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MDRD Internal Central Laboratory Manual of Operations

Volume 3, Chapter 2

Central Biochemistry Laboratory

December 1990

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A. Sample Processing at the CBL

1. Sample receipt and log-in

CBL Technician Responsibility

a. Record the receipt of the sample in the CBL sample log-in book.

b. Check Form 17 and all sample tubes closely for any errors, discrepancies or other problems. Record these in the Problem Log, which is included in the appendix.

c. Notify the clinical centers by electronic mail of any problems.

d. Xerox the log-in sheets for the various sections of MDRD lab.

e. All analyses should be completed by the end of the business day following receipt of the samples.

f. Any samples which are left over after analyses are completed will be kept refrigerated, space permitting, until the results are reported and reviewed by the clinical centers.

2. Sample Storage at the CBL

a. Urines.

Refrigerate urine samples until the time of analysis for creatinine, pH, phosphorus, potassium, protein, sodium and urea nitrogen.

b. Whole Blood (EDTA)

Refrigerate whole blood until analysis of hemoglobin A_{1c}.

c. Serum

1. Label and freeze serum (5ml) for the "after thought" sample at -70^{0}C.
2. Refrigerate serum for analysis of albumin, bilirubin, creatinine, HDL-cholesterol, LDH, phosphorus, SGOT, total cholesterol, transferrin, triglycerides, and uric acid until time of analysis.

3. Sample Distribution by the CBL Technicians

a. Add QC precision studies to each batch of MDRD samples.

b. Label tubes with ID name code, number and date of the sample.

c. Put required amount of sample in each tube.

d. Urine samples for urea nitrogen and phosphorus must be diluted 1:11 with

Saline diluent.

e. Hand carry the samples to the appropriate areas in MDRD lab.

1. Serum:

a. Beckman Array - Transferrin, Apolipoproteins A.I and B-0.5 ml.

b. Technicon RA 1000-Bilirubin, LDH, SGOT, -1.0 ml.

c. Hitachi 705 - Cholesterol, HDL 2, 3 total cholesterol, triglycerides, - 3.5 ml.

d. Astra - Albumin, Creatinine, Phosphorus, Urea Nitrogen, Uric acid, - 2.0 ml

2. Whole Blood:

Diamat HPLC - Hemoglobin A_{1c}, -2ml

3. 24 hour Urine Aliquot:

a. Astra - Creatinine, Potassium, Sodium-5ml urine Aliquot; and Urea Nitrogen, Phosphorus-2ml of urine dilution.

b. Manual section - pH, Protein (TCA-Ponceau S method) - 5 ml of urine aliquot.

4. Analytical Methods of the Central Biochemistry Laboratory

a. Serum

1. Transferrin, Apolipoproteins A-I and B: Beckman ARRAY Protein System using the principle of immuno kinetic-rate analysis. See Beckman Instruments ARRAy Operations Manual.

2. LDH,SGOT, T. Bilirubin - Technicon RA 1000 methods. See Technician RA 1000 Operations Manual.

3. Albumin, Creatinine, Urea, Phosphorus, Uric Acid: Beckman Astra 8 methods. See Beckman ASTRA 8 Operations.

4. Total Cholesterol and Triglycerides: Hitachi 705 Bichromatic Analyzer using BMD Enzymatic Assay systems. The triglyceride will be glycerol-blank to insure more precise estimation of VLDL-cholesterol. See Naito, H.K. and David, J.A. Lipid Research Methodology 1-76 (1984), Alan R. Liss, Inc., New York.

5. HDL-cholesterol: Hitachi 705 using the Dextran Sulfate -$MgCl_2$ Precipation Method. See Warnick et al., Clin. Chem. 28:1379 (1982).

6. LDL-cholesterol: The following calculation is used for LDL. LDL = cholesterol -0 [(Triglyceride divided by 6) + HDL].

b. Whole Blood

1. Hemoglobin A_{1c}: Diamet HPLC System. This is a totally dedicated system used to estimate HbA_{1c} analyzer by BIO-RAD.

c. Urine

1. Protein: TCA-Ponceau S. See Pesce, MA and Strande, CS, Clinical Chemistry, 19/11:1265-1267 (1973).

2. Sodium, Potassium, Creatinine, Phosphorus and Urea: Beckman Astra methods. See Beckman Astra-8 Operations Manual.

d. Alternate Methods

1. When problems occur with MDRD instrumentation alternate instrumentation will be used, as appropriate. Forms will indicate when alternate instrument results are reported. This will be done under supervision of the CBL Principal Investigator.

