

Modification of Diet in Renal Disease Study
LOCAL LABORATORY MEASUREMENT FORM

This form is to be completed whenever a local laboratory measurement is done for the study. It should be completed for scheduled routine study blood work and for action item repeated measurements. If and when extra blood work is done, not called for in the Protocol, do not complete the form.

QUESTION #INSTRUCTIONS

4b. B is a baseline visit, F is a follow-up visit and A is an abbreviated follow-up visit after stop points. P is used for blood work immediately after stop and X is used for Study F patients and always use K for Study C post stop point visits.

c. Visit numbers are sequential as follows:

0.0 = Baseline Visit 0	
1.0 = Baseline Visit 1	1.0 = Follow-up visit 1
2.0 = Baseline Visit 2	2.0 = Follow-up visit 2
3.0 = Baseline Visit 3	3.0 = Follow-up visit 3
	4.0 = Follow-up visit 4 (etc.)

If blood work is done at BOA instead of B0 or to supplement B0 data, complete by indicating the visit number by 0.5.

5. At all visits requiring serum biochemistry lab work, this section must be completed. (See Table 9.1. of the Protocol) The following is a table of units and allowed Datalex ranges for each of the laboratory values to be recorded. Be sure to watch for action items. See Section 10.3.1, page 10.4 for a complete list of items and definitions of action items.

a. Creatinine	mg/dl	0.1 - 15.0
b. Urea Nitrogen	mg/dl	10 - 180
c. Sodium	mEq/L	30 - 450
d. Potassium	mEq/l	3.0 - 7.0
e. Chloride	mEq/l	80.0 - 130.0
f. Bicarbonate	mEq/l	10 - 50
g. Glucose	mg/dl	1 - 900
h. Calcium	mg/dl	6.0 - 12.0
i. Iron	mcg/dl	10 - 220
j. Magnesium	mg/dl	1.0 - 5.0

6. a. WBC ($\times 10^3/\text{mm}^3$)	2.0 - 15.0
b. Hemoglobin (g/dl)	6.0 - 20.0
c. Hematocrit (%)	20.0 - 60.0

For each value entered in items 5 and 6 indicate whether it was a routine study protocol measurement for that visit or if it was measured as a response to an action item. If local lab work is done which is not required, do NOT complete form. If measure done as part of routine and for action, indicate measured in response to action item.

When a value is outside the above ranges, a -1 should be entered and a Form #24, Data-Out-Of-Range, completed.

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6. (cont'd) The following is a conversion equation for those centers where it is necessary to convert data prior to form completion and entry.
Serum magnesium (mg/dl) = 1.2*Magnesium (mEq/L)
- 7b. The following medications should not be taken for 48 hours prior to blood measurements: NSAID, inhibitors of tubular creatinine secretion (cimetidine, trimethoprim) or agents which interfere with chemical determination of creatinine (cephalosporins).

For DCC Use Only
Rev. 1 9/1/88

E ___
V ___
T ___

Form # 06
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Modification of Diet in Renal Disease Study Local Laboratory Measurement Form

This form is to be completed whenever a local laboratory measurement is done for the study.

FORM # 06

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. a. Date of visit (or measurement)..... / /
- b. Visit Type.....
- c. Visit Number.....

For items 5 and 6 give reasons for lab work

- 1 = Routine study measurement
- 2 = Repeated measurement for action item

5. Serum Biochemistry	Value	Reason
a. Creatinine (mg/dl)	_____	_____
b. Urea Nitrogen (mg/dl)	_____	_____
c. Sodium (mEq/l)	_____	_____
d. Potassium (mEq/l)	_____	_____
e. Chloride (mEq/l)	_____	_____
f. Bicarbonate (mEq/l)	_____	_____
g. Glucose (mg/dl)	_____	_____
h. Calcium (mg/dl)	_____	_____
i. Iron (mcg/dl)	_____	_____
j. Magnesium (mg/dl)	_____	_____

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6. Hematology	Value	Reason
a. WBC ($\times 10^3/\text{mm}^3$)	_____	_____
b. Hemoglobin (gm/dl)	_____	_____
c. Hematocrit (%)	_____	_____

7. a. How many hours was patient fasting prior to blood being drawn? _____
b. Were medications (NSAIDS, cimetidine, trimethorprim, cephalosporins) appropriately withheld 48 hours prior to the blood test? (1 = yes, 2 = no) _____

101. Date this form completed ____/____/____
102. Certification number of person filling out this form _____
103. Date form entered ____/____/____
104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196
