e. Working BSA (0.06% PBS-BSA)
Thaw two 50-ml aliquots of stock BSA (0.6%).
Add 900 ml of working PBS (0.01M).
Final volume = 1,000 ml 0.06% PBS-BSA.
Store at 2-8 °C.
The solution is stable for 3 months.

f. 1% Gluteraldehyde - To be made after volume of washed packed cells is obtained. (Refer to treatment of SRBCs in 3.g.)

Gluteraldehyde is received as a 25% solution.

A volume of 1% solution equal to 2,250 ml is needed:

(2,250) (1%) = (X) (25%)
(2,250) (0.01) = (X) (0.25)
$\frac{22.50}{0.25}$ = X = 90 ml of 25% gluteraldehyde
Add 2,250 - 90 ml or 2,160 ml of 0.85% saline.

g. SRBC (10% sheep red blood cells)
Process within 1 week of receipt.

(1) Spin down 2 L of SRBS at 2,500 rpm for 5 minutes. Remove supernatent. Wash three times with 0.85% saline, removing supernatent after each centrifugation. Measure final volume of packed cells.

(2) Add nine volumes of 1% gluteraldehyde.

i.e., packed cell volume (pcv) = 250 ml.
10% solution = packed cell volume X 10.
10% solution = 2,500 ml.
1% gluteraldehyde = 2,500 - 250 (pcv) = 2,250 ml
2,250 ml of 1% = 90 ml of 25%

10% treated SRBCs:
250 ml packed cells
90 ml 25% gluteraldehyde
2,160 ml 0.85% saline
2.5 gm NaN_3 (0.1% Sodium azide)
2,500 ml Final volume

(3) Mix and let stand for 2 hours at room temperature, shaking occasionally.

(4) Wash three times with 0.85% saline as before, or until centrifuged supernatent is free of cell matter.

(5) Wash twice with distilled water, aspirating supernatent each time.

(6) Dilute to a 10% solution in saline with 0.1% sodium azide preservative.

250 ml packed cells
2,250 ml of 0.85% saline
2.5 gm NaN_3
2,500 ml Final volume

(7) Store at 2-8 °C. The solution is stable for 1 year.

h. Microtiter plates -- non-sterile rigid U plates.

i. Sources of reagents

(1) NaN_3: Sigma catalog no. 5-2002 500 g. Store at room temperature (22-28 °C).

(2) BSA (bovine serum albumin): Sigma catalog no. A-7888 10 gm. Store at 2-8 °C.

(3) Sheep red blood cells: Colorado Serum Co. catalog no. CS115 two bottles, 500 ml each. Store at 2-8 °C. Process within 1 week of receipt.

(4) Antigen: Centers for Disease Control contact Dr. Harold Russell (1-404-639-3929) or Dr. Knox Harrell (ext. 3352). Store at 2-8 °C.

(5) Control sera: Centers for Disease Control: contact Dr. Harold Russell (1-404-639-3929). Store lyophilized sera at 2-8 °C.

4. Calibration

a. Calibration is to be performed each day on the diluters.

(1) Rinse each diluter in distilled water.
(2) Dip the diluter in working PBS-BSA to top of grooves.
(3) Blot on 50 ul Go-No-Go Blotter paper to check volume.
(4) If the ring is too small, rewash and repeat the test. If the ring is accurate, roll the diluter along the blotter to dry the sides and insert into arm.

b. Volume dispensed is checked daily.

(1) Visually check levels in wells, looking for equal levels.

(2) Fill one row of a blank plate from a precalibrated 50 ul dropper. Check level visually with automated dispenser level.

(3) If volumes are too high or low, check tubing for plugs or adjust the syringe volume.

(4) If volumes are unequal, check tubing for plugs or check to see that the syringe is fastened securely.

5. Quality Control Material

a. Positive control: Add 2 ml distilled water to lyophilized material. Aliquot in 50-ul volumes and freeze at -10 °C or lower.

b. Negative control: Use a human random sample tested as negative. Aliquot in 50-ul volumes and freeze at -10 °C or lower.

c. The positive and negative controls will be run daily, in duplicate, on different plates. The negative control should have a titer of <1:10. The positive control should have a titer of 1:320±one dilution (1:160-1:640). If these titers are not obtained, the run must be repeated.

d. Further, include in the run one sample of PBS-BSA to be titered as a participant sample. The PBS-BSA should show no agglutination. If agglutination is seen, the run must be repeated with new PBS-BSA.

6. Procedures for Cell Preparations

(These procedures may be done while sera are inactivating.)

a. Adsorbing cells: Spin down an adequate volume of 10% aldehyde-treated SRBCs (0.25 ml per participant sample or control). Remove supernatant and RESUSPEND TO ORIGINAL VOLUME with working PBS-BSA. Mix well. (The solution is good for 1 day.)

b. Sensitized and Nonsensitized Cells:

(1) Centrifuge 3 ml of 10% aldehyde-treated SRBCs. Decant supernatant.

(2) Resuspend cells with 30 ml of 0.01M PBS (total volume is 30 ml of 10% of 1.0% SRBCs).

(3) Remove 10 ml of 1.0% SRBCs. Label as "Heterophile." Cap tube.

(4) To remaining 20 ml of 1.0% RBCs, add 0.2 ml of antigen. Label as "Test." Cap tube.

(5) Incubate both tubes for 1 hour in a 37 °C water bath, inverting gently every 20 minutes.

(6) Centrifuge both tubes at 3,000 rpm for 5 minutes. Wash twice with 0.01M PBS. Decant final supernatant.

(7) To the "Heterophile" tube, add 19 ml PBS-BSA. To the "test" tube, add 38 ml PBS-BSA. The SRBC concentration is now 0.50%. The cells are good for 1 day.

c. Flow Chart: Test and Heterophile Cells

(For step 6.b.(2) above)

3 ml 10% SRBC
:
Spin/Decant
:
QS to 30 ml with PBS
:

Test	Heterophile
:	:
20 ml. SRBC	10 ml SRBC
:	:
:	:
0.2 ml Antigen	:
:	:
:	:
37 °C - 1 hour	37 °C - 1 hour
:	:
:	:
Wash two times	Wash two times
:	:
:	:
38 ml PBS-BSA	19 ml PBS-BSA

7. Hemagglutination Procedure

a. To 50 ul of serum (participant or control), add 200 ul of PBS-BSA. (1.5 dilution). Mix well, cover, and incubate in the 56 °C water bath for a minimum of 30 minutes (not to exceed 1 hour).

b. REMOVE the tubes from the heating block. Cool at room temperature for a minimum of 10 minutes.

c. To each tube add 250 ul (0.25 ml) of 10% adsorbing SRBCs. Shake gently to mix. Let the tube sit at room temperature for 30 minutes (1 hour maximum). Shake it gently every 10 minutes.

d. Centrifuge at 3,000 rpm for 5 minutes. When done, transfer the tube to the plate within 30 minutes.

e. Label plates.

f. To well 1 of the microtiter plate, add 0.1 ml of the appropriate supernatant with a 100-ul MLA pipet.

g. Set the machine to dispense 0.05 ml of working PBS-BSA to wells 2-12 of the plate.

h. Dilute sera through 12 wells with the automatic diluter. (Diluters pick up 50 ul each time, making two-fold dilutions from 1:10 to 1:20,480.) Rinse and blot the tips after each plate.

i. Add 0.025 ml of "Heterophile" cells to the heterophile plates with the automatic dispenser.

j. Add 0.025 ml of "Test" cells to the test plates with the automatic dispenser.

k. Mix by gentle rotation on the counter. Cover and stack on a nonvibrating surface. Incubate at room temperature overnight (22-28 °C).

l. Read and report the following morning. The value reported is the last well showing complete agglutination.

8. References

a. Jones WL, Hambie EA. Immune response to Pseudomonas. In: Rose NR, Friedman H, eds. Manual of clinical immunology. 2nd ed. Washington DC: American Society for Microbiology, 1980:504-5.

b. Russell H. Microhemagglutination test for Pseudomonas pseudomallei (melioidosis) antibodies: test procedure. Atlanta: Centers for Disease Control, 1985.

c. Russell H. Preparation of fresh sheet erythrocytes: test procedure. Atlanta: Centers for Disease Control, 1985.