2. Result Reporting

a. The technicians who run the Hitachi and Beckman Array will return the samples along with the results to the CBL technicians.

b. The CBL technicians run all other tests.

c. Record the QC and precision results in the MDRD QC book. See forms in Appendix.

1. Review QC results.

2. If out of range, write up discrepancy report and take corrective action, in accordance with CCF QC guidelines (See Pages 3.10 - 3.15)

d. Calculate urine results. Equations for calculations can be found in the CBL Calculations Notebook.

e. Write up Forms 32 and 33 for each patient, as needed. Make a

highlighting line over area in log-in book when Forms 32 and 33 are completed.

1. Another CBL technician checks all transferring of data from instrument printouts to the forms.
2. All calculations are visually rechecked for transcription errors.
3. Once error-free, Forms 32 and 33 are given to the CBL Principal Investigator or alternate to sign.

f. Enter Forms 32 and 33 into Datalex and transmit to the DCC. Record the data sent to the DCC in the Log-in book.

g. A copy of all reports is sent back to the CBL for another check.

1. Compare each report with the hard copy for errors.
2. Report any discrepancies to the DCC for correction.
3. The process is repeated until all reports are correct.
4. Keep a original copy of each form. File in file cabinet.

B. External Quality Control for Clinical Center Laboratories

The CBL will coordinate and monitor the External QC program for the Clinical Center Laboratories.

1. The CBL will request a copy of each Local Laboratory's CAP survey results once each year.

   a. The CBL Principal Investigator will review results of the following serum tests:

      1. Magnesium
      2. Calcium
      3. Urea Nitrogen
      4. Creatinine

   b. Any unacceptable results will be reported to the Quality Control Committee.

      1. Results of the next CAP survey will then be requested for review.
      2. Any on-going problems with a particular constituent will be brought to the attention of the QC Committee Chairman.

C. External Quality Control Protocol for the CBL

1. CAP Samples

An External QC Program has been set up using CAP Survey samples as the control material. Samples will be procured and stored by the CBL technician. One urine and one serum sample will be analyzed by the CBL every four months.

a. Distribution of the CAP sample

1. The Central GFR Lab technician will reconstitute one serum and one urine CAP sample and remove the lot number.
2. The sample is given to the CBL to assay in duplicate for serum albumin, bilirubin, creatinine, HDL cholesterol, LDH, phosphorus, SGOT, total cholesterol, triglycerides, urea nitrogen, and uric acid. The urine is assayed in duplicate for creatinine, phosphorus, potassium, sodium, protein, and urea nitrogen.

b. Sample Processing

1. Make up two sets of tubes for serums, and two sets of tubes for urines using fictitious name codes and numbers.
2. Mix the samples well and pour half of each into the two sets of tubes.
3. Send through the system as if they were actual patient samples.

c. Result Reporting

1. Calculate urine results
2. Complete Form 34 with results and test method/instrumentations codes and transmit to the DCC via Datalex.
3. Request the QC lot numbers from the GFR lab technician, only after reporting is completed.
4. Provide to the DCC the peer group limits based on historical data from the CAP surveys.

d. Review of results

1. The DCC will compile a report and send to the CBL Principal Investigator.
2. The CBL Principal Investigator will review all data.

a. If results are in range, no further action is necessary.

b. If results are not within range, the process will be repeated with another lot number of the QC sample being reconstituted and analyzed for the out of range constituent.

c. If the second sample is still out of acceptable range, the CBL Principal Investigator will investigate the problem with the CCF Laboratory supervisor in the appropriate section.

3. All results will be reported in the quality control summary report which will go the Quality Control Committee for review.

2. Duplicate Samples

Every six months, each clinical center will send one duplicate sample to the CBL utilizing the QC ID names and numbers provided by the DCC.

a. The CBL will analyze the samples in the same manner as patient samples.

1. Analyze serum for albumin, bilirubin, creatinine, HDL-cholesterol, LDH, phosphorus, SGOT, total cholesterol, triglycerides, urea nitrogen and uric acid.

