

21. Specimens for Local Labs

21.1 Introduction

The FHN Studies do not use a central lab. All lab data are measured locally. The study requires no specific methods for drawing blood or centrifuging for any of these lab tests. Each site should follow the procedures normally used in that dialysis unit. The name of the local lab used by each dialysis unit is recorded in the study database on the dialysis unit form. The time interval during which each local lab is used will also be recorded. Thus, if we ever need to, we will be able to determine the local lab where any patient local lab value was measured.

Local lab data can be divided into local lab data related to kinetic modeling and local lab data not related to kinetic modeling. Details on local lab values related to kinetic modeling are in the two kinetic modeling chapters of this Manual of Operations. This chapter addresses only the local lab data not related to kinetic modeling.

The local laboratory measurements required for the FHN studies are summarized in Table 21.1 for the Daily Study and 21.2 for the Nocturnal Study. During baseline, requirements for the two studies are the same.

21.2 Ordering Local Lab Tests

The frequency that any lab measure is done can vary from dialysis unit to dialysis unit. In many cases, it is anticipated that the study measurements will coincide with tests that the dialysis unit would routinely be measuring them anyway. The study measurements must be done whether or not the dialysis unit would routinely be measuring them anyway. The FHN team members (Principal Investigator and Study Coordinator) associated with any dialysis unit face several tasks

1) The team members must look at the dialysis unit's usual schedule and determine if the study will require extra local lab measures that would not routinely be measured.

If there are,

2) The team members must set a method in place so that the extra lab tests are requested whenever they protocol requires them

3) The team members must set a method in place so that these extra tests are billed to the patient's Clinical Center's budget, not to the patient himself or his insurance company.

It is important that these methods be in place before the first patient is enrolled.

21.3 Baseline

Baseline requirements are identical for the Nocturnal and Daily Study. The following tests must be measured (and entered into the study database) twice on each patient in order for the patient to be eligible for randomization: Pre-dialysis serum albumin, Pre- and post-dialysis serum phosphate, Pre- and post-dialysis serum creatinine, and Pre- and post-dialysis serum urea.

The following tests must be measured (and entered into the study database) once on each patient in order for the patient to be eligible for randomization: Interdialytic urine for urea, creatinine, phosphate; Pre-dialysis hemoglobin, calcium, bicarbonate, sodium, and potassium; Pre-dialysis transferrin and ferritin; and Pre-dialysis parathyroid hormone.

The patient eligibility checking program will look for each of these lab values and will not allow a patient to be randomized if the values have not been entered into the study database.

21.4 Follow Up

Follow up requirements are slightly different between the Nocturnal and Daily Study because the Nocturnal Study lasts two months longer. The detailed schedule of measurements is given in Tables 21.1 and 21.2. It is very important that in follow up, team members request extra lab tests whenever they protocol requires them and they would not usually be done or the unit missed doing them on a patient for any reason.

Note that pre-dialysis transferrin and ferritin and pre-dialysis parathyroid hormone must be entered into database at least once every 4 months, but that the center may optionally enter these labs at any additional time points.

21.5 Forms and Reports

Local Lab data is key entered onto Form 207, and, as noted, the name of the local lab used by each dialysis unit is recorded in the study database on the dialysis unit form.

Quality Control edit checks will be programmed into Form 207 so that any value that is too low or too high to be possible in a living human being, or would happen no more than once in, say, 100,000 measures, will be screened out of the form at the time of data entry. Also, the data will be cross tabulated and graphed for steering committee meeting reports, so steering committee members can scrutinize outliers.

During Baseline, as noted, the patient eligibility checking program will look for each of the required baseline lab values and will not allow a patient to be randomized if the values have not been entered into the study database.

During Follow Up, individual patient lab data reports, or flow-sheets, will include all data measured and will include normalized or calculated variables as needed.

The follow up missing forms reporting system will track cases in which a month passed and the required lab data form 207 was not entered by the middle of the next month. Special site-visit-like conference calls will be held as needed with any site that has significant numbers of missing forms.

The missing data report system will track cases in which a follow up Form 207 has been entered but not all required tests were run. These data will be summarized by Consortium Core, Clinical Center, and Dialysis Unit. Special site-visit-like conference calls will be held as needed with any site that has significant amounts of missing data.

Table 21.1 Daily Study Local Laboratory Measurements

Measurement	Baseline	1 mo	2 mo	3 mo	4 mo	5 mo	6 mo	7 mo	8 mo	9 mo	10 mo	11 mo	12 mo
Predialysis serum albumin	✓✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pre and post-dialysis serum phosphate, creatinine, urea	✓✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Interdialytic urine for urea, creatinine, phosphate	✓				✓								✓
Pre-dialysis hemoglobin, calcium, bicarbonate, sodium, and potassium	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pre-dialysis transferrin and ferritin ¹	✓		✓				✓				✓		
Pre-dialysis parathyroid hormone ¹	✓		✓				✓				✓		

Table 21.2 Nocturnal Study Local Laboratory Measurements

Measurement	Baseline	1 mo	2 mo	3 mo	4 mo	5 mo	6 mo	7 mo	8 mo	9 mo	10 mo	11 mo	12 mo	13 mo	14 mo
Predialysis serum albumin	✓✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pre and post-dialysis serum phosphate, creatinine, urea	✓✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Interdialytic urine for urea, creatinine, phosphate	✓					✓									✓
Pre-dialysis hemoglobin, calcium, bicarbonate, sodium, and potassium	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pre-dialysis transferrin and ferritin ¹	✓		✓			✓		✓			✓			✓	
Pre-dialysis parathyroid hormone ¹	✓		✓			✓		✓			✓			✓	

1 These local labs to be entered into database at least once every 4 months (center may optionally enter these labs at additional time points)