V. ANALYTICAL METHODS

CC. Occult Blood in Stool Specimens

1. Principle

The Hemoccult test is a simplified, standardized variation of the guaiac test for occult blood. It contains specially prepared guaiac-impregnated paper and is ready for use without additional preparation.

When a small stool specimen containing occult blood is applied to Hemoccult test paper, the hemoglobin comes in contact with the guaiac. Application of Hemoccult developer creates a guaiac/peroxidase-like reaction which, if occult blood is present, turns the test paper blue within 60 seconds.

The test reacts with hemoglobin released from lysed cells. When blood is present, hemolysis is promoted by substances in the stool, primarily water and salts.

The test depends on the oxidation of a phenolic compound, alpha guaiaconic acid, which yields a blue-colored conjugated structure. Hemoglobin exerts a peroxidase-like activity and facilitates the oxidation of this phenolic compound by hydrogen peroxide.

2. Specimen

A very small stool sample is required, thinly applied to the slide.

The slide may be prepared and developed immediately or prepared and stored for up to 12 days.

Participants with bleeding from other conditions that may show up in the stool specimen (e.g., hemorrhoids) are not appropriate test subjects while such bleeding is active.

Whenever possible, participants should be placed on a meat-free, high-residue diet, starting 2 days before and continuing through the test period. Such a diet may reduce the number of false-positive reactions and may also provide roughage to help uncover "silent" lesions that may bleed intermittently.

3. Reagents, Supplies, and Storage

a. Hemoccult slides -- High-quality filter paper impregnated with natural guaiac resin. Store at room temperature (15-30 °C) and protect from heat and light.

b. Hemoccult developer -- A developing solution containing a stabilized dilute mixture of hydrogen peroxide (less than 6%)

and 75% denatured ethyl alcohol in aqueous solution. Store at room temperature (15-30 °C).

4. Quality Control Material

   a. Both a positive and negative performance monitor are located under the flap and below the specimen windows on the back of the slides.

   b. The positive monitor contains a hemoglobin-derived catalyst that, when developer is applied, turns blue within 30 seconds.

   c. The negative monitor contains no such catalyst and should not turn blue after the developer is applied.

   d. If the performance monitors do not react as expected, the test results should be regarded as invalid.

5. Procedure

   For physician

   a. Collect a small stool sample on one end of the applicator.

   b. Apply a thin smear inside box A.

   c. Reuse applicator to obtain a second sample from a different part of the stool. Apply a thin smear inside box B.

   d. Close cover. Make sure that the slide is labeled with the participant identification and the date the specimen was collected.

   e. Deliver to the laboratory.

   Participant testing

   f. Check the slide to see if the stool is present.

   g. Open the flap in the back of the slide and apply two drops of developer to the guaiac paper directly over each smear.

   h. Read the results within 60 seconds.

   Control testing

   i. Apply one drop only of developer between the positive and negative performance monitors.

   j. Read the results within 30 seconds.

   Important note: Follow the procedure exactly as outlined above. Always develop the test, read the results, interpret them, and make a decision about whether the fecal specimen is

positive or negative for occult blood before you develop the performance monitors. Do not apply developer to the monitors before interpreting the test results. Any blue originating from the performance monitors should be ignored in reading the specimen test results.

6. Reference

Smith-Kline Diagnostics. Hemoccult product instructions [packet insert]. Sunnyvale, California: Smith-Kline Diagnostics, 1983.

V. ANALYTICAL METHODS

DD. Serologic Test for Syphilis
Hynson, Wescott, and Dunning RPR

1. Principle

The Rapid Plasma Reagin (RPR) is a screening test for syphilis that detects the presence of a nonspecific antibody to syphilis called "reagin."

Reagin is nonspecific in that it will react with cardiolipin, the antigen in this test. Cardiolipin, which is extracted from beef heart, is bound to charcoal particles so that when the antigen-antibody reaction produces flocculation, which is visible to the unaided eye.

2. Specimen

a. Serum is the specimen of choice.

b. Store at 2-8 °C for no more than 2 days.

c. Store at -20 °C or -70 °C for longer periods.

d. A volume of 50 ul is required for each test.

3. Reagents, Supplies, and Storage

a. RPR Antigen: HWD catalog no. 8703-33 (obtain through CMS) 0.003% cardiolipin, 0.020-0.022% lecithin, 0.09% cholesterol, 0.0125M EDTA, 0.01M $NasHPO_4$, 0.01975% charcoal, and 10% choline chloride with 0.1% Merthiolate.

Store at 2-8 °C. After being opened, reagent is usable for 3 months.

Transfer to plastic dispensing bottle and label with the reagent name, lot number, expiration date, and date opened.

Warm to 23-29 °C before use.

b. Test control card: Hynson, Wescott, and Dunning Catalog no. 8767-09 (obtain from CMS).

c. Control sera: SP no. B6734-10, from Dade. Store at 2-8 °C. One vial each of reactive, minimally reactive, and nonreactive.

d. Plastic coated cards with 18 mm circles. CMS no. 098-392, from Hynson, Wescott, and Dunning.

4. Quality Control Material

a. Record room temperature, which should be between 23-29 °C. (The temperature of the serum and RPR card test antigen should also be between 23 °-29 °C.)

b. Check the 20-gauge needle for delivery of 60 drops per 1 ml ±2 drops. (Use the antigen suspension for this test.)

c. The rotator must be checked and should be set at 100 rpm ±5 rpm.

d. RPR test control cards MUST be run daily.
   Expected values: Reactive (R)
   Nonreactive (N)
   Reactive minimal (RM)
   Record lot number and expiration date on control card.

e. Dade liquid controls must be run on each card.

5. Procedure

Note: Participant specimens are to be run singly. The tests on EVERY reactive specimen must be repeated to verify the result.

a. Hold the dispenser between thumb and forefinger near the stirring or sealed end. Squeeze and do not release pressure until the open end is below the surface of the specimen. Hold the specimen tube vertically to minimize stirring of the cellular elements. Release finger pressure to draw up the sample.

b. Hold the dispenser in a perpendicular position directly over the card to receive the specimen (not touching the card surface), squeeze the dispenser, allowing one drop to fall onto the card.

c. Invert the dispenser, and with sealed stirring end, spread the specimen within the circle. (If preferred, the sample remaining in the dispenser may be discharged into specimen tube from which it was drawn.) Discard stirrer.

   Repeat the procedure for the number of specimens to be tested.

d. Shake the antigen dispensing bottle before use. Holding the bottle in a vertical position, dispense one or two drops in the dispensing bottle cap to make sure that the needle passage is clear and that it is delivering 1/60 ml of antigen. Then place one "free falling" drop (20-gauge yellow hub needle) onto each test area. DO NOT RESTIR: ANTIGEN SUSPENSION AND SPECIMENS ARE MIXED DURING ROTATION. Pick up predropped antigen from bottle cap.

e. Rotate the RPR 8 minutes, under the humidifying cover, on the mechanical rotator at 100 rpm.

f. Remove the RPR card from the rotator platform and gently rotate and tilt the card three to four times. This helps differentiate nonreactive from minimally reactive results.

g. Read immediately by using an incandescent lamp on the bench.

h. Remove the needle, rinse it in water, air dry it. Recap the bottle. Store at 2-8 °C.

6. References

a. Brown WJ, ed. Syphilis, a synopsis. Atlanta: U.S. Department of Health, Education, and Welfare, 1968; Public Health Service publication no. 1660.

b. Hynson, Wescott and Dunning. RPR-card antigen suspension [package insert]. Baltimore: Hynson, Wescott, and Dunning, 1981.

c. Hynson, Wescott, and Dunning. RPR test control cards insert. Baltimore: Hynson, Wescott, and Dunning, 1981.

d. Venereal Disease Research Laboratory. Manual of tests for syphilis. Atlanta: U.S. Department of Health, Education, and Welfare, 1969; HEW publication no. (CDC) 79-8347 (originally PHS publication no. 411).

VI. QUALITY CONTROL FOR ANALYTICAL PROCEDURES

A. General Guidelines

1. New Controls

At least 20 runs of control material are made before the controls are used in the study. Each run is be performed as a "normal study participant run," i.e., the controls are placed within the run, and the run is as long as an average study run.

Values for the controls will be entered into the Community Health Computer (CHC) data management system. These data are transferred to an IBM personal computer by the quality control supervisor who processes them to compute means, standard deviations, ranges, and successive ranges for each parameter and each level of control. Preliminary average run means, standard deviations of the means, and average ranges are established after 20 control runs; values are adjusted after 50 control runs.

