AASK STUDY
GFR PROCEDURES AND MAILING FORM # 24

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1. Identification Number.....

2. Name Code.....

3. Visit Number.....

4. Date of GFR: mm/dd/yyyy
GFR_dt ↑

5. a. Type of GFR gfr-typ
- 1=Regularly Scheduled GFR
 - 2=Repeat after potential GFR stop point (50% or more decline from 2 GFR to next)
 - 3=Repeat due to high CV
 - 4=Other
 - 5=Repeat after potential GFR action item (#14) (>50% decline over mean baseline GFR)
 - 6=GFR done outside of visit window
 - 7=Extra Post Stop Point GFR (Protocol Pg. 11011, Section 11.c.1)

b. Status of GFR (0=not done, 1=done) gfr-stat

c. Comments on GFR Status stat-comm

- 0=No comments. The GFR was held.
- 1=Visit was missed and GFR was missed.
- 2=Visit was held, and GFR was missed even though the patient came in for a GFR. There was a procedural reason (missing sample, broken tube) a GFR could not be calculated. We could not get the GFR rescheduled.
- 3=Visit was held, and GFR was missed because the patient refused to do this GFR. The patient seems willing to do GFR's in the future.
- 4=Visit was held, and GFR was missed because the patient refused to do this GFR. The patient says he will never do another GFR again.
- Visit was held, and the GFR could not be rescheduled after it was missed for the following reason:
 - 102=The patient forgot
 - 103=The patient could not get off work
 - 104=The patient had a dependent care problem
 - 105=The patient had a transportation problem
 - 106=The patient was too sick to come in
 - 107=The patient was in the hospital
 - 112=The patient and the clinic staff had a scheduling conflict
 - 114=The patient was in jail or prison
 - 115=The patient has moved and it is harder to get GFR's
 - 113=Other reason

GFR-mailing

NOTE: Pregnancy tests must be done on women of child bearing potential.

- d. **NOTE: A reminder call should be made sometime during the week before the GFR, confirming the GFR time and reminding the patient to water load.**
 Results of reminder call 12 min
 0=A reminder call was not made.
 1=We tried once but could not reach the patient or leave a message.
 2=We tried twice but could not reach the patient or leave a message.
 3=We tried three times but could not reach the patient or leave a message.
 4=**We reached the patient.**
 5=We did not reach the patient, but left a message.
 6=The patient has no phone.

- 6. a. Date pregnancy test performed preg-de
 (leave blank if not done)
 b. Result: 0=Not done, 1=Positive result, 2=Negative result result

If positive, do not perform the GFR. Notify the Principal Investigator.

If patient has started Hydrochlorothiazide in the past 14 days, do not perform this GFR. The GFR may be performed when the patient has been on this drug at least 14 days.

- 7. Has the participant been fasting for at least 8 hours? (0=No, 1=Yes) fast-8hr
- 8. If Q07=0 (No), has participant been fasting for 2 hours after a meal containing < 2 gms of protein? (0=No, 1=Yes, 9=Not applicable) (See MOP Section 7.8 & 7.9) fast-2

If "No" to 7 and 8, reschedule test.

- 9. Has the participant had any radionuclide diagnostic tests OTHER than those (See MOO) done with 99-Techneium (99Tc as in 99Tc-DTPA renal flow scan) or ¹²⁵I-Iothalamate GFRs within the past 30 days? (0=No, 1=Yes) diag tes

If "Yes", do not perform GFR. Reschedule test for a date at least 30 days from date of radionuclide test.

NOTE: Usual diuretics and antihypertensive agents should not be withheld prior to the GFR test.

- 10. Has the participant taken any NSAIDS (e.g. ibuprofen) or aspirin in the past 48 hours? (0=No, 1=Yes) . If yes, what drug, message, will appear nsaids

If "Yes", do not perform GFR. Discontinue medications and reschedule GFR 48 hours after last medications.

- 11. The participant should take 5 ml/kg water prior to arrival.
 The participant should drink 10 ml/kg water during the first 60 to 90 minutes.

GFR - MAILING

Administer SSKI.