2. Analyze urine for creatinine, phosphorus, potassium, protein, sodium, and urea nitrogen.

3. Whole blood is analyzed for hemoglobin A1c.

b. Result reporting

1. Report results in the same manner as for patients

2. Complete Forms 32 and 33 and handle as described in the section on patient result reporting.

c. Review of results

1. The DCC will prepare a report comparing the duplicate QC results.

2. The report will be sent to the Clinical Center as well as the CBL Principal Investigator for review.

3. Results will also be reported in the QC Summary report for the Quality Control Committee to review.

a. Results which vary by an absolute difference of more than 10% or

more than 95% confidence limits on page 36 (whichever is greater) will be reviewed by the CBL technician according to the protocol on page 13.

b. On-going discrepancies and problems with reproducibility will be monitored by the CBL technicians and Principal Investigator.

Analysis of Discrepancies found on Split Patient QC samples analyzed by the CBL.

The purpose of this section is to define when CBL generated patient results should be deleted from the database. Discrepancies discovered by analysis of duplicate QC samples must be investigated. The following are guidelines for determining which results are valid. The CBL PI Will review all discrepancies and make the final decision based on these guidelines.

1. Patient and duplicate QC results which differ by an amount greater than 10% or more than the 95% confidence limits are to be rechecked.
   a. If the recheck results are within 10% absolute difference or 95% confidence limits of the original patient will be kept in the database.
   b. If the recheck results are within 10% absolute difference or 95% confidence limits of each other but either one differs from the original patient result by more than 10% absolute difference or 95% confidence limits, the original result on the actual patient will be deleted from the database.
   c. If the recheck results differ by an amount greater than 10% absolute difference or 95% confidence limits, then the original result on the actual patient will be deleted from the database.
2. If there is not enough sample to recheck the results, the patient result will be deleted from the database.
3. Recheck results which differ by greater than a 10% absolute difference or 95% confidence limits should be investigated to determine the source of the problem. Examples of problems which occurred in Phase II:
   a. An incorrect result was generated from the instrument.
   b. The aliquots of the actual patient and duplicate sample were not properly mixed.
   c. The aliquots were not from the same sample.

d. The aliquots were not stored properly.

4. All forms 32 and 33 with deletions will be flagged revised.

   a. The original duplicate QC result will always be kept in the database, but cannot be used as the patient result by the clinical center.

D. Internal Quality Control Protocol for the CBL

Currently, about 20% of the patient sample load constitute QC samples. Usually there are two to three known concentrations from several vendors, depending on the biochemical constituent being measured. Results for routine test measurements cannot be released if the QC does not meet the quality control guidelines. Also, each test has a specific protocol to address accuracy and precision throughout the day. Listed on pages 10 and 15 are the Biochemistry Department QC protocol which is revised each year by the Director of the Central Biochemistry Laboratory and the Departmental Chairman. The Department of Biochemistry has an official QC section with three medical technologists who manage the operation. All QC data will be open to inspection.

ACTION PROCEDURES FOR QUALITY CONTROL

The following guidelines have been incorporated from the CCF QC guidelines which were updated 12/88.

I. Daily Quality Control Action Procedure

Each control sample, for every constituent, should be checked against the calculated plus or minus two standard deviation (+ 2 S.D.) limits. If all control values are within the 2 S.D. limits, report out patient results.

A. One Control - The use of one level of control run once is acceptable for **only** qualitative testing, electrophoresis and the following tests:

   1. oxalate
   2. amino acids (quantitative)
   3. essential fatty acids
   4. fecal fat

5. d-xylose (urine)
6. porphyrin screen
7. pH by meter
8. pyruvate kinase
9. vitamin C
10. total lipids
11. mercury (blood)

If only one control is run and the result is outside the 2 S.D. limits, the test results are suspect. Take the following action:

1. Do not release patient results.
2. Recheck the control (if applicable) or recheck the control and a few patient results, or, if possible, repeat the entire assay.
3. If the control recheck specimen or reconstitute a fresh control specimen and analyze.
4. If the new/fresh control result is outside the 2 S.D. limits, troubleshoot the procedure for an apparent problem.
5. If the problem cannot be resolved, notify the supervisor/staff immediately.
6. Do not release patients' results until the problem has been corrected or an alternative procedure employed. Verify and record all corrective action.

