| RUSSELL 2-POINT GFR PROTOCOL (CLIA-88)CPT CODE: 78725UPDATED: SEPTEMBER 2019CPT CODE: 78725 | | | | |
|---|--|------------------------------|--|--|
| Indications: | Evaluation and follow up of renal side effects of chemotherapy or nephrotoxic drugs (e.g. cyclosporin). | | | |
| | Evaluation and follow up of renal function in chronic glomerulopa syndrome). | thies (e.g. hemolytic uremic | | |
| | Assessment of renal function in a potential kidney donor and/or serum creatinine result. | a patient with a misleading | | |
| Contra-indications: | Patient receiving intravenous hyperhydration will have an altered GF | R result. | | |
| | Patients with ascites, oedema or other expanded body space will result. | have an over estimated GFR | | |
| Patient Prep: | No caffeine products from 10 pm the night prior to procedure. | | | |
| | Adult and Pediatric patients: Should have a light breakfast, low in fruit, fruit smoothie) the morning of the procedure until the end of | | | |
| | Infants: May continue with normal feeding schedule. | | | |
| | Adults: The patient needs to drink four 8 ounce glass of clear liquid prior to appointment time. | (water, apple juice) 1 hour | | |
| | Infant and Pediatrics: Schedule AFCH Campground for IV placement a | and IV hydration. | | |
| Scheduling: | Required: patient's current height and weight. | | | |
| | Health Link allows for maximum of two patients to be scheduled per | day. | | |

Radiopharmaceutical & Dose:

 $3 \text{ mCi} \pm 20\%$ (2.4-3.6 mCi) Tc-99m-DTPA in 1.0 ml. Dose will be adjusted for patient weight per NMIS/nomogram. Two equal doses (within $\pm 5\%$) are required - one for injection and one for a counting standard. The purity of the Tc-DTPA must be > 98% as determined by ITLC chromatography within two hours of injection. Doses should be drawn within two hours of injection.

Procedure:

- A. Placement of 20 gauge angiocatheter is preferred (to prevent lysing), a smaller gauge angiocatheter may be used on rare occasions. After placement of angiocatheter ability to draw back blood without resistance is to be confirmed.
- B. Count patient and calibration doses in dose calibrator prior to injection. Record activity and time of assay measurements on Absolute GFR worksheet. If doses are not within 5% request a new dose pair.

Note: This recorded time will equal Time 0 for this procedure.

- C. Inject Tc99m DTPA and flush the syringe with normal saline 3 times. Record mid-point time of patient injection as recorded injection time.
- D. Assay Tc99m DTPA patient syringe and all removable parts (e.g.3-way stopcock) and record residual activity and assay time. Do not remove I.V. until all samples (60 & 180 minute) are drawn.

Note: Must use same dose calibrator for all assay measurements.

- E. Draw two blood samples as decribed below for your specific patient.
 - Adult: Draw two 4ml blood samples with a 5 ml syringe and transfer to a Lavender top vacuette via a vacutainer blood transfer device. Total volume: 8 ml.
 - Pediatric (1year to <18 years): Draw two 3ml blood samples with a 5 ml syringe and transfer to a Lavender top vacuette via a vacutainer blood transfer device. Total volume: 6 ml.
 - Infant (< 1 year): Draw two 2ml blood samples with a 3 ml syringe and transfer to a Lavender top vacuette via a vacutainer transfer device. Total volume: 4 ml (plus 1 ml waste). Check the patients weight against the "Maximum Blood Draw Guideline" (Appendix 1), if the maximum is less than the total of the two draws (10 ml), check with physician or patient nurse exceeding this maximum volume.

Blood samples are drawn at 60 and 180 minutes post injection. These timing points occur at mid-point of the blood sample draw. The time that the mid-point is reached must be accurately noted for each sample.

<u>Note</u>: Prior to the 60 and 180 minute blood samples draw a waste sample to prevent dilution of sample from line fluids.