2. Control Charts

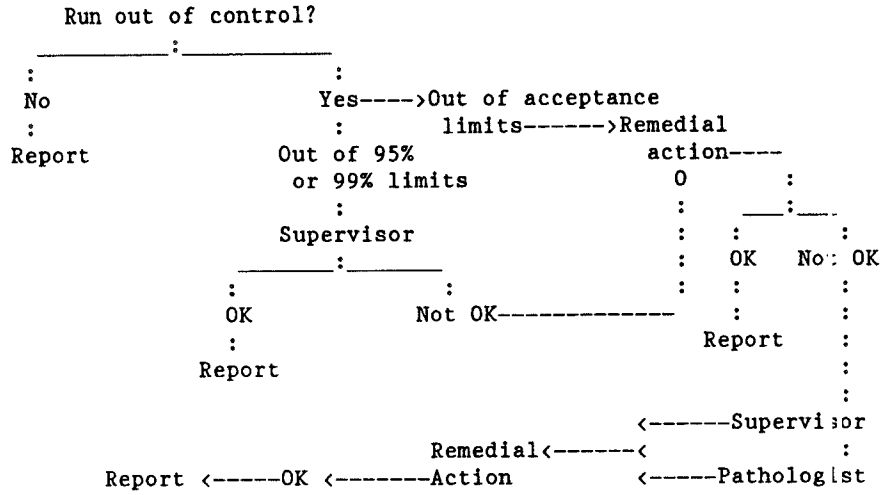
Charts are printed for use on the benches with control limits of 95% and 99% confidence for run means, ranges, and successive ranges. The technologists monitor their daily quality control and plot values on each chart. These charts are used to monitor trends and changes in precision over time.

3. Bench Monitoring of Quality Control QC

Any values falling outside the 95% control limits on ANY of the charts (mean, range or successive range) are reported to the quality control supervisor for a decision on whether the run is acceptable. Any value falling outside the 95% control limits on 2 successive days, or outside 99% control limits on 1 day automatically causes the run to be rejected. Remedial actions include the following:

a. Check for recording errors. If none are found, check and recalibrate the instruments as appropriate.
b. Redilute the controls if applicable.
c. Check all reagents and redo or exchange bottles if necessary.
d. After the problem is resolved, repeat the out-of-control run.
e. Document the problem and remedial action on the remedial action log.

4. Flow Chart--Bench Quality Control



5. Quality Control Data Transfer

All quality control (QC) results are transferred weekly from the CHC mainframe computer system to the IBM personal computer by the QC supervisor. Data are to be processed by using the CDC-prepared statistical QC program that provides a chronological summary of run means, ranges, and successive ranges, in the form of tables and control charts. These tables and charts are to be printed as a permanent hard copy record for review by the QC supervisor and CDC (as requested). The QC data are then sent to CDC via Crosstalk for independent statistical evaluation and review. CDC then provides feedback to the Lovelace Clinical Laboratory monthly (or sooner if a problem is identified that needs more immediate attention).

6. Blind Samples

"Blind samples" are run daily to total 5% of the study specimens. These split specimens are randomly assigned and labeled by the QC supervisor in such a way that the real identification is disguised from the performing technologists. When all laboratory tests are completed and reported for the day, the QC supervisor identifies the "blinds" to enable CDC to match them to the original participant.

7. Avoidance of Systematic Error

Systematic error is minimized as follows.

a. Initial methods are maintained without modifications.

b. Specimen integrity is maintained by strict adherence to collection, processing, and storage protocols and by documenting of these procedures.

c. Instruments are calibrated or the calibration is validated daily before the study specimens are analyzed.

d. Study specimens are analyzed separately from specimens not involved in the study.

e. Parallel runs are performed for all new reagents that are not controls. New calibrating material requires 10 parallel runs; all other reagents require 4 parallel runs. A parallel run is a repeat of a finished run, with the new reagent substituted for the old. A regression analysis is done on the original and the new data, and before the new reagent is used, the QC supervisor determines, on the basis of the results, whether the new reagent is acceptable.

8. Additional Quality Assurance

a. This laboratory is enrolled in the College of American Pathologists (CAP) proficiency testing program. Samples, received every 2 to 3 months, are tested for the following analytes:

Hematology/Coagulation:

Leukocyte count	Monocytes
Hemoglobin	Eosinophils
Hematocrit	Plasma cells
Red cell count	Nucleated red blood cells
Mean corpuscular volume	Hypochromasia
Mean corpuscular hemoglobin	Poikilocytosis
Platelets	Microcytosis
Early leukocytes	Macrocytosis
Metamyelocytes	Basophilic stippling
Banded neutrophils	Hypersegmentation
Segmented neutrophils	Howell-Jolly bodies
Lymphocytes	Basophils
Atypical lymphocytes	
Prothrombin time	

Serology:
Syphilis serology (RPR)

Lymphocyte subsets:
Absolute number of mononuclear cells
Lymphocyte differentiation antigen
Total T lymphocytes
Helper-inducer T lymphocytes
Cytoxic suppressor T lymphocytes

Chemistry Tests:

Blood urea nitrogen	Hepatitis B surface antigen
Creatinine	Hepatitis B surface antigen antibody
Bilirubin, total	
Aspartate aminotransferase	Hepatitis B core antigen antibody
Alanine aminotransferase	
Gamma glutamyl transferase	Thyroxine
Alkaline phosphatase	T3 uptake
Lactic dehydrogenase	Thyroid stimulating hormone
Creatine kinase	Cortisol (morning)
Cholesterol	Dehydroepiandosterone-SO4
HDL cholesterol	Luteinizing hormone
Triglycerides	Follicle stimulating hormone
Total protein	Testosterone
Albumin	Immunoglobulin A
Glucose, fasting	Immunoglobulin G
	Immunoglobulin M

Urinalysis Tests:

Specific gravity	White blood cells
pH	Red blood cells
Hemoglobin	Epithelial cells
Bilirubin	Renal tubular cells
Urobilinogen	Hyaline casts
Ketones	Granular casts
Glucose	White blood cell casts
Protein	Red blood cell casts
Crystals	Other casts

12-Hour Urine Tests:

Creatinine/12-hour
Uroporphyrins
Coporporphyrins

Results are reported to the College of American Pathologists rated by the College, and returned to the laboratory for review and comments by the pathologist and supervisors. Reports of results are also sent to designated CDC personnel.

b. Materials are used from the CDC-NHLBI Lipid Standardization Program to periodically check proficiency for cholesterol, triglycerides, and HDL cholesterol.

c. Materials from the World Health Organization (WHO standards) are used to periodically check proficiency for immunoglobulins A, G, and M.

B. Assay and Bench Control Information:

Quality control (QC) assays are to be reported in the units given below. Assays to which QC does not apply are indicated with an "NA" for the level of QC and number of measures. When QC does apply, the

number of levels of QC material and the number of times each QC material is measured in a given run are indicated. For example, cholesterol has two levels of QC (a "low normal" and a "high normal" control); each is measured in quadruplicate each analytic run. The first measure is for the beginning of the run, the second and third for random positions in the middle of the run, and the fourth for the end of the run. (Note: Each run has about 23 participant samples and one (1) blind repeat control.) For control material measured in duplicate, the first measure is for the beginning of the run and the second for the end of the run.

1. Hemotology Tests:

Assay Name	Result Units	Levels of QC	No. of Measures Per Level of QC
Leukocyte count	k/mm^3	2	4
Hemoglobin	g/dl	2	4
Hematocrit	%	2	4
Red cell count	ml/mm^3	2	4
Mean corpuscular volume	fl	2	4
Mean corpuscular hemoglobin	pg	2	4
Mean corpuscular hemoglobin concentration	%	2	4
Platelets	k/mm^3	2	4
Early leukocytes	%	NA	NA
Metamyelocytes	%	NA	NA
Banded neutrophils	%	2	4
Segmented neutrophils	%	2	4
Lymphocytes	%	2	4
Atypical lymphocytes	%	2	4
Monocytes	%	2	4
Eosinophils	%	2	4
Basophils	%	2	4
Plasma cells	%	2	4
Nucleated red blood cells	%	2	4
Polychromasia	Comment or NP	NA	NA
Hypochromasia	Comment or NP	NA	NA
Poikilocytosis	Comment or NP	NA	NA
Microcytosis	Comment or NP	NA	NA
Macrocytosis	Comment or NP	NA	NA
Basophilic stippling	Comment or NP	NA	NA
Hypersegmentation	Comment or NP	NA	NA
Howell-Jolly bodies	Comment or NP	NA	NA
Sedimentation rate	mm/h	4 specimens	2
Prothrombin time	sec	2	4

(Note: For erythrocyte sedimentation rate, four fresh blood specimens are to be collected and analyzed in duplicate on each run day. Specimens can to be drawn from different individuals from one day to the next.)