B. Two Controls - If two controls are used and if one control result is within the 2 S.D. limits and one control is between 2-3 S.D. limits, the test is in control. Proceed with analysis.

C. Two Controls - If two controls are used and if one control result is within the S.D. limits but one control is outside the 3 S.D. limits, the test results are suspect. Take the following action:

1a. If you are running a batch mode, i.e., controls always run with batch: do not release patient results.

or

1b. If you are running in defined intervals not associated with any batch of tests (e.g., once/day, once/shift, once/4 hours): stop running patient specimens until

the procedure is back in control.

2. Recheck the control (if applicable) and/or, if possible, repeat the entire assay or recheck the control and a few patient results in the range of the control outside the 3 S.D. range. Patient recheck results should not exceed the precision variance limit or the 10% precision rule for duplicate samples of a particular analyte.
3. If the control recheck remains outside the 3 S.D. limits, obtain a new control specimen or reconstitute a fresh control specimen and analyze.
4. If the new/fresh control results continue to fall outside the 2 S.D. limits, troubleshoot the procedure for an apparent problem.
5. If the problem cannot be resolved, notify the supervisor/staff immediately.
6. Do not release patients' results until the problem has been corrected or an alternative procedure employed. Verify and record all corrective action.

E. Three Controls - If three controls are used: two controls are within 2 S.D. limits and one observation is between 2-3 S.D. limits, report outpatient results; the assay is in control.

F. Three Controls - If three controls are used and one observation is outside 3 S.D. limits, then:

1a. If you are running in a batch mode, i.e., controls always run with the batch: do not release patient results.

or

1b. If you are running in defined intervals not associated with any batch of tests (e.g., once/day, once shift, once/4 hours): stop running patient specimens until the procedure is back in control.

2. Recheck the unacceptable control and/or repeat the assay before any patient results are released.
3. If the rechecked control remains outside the 3 S.D. limits, obtain a new control specimen or reconstitute a fresh control specimen and analyze.
4. If the new/fresh control result is still outside the 3 S.D. limits, then troubleshoot the procedure for an apparent problem.

5. If the problem cannot be resolved, then:
   a. **DO NOT** release patients' results in the out-of-control range.
   b. Notify the supervisor/staff immediately.
6. Do not release patients' results until the problem has been corrected or an alternative procedure employed. Verify and record all corrective action.

G. Three Controls - If three controls are used and two or more observations are outside 2 S.D. limits, then: Follow procedure described in ID.

H. More Than Three Controls - If more than three controls are used: 75% or more of the observations are within 2 S.D. limits and 25% or less of the observations are between 2-3 S.D. limits, report outpatient results; the assay is in control.

I. More Than Three Controls - If more than three controls are used and if 50% or more of the control values fall outside the 2 S.D. range or the 3 S.D. range, the test results are suspect. Take the following action:

1a. If you are running in a batch mode, i.e., controls always run with the batch: do not release patient results.

or

1b. If you are running in defined intervals not associated with any batch of tests (e.g., once/day, once/shift, once/4 hours): stop running patient specimens until the procedure is back in control.

2. Recheck the unacceptable control(s) and/or repeat the assay before any patient results are released.
3. If the rechecked control(s) remains outside the 3 S.D. limits or if 50% or more of the controls are within the 2-3 S.D. limits, obtain a new control specimen or reconstitute a fresh control specimen or reconstitute a fresh control specimen and analyze.
4. If the new/fresh control result(s) is still outside the 3 S.D. limits or of 50% of more of the controls are within the 2-3 S.D. limits, then troubleshoot the procedure for an apparent problem.
5. If the problem cannot be resolved, then:
   a. **DO NOT** release patients' results in the out-of-control range.

b. Notify the supervisor/staff immediately.

6. Do not release patients' results until the problem has been corrected or an alternative procedure employed. Verify and record all corrective action.