Gently invert the blood sample after transfer to Lavender top vacuette to ensure adequate mixing of blood with the anticoagulant.

- F. Each tube must be labeled with the patient name or MR number or birth date and sample time point in the presence of the patient.
- G. Standard dilution samples. All tubes used must be labeled with the patient name or MR number or birth date.
- H. Processed plasma samples. All tubes used must be labeled with the patient name or MR number or birth date and sample time point.
- I. Samples are counted Multi-Wiper TM using the ABSGFR protocol #6. This program counts all 8 samples for 2 minutes simultaneously.
- J. Document all work on Absolute GFR Worksheet.
- K. <u>Blood Processing</u>:
 - Centrifuge 60 min & 180 min drawn whole blood samples in Ultra-8S fixed angle centrifuge set at 3300 rpms for 20 minutes.
 - At completion of centrifuging of 60 min & 180 min whole blood samples check that the plasma does not have any red colorization, indicating lysis of RBC's. If the plasma has significant redness, draw another sample and record time of new blood collection.
 - Pipette a 1.0 ml plasma aliquot from each separated blood sample into Centrifree ultra filtration devices for centrifuging.
 - Place all plasma samples in Ulta-8S fixed angle centrifuge set at 3300 g for 30 minutes.
 - Retrieve the Centrifree apparatus. Remove the filtrate cup containing the clear, colorless ultrafiltrate. Pipette accurately 100 µl from each cup into scintillation tubes for counting. Cap tube, label, and save for counting.

NOTE: A swinging bucket head centrifuge results in inadequate ultrafiltration.

L. <u>Standard Preparation (Note 1)</u>: A serial dilution is used for making the 1:10,000 counting standard.

Note: Must use same dose calibrator for all assay measurements.

- Carefully inject the standard into a 100 ml volumetric flask(A) containing 50-75 ml sterile water.
- Rinse the syringe 3x with sterile water. Add sterile water to the 100 ml fill mark on the volumetric flask (A), mix thoroughly and label 1:100.
- Assay the calibration syringe again including the needle for residual activity. If more than 2% activity remains, rinse again and re-assay.

Record residual activity and assay time on Absolute GFR worksheet.

- Accurately pipette 1.0 ml of this 1:100 dilution into a second 100 ml volumetric flask(A) labeled 1:10,000 dilution which contains 50-75 ml sterile water, add sterile water to the 100 ml fill mark on the volumetric flask(A), and mix thoroughly.
- Accurately pipette 100 μ l of this 1:10,000 dilution into each of two counting tubes. Cap the tubes, label, and save for counting.
- M. <u>Counting Procedure</u>: Counting device used is the Multi-Wiper Multi-Well Nuclear Medicine Counter with the following processing protocol, ABSGFR (protocol 6) under the Wipe Set Library (protocol 1). This protocol uses an isotope setting of 140 KeV ± 20% window.
- N. Place the sample tubes in the counting tray as follows: Wells 1& 2 Background, Wells slots 3 & 4 Standard, Wells 5 & 6 60 minute plasma sample and Wells slots 7 & 8 180 minute plasma samples. Record the start time of counting of samples on the ABSOLUTE GFR worksheet.
- O. <u>Computer Processing</u>:
 - 1. Xeleris: ABSGFR
 - 2. GFR is calculated by the Russell 2-Point Method.
 - 3. The results are normalized to 1.73 m^2 body surface area using the formula

BSA (cm) = $[wt (kg)]^{0.425} \times [ht (cm)]^{0.725} \times 71.84$.

Data Analysis: Xeleris: AbsGFR.

Interpretation: Normal GFR is 125 ml/min/1.73 m².

Verifications:

<u>Accuracy</u>

Semi-annually all performing technologists will run a split patient sample. Results will be reviewed and approved as acceptable by the Chief of Nuclear Medicine and Point of Care Coordinater. These results will to stored on the J:Drive and the three most recent will be in the protocol manual as a reference for this protocol.