2. Urinalysis Tests:

Assay Name	Results Units	Levels of QC	No. of Measures
Specific gravity	Rel. den.	1	2
pH	pH unit	1	2
Hemoglobin	Comment	1	2
Bilirubin	Comment	1	2
Urobilinogen	mg/dl	1	2
Ketones	mg/dl	1	2
Glucose	mg/dl	1	2
Protein	mg/dl	1	2
Appearance	Comment	NA	NA
Color	Comment	NA	NA
Red blood cells	Rbc/hpf	NA	NA
White blood cells	Wbc/hpf	NA	NA
Epithelial cells	Cell/lpf	NA	NA
Renal tubular cells	Cell/lpf	NA	NA
Hyaline casts	Cast/lpf	NA	NA
Granular casts	Cast/lpf	NA	NA
WBC casts	Cast/lpf	NA	NA
RBC casts	Cast/lpf	NA	NA
Other casts	Cast/lpf	NA	NA

3. 12-Hour Urine Tests:

Urine creatinine	mg/dl	2	4
Porphobilinogen	ug/ml	1	2
D-glucaric acid	ug/ml	1	2
Uroporphyrins	ug/L	1	2
Heptacarboxylporphyrin	ug/L	1	2
Coproporphyrin I	ug/L	1	2

4. Chemistry Tests:

Blood urea nitrogen	mg/dl	2	4
Serum creatinine	mg/dl	2	4
Total bilirubin	mg/dl	2	4
Conjugated bilirubin	Comment or NP	NA	NA
Unconjugated bilirubin	mg/dl	2	4
Aspartate amino-transferase (SGOT)	IU/L	2	4
Alanine amino-transferase (SGPT)	IU/L	2	4

4. Chemistry Tests (Continued):

Assay Name	Results Units	Levels of QC	No. of Measures
Gamma glutamyl transferase	IU/L	2	4
Alkaline phosphatase	IU/L	2	4
Lactic dehydrogenase	IU/L	2	4
Creatine phosphokinase	IU/L	2	4
Cholesterol	mg/dl	2	4
HDL cholesterol	mg/dl	2	4
Glycerol blank	mg/dl	2	4
Triglycerides	mg/dl	2	4
Total protein	g/dl	2	4
Albumin	g/dl	2	4
Fasting glucose	mg/dl	2	4
Hepatitis B surface antigen	Comment	NA	NA
Antibody to hepatitis B surface antigen	Comment	NA	NA
Antibody to hepatitis B core antigen	comment	NA	NA
Thyroxine-T4	ug/dl	2	2
T3 Uptake	%	2	2
Thyroid stimulating hormone	mIU/L	2	2
Cortisol (morning)	ug/dl	2	2
Dehydroepiandrosterone-SO4	ug/dl	2	2
Luteinizing hormone	IU/L	2	2
Follicle stimulating hormone	IU/L	2	2
Testosterone	ng/dl	2	2
Delta-aminolevulinic acid	ug/dl	1	2
Immunoglobulin A	mg/dl	2	2
Immunoglobulin G	mg/dl	2	2
Immunoglobulin M	mg/dl	2	2

5. Lymphocyte Subsets:

T-lymphocyte (relative)	%	2	2
T-lymphocyte (absolute)	k/mm^3	NA	NA
B-lymphocyte (relative)	%	2	2
B-lymphocyte (absolute)	k/mm^3	NA	NA
T4-lymphocyte (relative)	%	2	2
T4-lymphocyte (absolute)	k/mm^3	NA	NA
T8-lymphocyte (relative)	%	2	2
T8-lymphocyte (absolute)	k/mm^3	NA	NA
T4/T8 ratio	Ratio	2	2

6. Semen Analysis

Assay Name	Results Units	Levels of QC	No. of Measures
Sperm concentration	Cells/ml	2	1
Percent motile sperm	%	2	1
Mean linear velocity	um/sec	2	1
Total mean area	um^2	2	1
Total mean perimeter	mic	2	1
Total mean length/width ratio	Ratio	2	1
Total mean major axis length	um	2	1

7. Other Tests:

Occult blood (feces)	Comment	NA	NA
Breath alcohol (day 1)	%	NA	NA
Patient preparation-1 (day 1)	Comment	NA	NA
Breath alcohol (day 2)	%	NA	NA
Patient preparation-2 (day 2)	Comment	NA	NA
Collection time for 12-Hour urine sample	h	NA	NA
Collection status	Comment	NA	NA

Definitions of Codes:

RBC = Red blood cells
WBC = White blood cells
pg = Picagrams
ng = Nanograms
ug = Micrograms
mg = Milligrams
g = Grams
fl = Femptoliters
dl = Deciliters
ml = Milliliters
L = Liters
k = One thousand
% = Percent
mm^3 = Cubic millimeters
mm = Millimeters
sec = Seconds
h = Hour
IU = International units
mIU = Milli-international units
rel. den. = Relative density
lpf = Low Power fields
hpf = High Power fields
um = micrometers

D. Statistical Formulas

These formulas are to be used to compute means, standard deviations, and ranges for statistical QC.

Run mean:	$\bar{X}j = \sum Xji)/n$
Grand mean:	$\bar{\bar{X}} = (\sum \bar{X}j)/N$
Standard deviation:	$Sx = \text{sqrt}(\sum(Xj - \bar{\bar{X}})^2 / N - 1)$
Range:	Rj = (largest Xji - smallest Xji)
Average range:	$\bar{R} = (\sum Rj)/N$
Successive range:	Rs = $\bar{X}$ (day 2) - $\bar{X}$ (day 1)
Average successive range:	$\bar{Rs} = (\sum Rs)/N$
Coefficient of variation:	$CV = (100)\bar{Sx}/\bar{\bar{X}}$

Symbol interpretation:
- n = number replicates per control
- i = replicate
- j = control
- N = number of runs

E. Control Limits for Quality Control (QC) Charts

These formulas are to be used to calculate control limits for QC charts used at the bench by the laboratory technician.

Mean Charts:	95% Control limits = $\bar{\bar{X}} \pm (1.96)\bar{Sx}$
	99% Control limits = $\bar{\bar{X}} \pm (2.58)\bar{Sx}$
Range Charts: (for duplicates)	95% Control Limit = $(2.46)\bar{R}$
	99% Control Limit = $(3.27)\bar{R}$
Range Charts: (for quadruplicates)	95% Control Limit = $(1.855)\bar{R}$
	99% Control Limit = $(2.290)\bar{R}$

F. Acceptable Performance for Laboratory Assay Controls

The following criteria constitute acceptable performance standards outlined in the Lovelace Veterans Health Study contract with CDC. Control limits calculated for bench control "mean" charts should not exceed these limits. Each month throughout the study, the quality control (QC) supervisors and CDC, working independently, will monitor variations in measurements.