GENERAL NOTES

1. If there is any doubt or question concerning the validity of patient results, contact the supervisor/staff immediately.
2. If any equipment or instrumentation required adjustment or repair, record the problem and the corrective action that was taken in the maintenance manual for future reference.
3. It is still necessary to document out-of-control situations even though patient results were not released.
4. When it is not possible to repeat a control and/or patients, an assay may be accepted at the discretion of the supervisor/staff.
5. A trend or an abrupt change of observed control values indicate that the performance of the analytical method has deteriorated. Again, if there is any doubt or question concerning the validity of patient results, contact the supervisor/staff.

II. Precision Studies Guidelines

Precision studies should be run on multiple analysis automated instruments or systems and are recommended for assays that are run in multiple batches per day. Precision studies will be run once a day on first shift for interbatch or batch-to-batch comparisons. The only exception to this regimen is the TDx. Precision studies will be performed on the following instruments/assays:

ACP - cyclosporine

Automated/Acute Care - Hitachi 736, ASTRA, TDx (high volume drugs)

Enzymes - CPK, LDH, SGOT, SGPT; CPK and LDH isoenzymes

LNMD - Hitachi 705, Beckman Array

The Precision study duplicate sample difference should be checked against the posted precision study limits for the assay performed.

A. If the assay is in control, but the precision study difference exceeds the 2 S.D. precision study limits, the assay is still in control and results may be reported.

B. If the assay is out of control and the precision study also exceeds the defined limits, refer to the Quality Control Action Guidelines for the out-of-control situation.

NOTE: A precision study does not replace a quality control.

Reviewed by:_____

Dept. Chairman (Date)

_____

(Date)

_____

(Date)

Appendix E

E. References Ranges for the Central Biochemistry Laboratory

Serum	Sex	Range	Units
Transferrin		210 to 375	mg/dl
Albumin		3.7 to 4.9	g/dl
Phosphorus		2.5 to 4.5	mg/dl
Creatinine		0.7 to 1.4	mg/dl
Urea Nitrogen	M	10 to 25	mg/dl
Urea Nitrogen	F	8 to 25	mg/dl
Uric Acid	F	2.0 to 7.0	mg/dl
Uric Acid	M	3.0 to 8.0	mg/dl
T. Bilirubin		0.0 to 1.5	mg/dl
AST (SGOT)		7 to 40	IU/L
LDH		50 to 210	IU/L
Triglycerides		30 to 200	mg/dl

Whole Blood		Range	Units
Hemoglobin A1c		3.5 to 6.5	%

24 hr. Urine		Range	Units
Creatinine	M	1000 to 2000	mg/day
	F	800 to 1800	mg/day
Urea Nitrogen		12 to 20	g/day
Protein		<0.15	g/day
Phosphorus		900 to 1300	mg/day
Sodium		40 to 220	mEq/day
Potassium		30 to 99	mEq/day

Lipid Reference Ranges

				Risk Classification	
	Age	Sex	Desirable	Borderline/High	High
Total Cholesterol	<20	M,F	75 - 169	170 - 199	≥200
	≥20	M,F	100 - 199	200 - 239	≥240
LDL-Cholesterol	<20	M,F	50 - 99	100 - 129	≥130
	≥20	M,F	60 - 129	130 - 159	≥160
HDL-Cholesterol	All	M	>45	36 - 45	≤35
	All	F	>55	36 - 55	≤35
HDL-2-Cholesterol	All	M	>14	10 - 14	≤10
	All	F	>20	10 - 20	≤10
HDL-3-Cholesterol	All	M	>31	25 - 31	≤25
	All	F	>35	25 - 35	≤25
VLDL-Cholesterol	<15	M,F	4 - 20	21 - 49	≥50
	≥15	M,F	5 -33	34 - 82	≥83
Triglycerides	<15	M,F	25 - 120	121 - 299	≥300
	≥15	M,F	30 - 200	201 - 499	≥500
Apolipoprotein A-I	<20	M	>127	110 - 127	<110
	≥20	F	>147	127 - 147	<127
Apolipoprotein B	<20	M	<98	98 - 112	>112
	≥20	F	<92	92 - 112	>112
A-I/B Ratio	<20	M	>1.30	0.98 - 13.0	<0.98
	≥20	F	>1.60	1.13 - 1.60	<1.13

Risk of Developing Coronary Heart Disease and the Total Cholesterol/HDL Cholesterol