- a. Time of ingestion (24-hour clock) : inges-tm
 - 12. **Have participant void. Collect urine, labelling Background Urine.**
 - a. Time Background Urine collected (24-hour clock) : ubck-tm
 - 13. Has Background Blood been drawn? (0=No, 1=Yes) bld-bck
- Wait until 30 minutes have elapsed after the SSKI ingestion.
- 14. Inject Glofil subcutaneously.
Time of injection (24-hour clock) : inj-tm

After waiting at least 60 minutes after the Glofil injection, collect Discard Urine (Urine #0.)

- 15. a. Time #0 (24-hour clock) : tm0
- b. Volume of Discard Urine (ml) uvol-dec
- c. Time elapsed: Time #0-Time Background *
- d. Urine Flow Rate at Time #0 (ml/min) *

If urinary flow rate ≥ 3 ml/min, proceed. If urinary flow rate < 3 ml/min, continue hydration and wait another 30 minutes and report the new time in "a" and add the volume to "b." If new urine flow rate is ≥ 3 ml/min proceed. If not, contact the Central GFR Laboratory Technicians at (216) 444-4552.

- e. Has Blood # 0 been drawn (0=No, 1=Yes) bld-0
- 16. a. Wait at least 30 minutes. Time # 1 (24-hour clock) : tm-1
- b. Volume of Urine # 1 (ml) uvol-1
- c. Has Blood # 1 been drawn? (0=No, 1=Yes) bld-1
- d. Time elapsed: Time # 1 - Time # 0 *
- 17. a. Wait at least 30 minutes. Time # 2 (24-hour clock) : tm-2
- b. Volume of Urine # 2: (ml) uvol-2
- c. Has Blood # 2 been drawn? (0=No, 1=Yes) bld-2
- d. Time elapsed: Time # 2 - Time # 1 *

* not stored on table

- 18. a. Wait at least 30 minutes. Time # 3 (24-hour clock) ___:___ *tm-3*
- b. Volume of Urine # 3: (ml) ___ *UVol-3*
- c. Has Blood # 3 been drawn? (0=No, 1=Yes) ___ *bld-*
- d. Time elapsed: Time # 3 - Time # 2 ___ ***

- 19. a. Wait at least 30 minutes. Time # 4 (24-hour clock) ___:___ *tm-4*
- b. Volume of Urine # 4: (ml) ___ *UVol-*
- c. Has Blood # 4 been drawn? (0=No, 1=Yes) ___ *bld-*
- d. Time elapsed: Time # 4 - Time # 3 ___ ***

20. Optional 5th Period (to be done when a problem occurs during one of the first four periods).

- a. Wait at least 30 minutes. Time # 5 (24-hour clock) ___:___ *tm-5*
- b. Volume of Urine # 5: (ml) ___ *UVol-5*
- c. Has Blood # 5 been drawn? (0=No, 1=Yes) ___ *bld-5*
- d. Time elapsed: Time # 5 - Time # 4 ___ ***

21. Confirm that the following samples have been sent: (0=No, 1=Yes)

- a. Background Serum #B ___ *S_bck*
- b. Background Urine #0 ___ *U_bck*
- c. Serum #0 ___ *S-0*
- d. Urine #1 ___ *U-2*
- e. Serum #1 ___ *S-2*
- f. Urine #2 ___ *U-2*
- g. Serum #2 ___ *S-2*
- h. Urine #3 ___ *U-3*
- i. Serum #3 ___ *S-3*
- j. Urine #4 ___ *U-4*

** not stored on table*

- k. Serum #4 _
 - l. Urine #5 _
 - m. Serum #5 _
 - 22. a. Which urine collections had a problem or are thought to be incomplete? .. 6
0=None, 1=Urine #0, 2=Urine #1, 3=Urine #2, 4=Urine #3, 5=Urine #4, 6=Urine #5
 - b. Which urine collections were collected but have not been sent?
(use codes above) U
 - 23. a. Which serum collections had a problem? 5
0=None, 1=Background Serum, 2=Serum #0, 3=Serum #1, 4=Serum #2, 5=Serum #3, 6=Serum #4, 7=Serum #5
 - b. Which serum collections were collected but have not been sent?
(use codes above) SC
 - c. Comments: (anything unusual about the test: Enter 128 characters) CC - Com
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24. Date samples sent to GFR Lab (mm/dd/yyyy) de

GFR - mailing

- 201. Certification ID of person completing this form Com
(The person who performed the GFR must be the person who completed the form.)
- 202. Certification ID of person entering this form ent

Certification

For Clinical Center Use Only

Date Entered ____/____/____

Verified? _____