1. Acceptable Performance Terms and Definitions

a. CV = Coefficient of variation
b. SD = Standard deviation
c. PSD = Pooled standard deviation
d. AD = Average difference between replicates over eight runs

2. Hematology Profile	Acceptable Performance
a. Hematocrit	3.0% (CV)
b. Hemoglobin	2.0% (CV)
c. RBC count	2.0% (CV)
d. RBC indices (MCV, MCH, MCHC)	2.0% (CV)
e. WBC count	3.0% (CV)
f. WBC differential	
(1) Lymphocytes	5.0% (CV)
(2) Segmented neutrophils	3.0% (CV)
(3) Atypical lymphocytes	2.0 (SD)
(4) Others (mono, eos, baso, banded neut)	1.0 (SD)
g. Platelet count	4.0% (CV)
h. Erythrocyte sedimentation rate (mm/h)	<2.0 (AD)
i. Prothrombin time	2.0% (CV)

3. Urinalysis	
a. Specific gravity	0.1% (CV)
b. pH	N/A
c. Dipstick (HGB, bili, urobil, ketones, glucose, protein)	N/A
d. Microscopy (RBC, casts, epi, WBC)	N/A

4. 12-Hour Urinalysis (UA)	
a. Creatinine, quantitative	6.0% (CV)
b. D-glucaric acid	15.0% (CV)
c. Porphobilinogen	15.0% (CV)
d HPLC prophyrin (uro and copro)	10.0% (CV)

5. Routine and Specific Chemistry Assays

a. Blood urea nitrogen	2.0% (CV)
b. Fasting glucose	4.0% (CV)
c. Creatinine, serum	
(1) Level I (low)	0.1 (SD)
(2) Level II (high)	0.4 (SD)
d. Cholesterol	2.0% (CV)
e. HDL-cholesterol	4.0% (CV)
f. Triglycerides	3.0% (CV)
g. SGOT (AST)	4.0% (CV)
h. SGPT (ALT)	5.0% (CV)
i. Alkaline phosphatase	5.0% (CV)
j. LDH	3.0% (CV)
k. CPK	3.0% (CV)
l. GGT	5.0% (CV)
m. Bilirubin (total and unconjugated)	5.0% (CV)
n. Total protein	5.0% (CV)
o. Albumin	5.0% (CV)
p. Delta-aminolevulinic acid	15.0% (CV)

6. Steroid/Hormone Chemistry Assays

a. Cortisol (morning)	10.0% (CV)
b. Luteinizing hormone	10.0% (CV)
c. Testosterone	10.0% (CV)
d. T3 uptake	10.0% (CV)
e. TSH	10.0% (CV)
f. FSH	10.0% (CV)
g. DHEAS	10.0% (CV)
h. T4 (thyroxine)	10.0% (CV)

7. Immunology Profile

a. T and B cell subsets (relative)	
(1) T-lymphocytes (%)	5.0 (PSD)
(2) B-lymphocytes (%)	2.0 (PSD)
(3) T4-lymphocytes (%)	5.0 (PSD)
(4) T8-lymphocytes (%)	3.0 (PSD)
(5) T4/T8 ratio	0.3 (PSD)
b. IgA	10.0% (CV)
c. IgG	10.0% (CV)
d. IgM	10.0% (CV)

8. Semen Analysis

a. Sperm concentration	10.0% (CV)
b. Percent motile sperm	10.0% (CV)
c. Mean linear velocity	10.0% (CV)
d. Total mean area	10.0% (CV)
e. Total mean perimeter	5.0% (CV)
r. Total mean length/width ratio	5.0% (CV)
g. Total mean major axis length	5.0% (CV)

9. Miscellaneous Tests

a. RPR (syphilis serology)	N/A
b. Hepatitis B antibodies/antigens	
(1) HBsAG	N/A
(2) HBcAB	N/A
(3) HBsAB	N/A
c. Occult blood (stool)	N/A
d. Melioidosis	Titer-mean $\pm$ 1 dilution

VII. SUMMARY OF QUALITY CONTROL DATA

A. Overview

In general, QC data indicate good precision for all laboratory assays, except for the melioidosis titer, over the 16-month examination period of the Vietnam Experience Study (VES). The efforts of Lovelace Clinical Laboratory to conform to the acceptable performance criteria of the contract were successful, and Lovelace provided high quality laboratory data. The quality of these results are supported by the QC data presented in Part B of this section.

In Part B, summary statistics of QC data for hematologic, serum/urine chemistry, steroid/hormone, and immunologic quantitative measurements, as well as sperm count and measures of sperm, motility, morphology, and morphometry, are presented in Tables 1-57 and Figures 1-36. In these tables, means, standard deviations, and coefficients of variation are used to summarize measurement error for bench control material associated with each assay. The standard deviation was computed as the square root of the total variance estimated over the period of use. The total variance was the sum of the within- and among-day (or analytic run) components estimated from a one-way analysis of variance. The coefficient of variation was computed as the standard deviation divided by the mean value of the control material over the period of use. Coefficients of variation are not presented for relative measures, such as white blood cell differentials and T- and B-lymphocyte subsets.

Long-term trends are shown in the figures as plots of monthly mean values given for bench control material associated with each assay. Plots of monthly mean values are not given for hematologic measures because bench control materials were changed every few weeks to avoid problems with instability. For hematology assays, overlapping runs of "old" and "new" control material at the time of changeover were used to ensure consistency in measurement over time. Plots of monthly means are also not given for T- and B-lymphocyte subsets because these control materials were blood specimens drawn fresh each analytic day from 2 individuals in a pool of 19 volunteers.

Monthly mean values shows two notable trends.

First, QC data obtained for D-glucaric acid between September 23, 1985, and January 16, 1986, shows a systematic downward trend (Figure 11). Second, QC data for the total porphyrin screen test obtained between September 23, 1985, and January 9, 1986, shows a systematic upward trend (Figure 13). Both D-glucaric acid and total porphyrin screen values were reevaluated for a sample of participant specimens obtained during this time. The results suggested no systematic change in participant values. Therefore, participant values obtained during this time were accepted. The total porphyrin screen test

was used only to identify participant urine samples with elevated porphyrin values during the first 6-months of the study. Porphyrins in these samples were then quantified by using high performance liquid chromatography (HPLC). After January 9, 1986, the porphryin screen test was stopped, and porphyrins were quantified by using the HPLC method for all participant samples subsequently collected.

The laboratory encountered some problems that resulted in loss of data:

Because of a calibrator problem identified by the manufacturer, total bilirubin values were determined to be falsely elevated for participant samples analyzed from February 17, 1986, through July 2, 1986. The calibrator proved to be unstable over time. No attempt was made to recover these participant data because of the instability of bilirubin (particularly when exposed to light) in frozen serum samples maintained over time. Thus, QC and participant data for this assay were removed from the analysis. Unconjugated bilirubin determinations were not affected, since a different calibrator was used for that assay.

Statistical analysis of melioidosis titers indicated substantial variation according to the technician performing the assay. As a result, sera from 183 veterans examined at Lovelace were reassessed by the CDC laboratory personnel who designed the melioidosis protocol used in the VES. Results showed poor agreement between the titer reported by Lovelace and the titer reported by CDC (on the same veteran's serum sample). The reasons for this discrepancy are not clear, since both laboratories used the same procedure. Because of uncertainty about the accuracy of these titers and the potential bias in the direction of artificially high titers, neither the QC nor the participant results for melioidosis titers are reported.

QC data for selected sperm measures obtained from automated semen analysis are summarized in Table 57. According to the performance guidelines, the sperm measures for each of the control specimens were acceptable.

B. Analysis of Variance Tables and Long-Term Quality Control Charts

Quality control data for specific bioassays are shown in Tables 1-5 and Figures 1-36.

Table 1. Summary of Quality Control Data: Hematocrit

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	Coefficient of Variation	No. Observations
PARA-8H1	H538-85	06/03/85	07/08/85	48.9	0.42	0.86	72
PARA-8N1	N538-85	06/03/85	07/08/85	36.1	0.39	1.07	72
PARA-8H2	H538-85	07/15/85	08/26/85	50.5	0.82	1.62	100
PARA-8N2	N538-85	07/15/85	08/26/85	37.1	0.59	1.60	100
PARA8H2B	H588-85	08/27/85	10/14/85	49.7	0.71	1.43	108
PARA8N2B	N588-85	08/27/85	10/14/85	39.4	0.57	1.44	108
PARA8H2C	H598-85	10/15/85	12/03/85	53.5	0.73	1.36	104
PARA8N2C	N598-85	10/15/85	12/03/85	40.4	0.49	1.21	104
PARA8H2D	H5118-86	12/04/85	02/05/86	50.8	0.66	1.29	108
PARA8N2D	N5118-86	12/04/85	02/05/86	40.8	0.51	1.25	108
PARA8H1D	H5118-86	01/21/86	01/29/86	53.6	2.94	5.49	8
PARA8N1D	N5118-86	01/21/86	01/29/86	41.5	1.48	3.57	8
TRICOH2A	H1121-86	02/06/86	04/03/86	52.7	0.71	1.36	136
TRICON2A	N1121-86	02/06/86	04/03/86	39.4	0.53	1.35	136
TRICOH2B	H1122-86	04/07/86	07/01/86	46.9	0.73	1.56	168
TRICON2B	N1122-86	04/07/86	07/01/86	33.7	0.51	1.51	168
TRICOH2C	H1123-86	07/07/86	09/04/86	44.2	0.84	1.90	108
TRICON2C	N1123-86	07/07/86	09/04/86	34.8	0.62	1.77	108
HIGH880A	H1123-86	09/08/86	09/25/86	46.2	0.59	1.28	36
NORM880A	N1123-86	09/08/86	09/25/86	35.9	0.38	1.05	36