	Risk	TC/HDL-C Ratio
Men	1/2 average	3.43
	average	4.97
	2x average	9.55
	3x average	23.99
Women	1/2 average	3.27
	average	4.44
	2x average	7.05
	3x average	11.04

Appendix F

F. MDRD Problem Record

Date	Date Msg Sent	Center	Problem	Response	Tech

NORD BECKMAN ASTRA 8 QUALITY CONTROL RESULTS

MONTH/YEAR_____ REVIEWED BY_____

Level 1 Level 2

SERUM CONTROL_____LOT NO._____ SERUM CONTROL_____LOT NO._____

3SD RANGE						3SD						Tech. Initials	Daily Supvr. Review
2SD RANGE						2SD							
DATE	UREA	ALB	CRE	PHOS	URIC ACID		UREA	ALB	CRE	PHOS	URIC ACID		

HDRD BECKMAN ASTRA 8 SERUM CONTROL CORRECTIVE ACTION RECORD

REVIEWED BY_____

MONTH/YEAR_____

Date	Comments	Corrective Action	Tech. Initials	Daily Supvr. Review

MDRD TECHNICON RA 1000 QUALITY CONTROL RESULTS

MONTH/YEAR_____ REVIEWED BY_____

Level 1 Level 2

SERUM CONTROL_____LOT NO._____ SERUM CONTROL_____LOT NO._____

3SD RANGE				3SD RANGE			Tech. Initials	Daily Supvr. Review
2SD RANGE				2SD RANGE				
DATE	AST	LDH	T.BILIRUBIN	AST	LDH	T.BILIRUBIN		

MDRD TECHNICON RA 1000 CORRECTIVE ACTION RECORDS

MONTH/YEAR_____ REVIEWED BY_____

Date	Comments	CORRECTIVE ACTION	Tech. Initials	Daily Supvr. Review

KDRD URINE PROTEIN QUALITY CONTROL & PRECISION RESULTS

CONTROL LEVEL 1 (BIORAD 1) LOT NO._____ MONTH/YEAR_____ REVIEWED BY_____

CONTROL LEVEL 2 (BIORAD 2) LOT NO._____

LEVEL 1 x 4 (BIORAD 1 X 4)

2SD RANGE				Precision Records								Tech. Initials	Daily Supvr. Review
2SD RANGE				Precision Limit = 1.9									
Date	Level 1	Level 2	Level 1x4	Date	Result 1	Result 2	Diff	Date	Result 1	Result 2	Diff		

MDRD URINE PROTEIN CORRECTIVE ACTION RECORD

REVIEWED BY_____

MONTH/YEAR_____

Date	Comments	Corrective Action	Tech. Initials	Daily Supvr. Review

NORD BECKMAN ASTRA 8 QUALITY CONTROL RESULTS

MONTH/YEAR_____ REVIEWED BY_____

Level 1 Level 2

URINE CONTROL_____LOT NO._____ URINE CONTROL_____LOT NO._____

3SD RANGE						3SD						
2SD RANGE						2SD					Tech. Initials	Daily Supvr. Review
DATE	NA	K	CRE	UREA	PHOS	NA	K	CRE	UREA	PHOS		