Documentation

All blood collection tubes are labeled with two patient identifiers in the presence of the patient and documented on the ABSOLUTE GFR BLOOD DRAW VERIFICATION form.

All counting tubes are labeled with two patient identifiers and documented on the ABSOLUTE GFR / SMALL BOWEL LABEL VERIFICATION (PT IDENTIFIER) S/P PROCEDURE form.

Nuclear Medicine Absolute GFR Worksheet

| University of | Wisconsin | Hospital | & | Clinics |
|---------------|-----------|----------|---|---------|
| 600 Highland | Ave | | | |
| Madison, Wi | 53792 | | | |

WORKSHEET: ABSOLUTE GFR (CLIA-88)

UPDATED: MARCH 2017

| PATIENT INFORMATION: | RADIOPHARMACEUTICAL T99m DTPA: |
|---|--------------------------------|
| Name | Inventory Control # |
| MR# | % Tag |
| Date | |
| Age | |
| Height (cm) | |
| Weight (kg.) | |
| DTPA IN DOSE CALIBRATOR: | |
| Patient (mCi) | |
| Standard (mCi) | |
| Time of Injection (SWT) | |
| Time of Post Injection | |
| Dose in Dose Calibrator (SWT) | |
| Post Injection | |
| In Dose Calibrator (mCi) | |
| STANDARD DILUTION: | |
| Time of Standard in Dose Calibrator (SWT) | |
| Rinse (mCi) | |
| BLOOD SAMPLES: | |
| Draw 60-Minute Sample (SWT) | |
| Draw 180-Minute Sample (SWT) | |
| Samples Counted in Gamma (SWT) | |
| Processed | |
| Reviewed | |
| Discrepancies | |
| PROCESSING PROTOCOL: XELERIS ABSGFR | |



University of Wisconsin Hospital and Clinics

Division of Nuclear Medicine Procedure / Protocol University Hospital

WORKSHEET: ABSOLUTE GFR BLOOD DRAW VERIFICATION

UPDATED: MARCH 2017

| PROCEDURE | PT NAME | PT ID NUMBER | Initial Sample Labeled and Verified with two (2) patient identifiers | | | |
|-----------|---------|-----------------|--|-----|--|--|
| | | 60 Min | Y N | | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |
| | | | 60 Min | Y N | | |
| | | | 180 Min | Y N | | |



WORKSHEET: ABSOLUTE GFR / SMALL BOWEL LABEL VERIFICATION (PT IDENTIFIER) S/P PROCEDURE UPDATED: MARCH 2017

| PROCEDURE/DATE | PT NAME | PT ID NUMBER | PT ACCESSION # | Number of Patient Samples Labeled (signed by designee) |
|----------------|---------|--------------|----------------|--|
| | | | | of 16 GFR |
| | | | | of 6 sm bowel |
| | | | | of 16 GFR |
| | | | | of 6 sm bowel |
| | | | | of 16 GFR |
| | | | | of 6 sm bowel |
| | | | | of 16 GFR |
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| | | | | of 16 GFR |
| | | | | of 6 sm bowel |
| | | | | of 16 GFR |
| | | | | of 6 sm bowel |

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Notes

1) Flasks used for the serial dilution must meet Class A Glass Standards.

2) Reagent Safety: The only reagent is 99mTc-DTPA injection (DRAXIMAGE); it has been evaluated for risks including

- Acute toxicity risk have been tested and none were found
- Carcinogenic potential in the State of California
- Reproductive toxicity testing has not been performed. ٠

| Reviewed By: | | Updated By: Rosalie R Hovey |
|--|---|---|
| Scott B. Perlman, MD, MS Chief, Nuclear Medicine | Diane H. Norback, MD CLIA Director | John Vetter, PhD, DABR Medical Physicist |
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