Table 2. Summary of Quality Control Data: Hemoglobin

Control Name	Lot No.	Begin Date	End Date	Mean (g/dl)	Standard Deviation	Coefficient of Variation	No. Observations
PARA-8H1	H538-85	06/03/85	07/08/85	18.7	0.15	0.81	72
PARA-8N1	N538-85	06/03/85	07/08/85	13.6	0.12	0.90	72
PARA-8H2	H538-85	07/15/85	08/26/85	18.2	0.21	1.13	100
PARA-8N2	N538-85	07/15/85	08/26/85	13.4	0.14	1.08	100
PARA8H2B	H588-85	08/27/85	10/14/85	17.7	0.30	1.67	108
PARA8N2B	N588-85	08/27/85	10/14/85	13.9	0.23	1.68	108
PARA8H2C	H598-85	10/15/85	12/03/85	18.5	0.22	1.17	104
PARA8N2C	N598-85	10/15/85	12/03/85	13.7	0.16	1.19	104
PARA8H2D	H5118-86	12/04/85	02/05/86	18.0	0.20	1.10	108
PARA8N2D	N5118-86	12/04/85	02/05/86	14.1	0.20	1.40	108
PARA8H1D	H5118-86	01/21/86	01/29/86	18.2	0.25	1.39	16
PARA8N1D	N5118-86	01/21/86	01/29/86	14.2	0.13	0.95	16
TRICOH2A	H1121-86	02/06/86	04/03/86	18.1	0.24	1.33	132
TRICON2A	N1121-86	02/06/86	04/03/86	13.1	0.16	1.21	132
TRICOH2B	H1122-86	04/07/86	07/01/86	16.7	0.24	1.43	168
TRICON2B	N1122-86	04/07/86	07/01/86	12.1	0.17	1.37	168
TRICOH2C	H1123-86	07/07/86	09/04/86	16.3	0.19	1.15	108
TRICON2C	N1123-86	07/07/86	09/04/86	12.8	0.21	1.63	108
HIGH880A	H1123-86	09/08/86	09/25/86	16.4	0.15	0.92	36
NORM880A	N1123-86	09/08/86	09/25/86	13.0	0.11	0.86	36

Table 3. Summary of Quality Control Data: Mean Corpuscular Cell Volume

Control Name	Lot No.	Begin Date	End Date	Mean (fl)	Standard Deviation	Coefficient of Variation	No. Observations
PARA-8H1	H538-85	06/03/85	07/08/85	89.8	0.37	0.42	72
PARA-8N1	N538-85	06/03/85	07/08/85	83.8	0.36	0.43	72
PARA-8H2	H538-85	07/15/85	08/26/85	91.3	0.93	1.01	100
PARA-8N2	N538-85	07/15/85	08/26/85	84.8	0.77	0.91	100
PARA8H2B	H588-85	08/27/85	10/14/85	89.7	0.61	0.68	108
PARA8N2B	N588-85	08/27/85	10/14/85	83.9	0.60	0.71	108
PARA8H2C	H598-85	10/15/85	12/03/85	92.7	0.57	0.62	104
PARA8N2C	N598-85	10/15/85	12/03/85	86.3	0.48	0.56	104
PARA8H2D	H5118-86	12/04/85	02/05/86	89.3	0.38	0.42	108
PARA8N2D	N5118-86	12/04/85	02/05/86	84.5	0.46	0.54	108
PARA8H1D	H5118-86	01/21/86	01/29/86	93.1	3.42	3.68	8
PARA8N1D	N5118-86	01/21/86	01/29/86	87.2	4.24	4.86	8
TRICOH2A	H1121-86	02/06/86	04/03/86	88.9	0.97	1.09	136
TRICON2A	N1121-86	02/06/86	04/03/86	88.6	1.04	1.18	136
TRICOH2B	H1122-86	04/07/86	07/01/86	89.4	1.31	1.47	168
TRICON2B	N1122-86	04/07/86	07/01/86	83.7	1.23	1.47	168
TRICOH2C	H1123-86	07/07/86	09/04/86	86.2	0.50	0.58	108
TRICON2C	N1123-86	07/07/86	09/04/86	83.2	0.42	0.51	108
HIGH880A	H1123-86	09/08/86	09/25/86	90.4	0.51	0.56	36
NORM880A	N1123-86	09/08/86	09/25/86	86.8	0.35	0.41	36

Table 4. Summary of Quality Control Data: Mean Corpuscular Hemoglobin

Control Name	Lot No.	Begin Date	End Date	Mean (pg)	Standard Deviation	Coefficient of Variation	No. Observations
PARA-8H1	H538-85	06/03/85	07/08/85	34.3	0.28	0.81	72
PARA-8N1	N538-85	06/03/85	07/08/85	31.6	0.35	1.10	72
PARA-8H2	H538-85	07/15/85	08/26/85	32.9	0.45	1.36	100
PARA-8N2	N538-85	07/15/85	08/26/85	30.6	0.48	1.55	100
PARA8H2B	H588-85	08/27/85	10/14/85	32.0	0.60	1.87	108
PARA8N2B	N588-85	08/27/85	10/14/85	29.5	0.56	1.90	108
PARA8H2C	H598-85	10/15/85	12/03/85	32.0	0.49	1.54	104
PARA8N2C	N598-85	10/15/85	12/03/85	29.2	0.47	1.60	104
PARA8H2D	H5118-86	12/04/85	02/05/86	31.6	0.47	1.48	108
PARA8N2D	N5118-86	12/04/85	02/05/86	29.2	0.56	1.93	108
PARA8H1D	H5118-86	01/21/86	01/29/86	31.7	0.61	1.91	16
PARA8N1D	N5118-86	01/21/86	01/29/86	29.6	0.58	1.96	16
TRICOH2A	H1121-86	02/06/86	04/03/86	30.5	0.45	1.48	132
TRICON2A	N1121-86	02/06/86	04/03/86	29.5	0.41	1.38	132
TRICOH2B	H1122-86	04/07/86	07/01/86	31.7	0.29	0.92	168
TRICON2B	N1122-86	04/07/86	07/01/86	30.1	0.35	1.18	168
TRICOH2C	H1123-86	07/07/86	09/04/86	31.8	0.61	1.93	108
TRICON2C	N1123-86	07/07/86	09/04/86	30.6	0.64	2.09	108
HIGH880A	H1123-86	09/08/86	09/25/86	32.2	0.49	1.52	36
NORM880A	N1123-86	09/08/86	09/25/86	31.6	0.46	1.47	36

Table 5. Summary of Quality Control Data: Mean Corpuscular Hemoglobin Concentration

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	Coefficient of Variation	No. Observations
PARA-8H1	H538-85	06/03/85	07/08/85	38.2	0.37	0.96	72
PARA-8N1	N538-85	06/03/85	07/08/85	37.7	0.43	1.13	72
PARA-8H2	H538-85	07/15/85	08/26/85	36.0	0.60	1.68	100
PARA-8N2	N538-85	07/15/85	08/26/85	36.0	0.69	1.90	100
PARA8H2B	H588-85	08/27/85	10/14/85	35.7	0.63	1.76	108
PARA8N2B	N588-85	08/27/85	10/14/85	35.2	0.62	1.75	108
PARA8H2C	H598-85	10/15/85	12/03/85	34.6	0.56	1.61	104
PARA8N2C	N598-85	10/15/85	12/03/85	33.9	0.57	1.67	104
PARA8H2D	H5118-86	12/04/85	02/05/86	35.4	0.54	1.51	108
PARA8N2D	N5118-86	12/04/85	02/05/86	34.5	0.69	2.01	108
PARA8H1D	H5118-86	01/21/86	01/29/86	34.2	1.76	5.14	8
PARA8N1D	N5118-86	01/21/86	01/29/86	34.2	1.06	3.09	8
TRICOH2A	H1121-86	02/06/86	04/03/86	34.3	0.67	1.97	132
TRICON2A	N1121-86	02/06/86	04/03/86	33.3	0.58	1.75	132
TRICOH2B	H1122-86	04/07/86	07/01/86	35.5	0.52	1.46	168
TRICON2B	N1122-86	04/07/86	07/01/86	36.0	0.52	1.44	168
TRICOH2C	H1123-86	07/07/86	09/04/86	36.9	0.72	1.94	108
TRICON2C	N1123-86	07/07/86	09/04/86	36.7	0.74	2.02	108
HIGH880A	H1123-86	09/08/86	09/25/86	35.6	0.58	1.62	36
NORM880A	N1123-86	09/08/86	09/25/86	36.4	0.56	1.53	36