MDRD BECKMAN ASTRA 8 URINE CONTROL CORRECTIVE ACTION RECORD

REVIEWED BY_____

MONTH/YEAR_____

Date	Comments	Corrective Action	Tech. Initials	Daily Supvr. Review

TABLE 12.1 FREQUENCY AND LOCATION OF FOLLOW-UP LABORATORY TESTING FOR PHASE III

Tests		Month # 1	2+	3	4+	5	6	7	8+	9	10	11	12+	13	14	15	16+	17	18	19	20+	21	22	23	24+,1
Glucose	R		L		L		L		L		L		L		L		L		L		L		L		L
Sodium			L		L		L		L		L		L		L		L		L		L		L		L
Chloride			L		L		L		L		L		L		L		L		L		L		L		L
Potassium			L		L		L		L		L		L		L		L		L		L		L		L
Bicarbonate	A		L		L		L		L		L		L		L		L		L		L		L		L
CBC			L		L		L		L		L		L		L		L		L		L		L		L
WBC																									
Hgb																									
Hct	N																								
Iron					L				L				L				L				L				L
Magnesium					L				L				L				L				L				L
Phosphorus	D		C		C		C		C		C		C		C		C		C		C		C		C
Calcium			L		L		L		L		L		L		L		L		L		L		L		L
SUN			C		C		L		C		L		C		L		C		L		C		L		C
Creatinine	O		C		C		L		C		L		C		L		C		L		C		L		C
Albumin			C		C		C		C		C		C		C		C		C		C		C		C
Transferrin			C		C		C		C		C		C		C		C		C		C		C		C
LDH	M								C								C								C
SGOT									C								C								C
Bilirubin									C								C								C
Uric Acid									C								C								C
Standard Lipid Profile	I				C				C				C				C				C				C
Total, HDL, LDL Cholesterol, Triglycerides																									
Complete Lipid Profile	Z												C												C
HDL2, HDL3, Apo-liproteins A1 and B																									
Hemoglobin A_{1c}					C				C				C				C				C				C
Amino Acids	A		C						C								C								C
Amino Acids*			C		C				C				C				C				C				C
Plasma "After Thought"													C												C
24 Hr Urine	T																								
pH		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Protein		C	C	C	C	C	C	C	C				C				C				C				C
Urea Nitrogen	I	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Creatinine		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Phosphorus		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Sodium		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Potassium	O	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
"After Thought"													C												C
GFR			C		C				C				C				C				C				C
Electrocardiogram	M					C						C						C						C	

*Diet K Patients

[1]Follow-up beyond two years will follow a similar pattern.

+Fasting Measurements (12 hour fast, except for F2 which requires an 8 hour fast.

L = Local Laboratory Determination C = Central Laboratory Determination

CAP COMPARATIVE METHODS FOR QUARTERLY QUALITY CONTROL

	Constituent	Comparative Method	Instrument
SERUM	Magnesium	Atomic Absorption	Atomic Absorption Spec
	Phosphorus	Phosphomol. W/any Red	"All" Instruments
	Calcium	Atomic Absorption	Atomic Absorption Spec
	SUN	Diacetyl Monoxime	"All" Instruments
	Creatinine	"All" Method Principle	"All" Instruments
URINE	Urea Nitrogen	"All" Methods	
	Phosphorus	"All" Methods	
	Creatinine	"All" Methods	

COMPARATIVE METHODS are considered to be historically reliable methods by laboratorians and reflects the best available technology when no reference or definitive method has been agreed upon.

Results obtained by the Clinical Centers are compared to their peer group using the test method/instrumentation combination indicated by their laboratory director. Results should fall within a two standard deviation range of their peer group mean. A different QC sample is sent if reported results fall outside of this range. If unacceptable results are received on the second QC sample, the results are forwarded to the Laboratory Quality Control Committee to determine if corrective action is needed.

Appendix

95% Confidence Limits for Absolute Differences

between Split Sample Results

Serum Tests		Whole Blood Test	
Transferrin	39	Hemoglobin A1c	0.6
Albumin	0.1		
Creatinine	1.1		
SUN	2		
T. Cholesterol	6		
HDL Chol.	4		
Triglycerides	11		
Phosphorus	0.3		
Uric Acid	0.5		
T. Bilirubin	0.6		
SGOT	11		
LDH	17		
Magnesium	0.6		
Calcium	0.8		
Urine Test*			
Creatinine	9.8 x T.V./100		
Urea Nitrogen	49.3 x T.V./100,000		
Protein	5.6 x T.V./100,000		
Phosphorus	9.2 x T.V./100		
Na	4.8 x T.V./1000		
K	8.4 x T.V./1000		

*Review of the urine split sample results must take into account the total volume of the sample, because this is used in the calculations.

Appendix

Central Biochemistry Laboratory
"Supply Order Form"

Center Number_____ Date of Request_____

Please check supplies needed and return this form to the CBL in your next sample mailing. We will send the supplies when we return the sample mailer. Please notify us before you run out completely.

- [ ] Packing Tape
- [ ] Ziplock Bags
- [ ] Polar Packs
- [ ] 30 ml Sample Tubes (Urine)
- [ ] 15 ml Sample Tubes (Serum)
- [ ] 7 ml Sample Tubes (Whole Blood)
- [ ] Other (Specify):_____

Comments:_____

_____

Date Supplies Mailed:_____