Table 6. Summary of Quality Control Data: Platelet Count

Control Name	Lot No.	Begin Date	End Date	Mean (k/mm^3)	Standard Deviation	Coefficient of Variation	No. Observations
PARA-8H1	H538-85	06/03/85	07/08/85	659.2	11.98	1.82	72
PARA-8N1	N538-85	06/03/85	07/08/85	259.0	9.18	3.55	72
PARA-8H2	H538-85	07/15/85	08/26/85	636.2	16.16	2.54	100
PARA-8N2	N538-85	07/15/85	08/26/85	247.7	8.75	3.53	100
PARA8H2B	H588-85	08/27/85	10/14/85	598.5	15.11	2.53	108
PARA8N2B	N588-85	08/27/85	10/14/85	230.9	7.06	3.06	108
PARA8H2C	H598-85	10/15/85	12/03/85	638.1	12.90	2.02	104
PARA8N2C	N598-85	10/15/85	12/03/85	242.3	8.12	3.35	104
PARA8H2D	H5118-86	12/04/85	02/05/86	619.4	15.28	2.47	108
PARA8N2D	N5118-86	12/04/85	02/05/86	248.1	8.54	3.44	108
PARA8H1D	H5118-86	01/21/86	01/29/86	656.7	25.09	3.82	16
PARA8N1D	N5118-86	01/21/86	01/29/86	257.2	14.40	5.60	16
TRICOH2A	H1121-86	02/06/86	04/03/86	590.9	16.15	2.73	132
TRICON2A	N1121-86	02/06/86	04/03/86	293.5	8.09	2.76	132
TRICOH2B	H1122-86	04/07/86	07/01/86	585.7	17.23	2.94	168
TRICON2B	N1122-86	04/07/86	07/01/86	246.0	9.59	3.90	168
TRICOH2C	H1123-86	07/07/86	09/04/86	510.9	14.67	2.87	108
TRICON2C	N1123-86	07/07/86	09/04/86	274.0	9.38	3.42	108
HIGH880A	H1123-86	09/08/86	09/25/86	512.9	13.34	2.60	36
NORM880A	N1123-86	09/08/86	09/25/86	267.9	7.61	2.84	36

Table 7. Summary of Quality Control Data: Red Cell Count

Control Name	Lot No.	Begin Date	End Date	Mean (mil/mm^3)	Standard Deviation	Coefficient of Variation	No Observations
PARA-8H1	H538-85	06/03/85	07/08/85	5.4	0.04	0.79	7
PARA-8N1	N538-85	06/03/85	07/08/85	4.3	0.04	0.97	7
PARA-8H2	H538-85	07/15/85	08/26/85	5.5	0.06	1.00	10
PARA-8N2	N538-85	07/15/85	08/26/85	4.4	0.05	1.06	10
PARA8H2B	H588-85	08/27/85	10/14/85	5.5	0.06	1.15	10
PARA8N2B	N588-85	08/27/85	10/14/85	4.7	0.05	1.12	10
PARA8H2C	H598-85	10/15/85	12/03/85	5.8	0.07	1.25	10
PARA8N2C	N598-85	10/15/85	12/03/85	4.7	0.05	1.09	10
PARA8H2D	H5118-86	12/04/85	02/05/86	5.7	0.07	1.29	10
PARA8N2D	N5118-86	12/04/85	02/05/86	4.8	0.11	2.23	10
PARA8H1D	H5118-86	01/21/86	01/29/86	5.8	0.10	1.78	1
PARA8N1D	N5118-86	01/21/86	01/29/86	4.8	0.10	2.14	1
TRICOH2A	H1121-86	02/06/86	04/03/86	5.9	0.05	0.87	13
TRICON2A	N1121-86	02/06/86	04/03/86	4.4	0.04	0.99	13
TRICOH2B	H1122-86	04/07/86	07/01/86	5.2	0.08	1.43	16
TRICON2B	N1122-86	04/07/86	07/01/86	4.0	0.06	1.38	16
TRICOH2C	H1123-86	07/07/86	09/04/86	5.1	0.09	1.80	10
TRICON2C	N1123-86	07/07/86	09/04/86	4.2	0.07	1.78	10
HIGH880A	H1123-86	09/08/86	09/25/86	5.1	0.05	1.04	3
NORM880A	N1123-86	09/08/86	09/25/86	4.1	0.04	0.93	3

Table 8. Summary of Quality Control Data: White Cell Count

Control Name	Lot No.	Begin Date	End Date	Mean (k/mm^3)	Standard Deviation	Coefficient of Variation	No Observations
PARA-8H1	H538-85	06/03/85	07/08/85	30.6	0.41	1.35	7
PARA-8N1	N538-85	06/03/85	07/08/85	7.7	0.16	2.12	7
PARA-8H2	H538-85	07/15/85	08/26/85	30.5	0.59	1.95	10
PARA-8N2	N538-85	07/15/85	08/26/85	7.7	0.17	2.22	10
PARA8H2B	H588-85	08/27/85	10/14/85	27.6	0.61	2.23	10
PARA8N2B	N588-85	08/27/85	10/14/85	7.8	0.22	2.87	10
PARA8H2C	H598-85	10/15/85	12/03/85	28.8	0.49	1.70	10
PARA8N2C	N598-85	10/15/85	12/03/85	7.7	0.19	2.54	10
PARA8H2D	H5118-86	12/04/85	02/05/86	29.0	0.60	2.09	10
PARA8N2D	N5118-86	12/04/85	02/05/86	8.4	0.26	3.08	10
PARA8H1D	H5118-86	01/21/86	01/29/86	29.3	0.51	1.73	1
PARA8N1D	N5118-86	01/21/86	01/29/86	8.4	0.20	2.37	1
TRICOH2A	H1121-86	02/06/86	04/03/86	31.3	0.78	2.48	13
TRICON2A	N1121-86	02/06/86	04/03/86	9.0	0.23	2.61	13
TRICOH2B	H1122-86	04/07/86	07/01/86	28.6	0.53	1.85	16
TRICON2B	N1122-86	04/07/86	07/01/86	9.0	0.16	1.73	16
TRICOH2C	H1123-86	07/07/86	09/04/86	21.4	0.46	2.16	10
TRICON2C	N1123-86	07/07/86	09/04/86	7.7	0.21	2.73	10
HIGH880A	H1123-86	09/08/86	09/25/86	19.7	0.17	0.85	3
NORM880A	N1123-86	09/08/86	09/25/86	7.2	0.11	1.48	3

Table 9. Summary of Quality Control Data: Relative Basophils

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	0.6	0.48	188
DIFF-LII	SET 1	06/03/85	09/03/85	0.0	0.16	188
DIFF-LIB	SET 2	09/04/85	12/06/85	0.7	0.55	208
DIFFLIIB	SET 2	09/04/85	12/06/85	0.1	0.35	208
DIFF-LIC	SET 3	12/09/85	05/29/86	0.6	0.56	360
DIFFLIIC	SET 3	12/09/85	05/29/86	0.1	0.26	360
DIFF-LID	SET 4	06/02/86	09/25/86	0.4	0.49	200
DIFFLIID	SET 4	06/02/86	09/25/86	0.5	0.50	200

Table 10. Summary of Quality Control Data: Relative Eosinophils

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	3.1	0.92	188
DIFF-LII	SET 1	06/03/85	09/03/85	0.5	0.52	188
DIFF-LIB	SET 2	09/04/85	12/06/85	3.7	1.45	208
DIFFLIIB	SET 2	09/04/85	12/06/85	0.8	0.95	208
DIFF-LIC	SET 3	12/09/85	05/29/86	2.9	1.11	360
DIFFLIIC	SET 3	12/09/85	05/29/86	0.8	0.62	360
DIFF-LID	SET 4	06/02/86	09/25/86	8.4	1.01	200
DIFFLIID	SET 4	06/02/86	09/25/86	0.9	0.55	200

Table 11. Summary of Quality Control Data: Relative Atypical Lymphocytes

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	2.0	1.55	188
DIFF-LII	SET 1	06/03/85	09/03/85	3.4	1.80	188
DIFF-LIB	SET 2	09/04/85	12/06/85	1.7	0.99	208
DIFFLIIB	SET 2	09/04/85	12/06/85	4.5	1.80	208
DIFF-LIC	SET 3	12/09/85	05/29/86	2.1	1.34	360
DIFFLIIC	SET 3	12/09/85	05/29/86	3.7	1.96	360
DIFF-LID	SET 4	06/02/86	09/25/86	4.1	1.91	200
DIFFLIID	SET 4	06/02/86	09/25/86	2.3	1.46	200

Table 12. Summary of Quality Control Data: Relative Monocytes

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	6.8	1.75	188
DIFF-LII	SET 1	06/03/85	09/03/85	8.0	1.76	188
DIFF-LIB	SET 2	09/04/85	12/06/85	7.9	1.27	208
DIFFLIIB	SET 2	09/04/85	12/06/85	7.5	1.42	208
DIFF-LIC	SET 3	12/09/85	05/29/86	6.8	1.04	360
DIFFLIIC	SET 3	12/09/85	05/29/86	8.0	1.21	360
DIFF-LID	SET 4	06/02/86	09/25/86	4.7	1.15	200
DIFFLIID	SET 4	06/02/86	09/25/86	11.8	1.22	200

Table 13. Summary of Quality Control Data: Relative Band Neutrophils

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	3.4	1.52	188
DIFF-LII	SET 1	06/03/85	09/03/85	1.6	0.80	188
DIFF-LIB	SET 2	09/04/85	12/06/85	3.6	1.15	208
DIFFLIIB	SET 2	09/04/85	12/06/85	1.4	0.90	208
DIFF-LIC	SET 3	12/09/85	05/29/86	3.0	0.96	360
DIFFLIIC	SET 3	12/09/85	05/29/86	1.6	0.79	360
DIFF-LID	SET 4	06/02/86	09/25/86	2.2	0.83	200
DIFFLIID	SET 4	06/02/86	09/25/86	0.9	0.63	200

Table 14. Summary of Quality Control Data: Relative Segmented Neutrophils

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	58.9	5.05	188
DIFF-LII	SET 1	06/03/85	09/03/85	57.9	4.00	188
DIFF-LIB	SET 2	09/04/85	12/06/85	57.5	2.72	208
DIFFLIIB	SET 2	09/04/85	12/06/85	57.6	3.29	208
DIFF-LIC	SET 3	12/09/85	05/29/86	58.5	1.85	360
DIFFLIIC	SET 3	12/09/85	05/29/86	56.7	2.07	360
DIFF-LID	SET 4	06/02/86	09/25/86	42.0	1.90	200
DIFFLIID	SET 4	06/02/86	09/25/86	56.7	1.70	200

Table 15. Summary of Quality Control Data: Relative Lymphocytes

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
DIFF--LI	SET 1	06/03/85	09/03/85	25.2	3.98	188
DIFF-LII	SET 1	06/03/85	09/03/85	28.4	3.04	188
DIFF-LIB	SET 2	09/04/85	12/06/85	24.6	2.56	208
DIFFLIIB	SET 2	09/04/85	12/06/85	28.1	2.04	208
DIFF-LIC	SET 3	12/09/85	05/29/86	25.7	1.89	360
DIFFLIIC	SET 3	12/09/85	05/29/86	29.1	1.97	360
DIFF-LID	SET 4	06/02/86	09/25/86	38.2	1.82	200
DIFFLIID	SET 4	06/02/86	09/25/86	26.8	1.43	200

Table 16. Summary of Quality Control Data: Relative B-Lymphocytes

Control Name	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
HUMAN-01	06/03/85	09/01/86	9.3	1.65	59
HUMAN-02	06/03/85	09/25/86	10.6	1.78	118
HUMAN-03	06/03/85	09/11/86	17.3	2.45	94
HUMAN-04	06/04/85	09/04/86	5.9	1.27	98
HUMAN-05	06/04/85	08/19/86	8.6	1.60	114
HUMAN-06	06/04/85	04/10/86	9.9	1.66	27
HUMAN-07	06/05/85	07/07/86	9.8	2.72	66
HUMAN-08	06/06/85	09/23/86	8.6	1.82	64
HUMAN-09	06/13/85	08/04/86	11.6	1.79	72
HUMAN-10	06/18/85	09/09/86	9.6	1.26	55
HUMAN-11	09/03/85	05/12/86	10.1	1.97	46
HUMAN-12	09/04/85	09/23/86	8.9	1.77	58
HUMAN-13	09/05/85	09/05/85	11.7	0.07	2
HUMAN-14	09/10/85	09/18/85	5.3	2.78	6
HUMAN-15	09/12/85	07/17/86	11.1	1.58	88
HUMAN-16	07/10/86	09/16/86	7.0	1.33	14
HUMAN-17	07/29/86	09/25/86	10.7	0.74	10
HUMAN-18	09/09/86	09/22/86	7.8	2.83	4
HUMAN-19	09/16/86	09/22/86	12.7	1.55	4

Table 17. Summary of Quality Control Data: Relative T-Lymphocytes

Control Name	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
HUMAN-01	06/03/85	09/01/86	57.3	6.36	59
HUMAN-02	06/03/85	09/25/86	71.1	4.55	118
HUMAN-03	06/03/85	09/11/86	66.3	3.12	94
HUMAN-04	06/04/85	09/04/86	71.2	4.19	98
HUMAN-05	06/04/85	08/19/86	77.6	4.86	114
HUMAN-06	06/04/85	04/10/86	71.6	2.90	26
HUMAN-07	06/05/85	07/07/86	74.5	6.05	66
HUMAN-08	06/06/85	09/23/86	79.1	2.69	64
HUMAN-09	06/13/85	08/04/86	68.5	4.08	72
HUMAN-10	06/18/85	09/09/86	75.2	5.24	55
HUMAN-11	09/03/85	05/12/86	78.9	3.46	46
HUMAN-12	09/04/85	09/23/86	77.3	3.73	58
HUMAN-13	09/05/85	09/05/85	75.2	0.99	2
HUMAN-14	09/10/85	09/18/85	77.3	4.83	6
HUMAN-15	09/12/85	07/17/86	76.9	5.10	88
HUMAN-16	07/10/86	09/16/86	73.7	2.90	14
HUMAN-17	07/29/86	09/25/86	70.7	5.46	10
HUMAN-18	09/09/86	09/22/86	73.5	4.55	4
HUMAN-19	09/16/86	09/22/86	74.4	4.62	4

Table 18. Summary of Quality Control Data: Relative T4-Lymphocytes

Control Name	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
HUMAN-01	06/03/85	09/01/86	38.6	5.11	59
HUMAN-02	06/03/85	09/25/86	53.4	3.75	118
HUMAN-03	06/03/85	09/11/86	43.7	3.76	94
HUMAN-04	06/04/85	09/04/86	48.2	3.58	98
HUMAN-05	06/04/85	08/19/86	53.1	4.01	114
HUMAN-06	06/04/85	04/10/86	44.0	3.34	27
HUMAN-07	06/05/85	07/07/86	41.9	6.29	66
HUMAN-08	06/06/85	09/23/86	50.3	4.54	64
HUMAN-09	06/13/85	08/04/86	45.6	3.53	72
HUMAN-10	06/18/85	09/09/86	51.1	4.21	55
HUMAN-11	09/03/85	05/12/86	58.2	3.40	46
HUMAN-12	09/04/85	09/23/86	44.3	3.56	58
HUMAN-13	09/05/85	09/05/85	59.0	2.69	2
HUMAN-14	09/10/85	09/18/85	55.1	2.00	6
HUMAN-15	09/12/85	07/17/86	52.5	4.06	88
HUMAN-16	07/10/86	09/16/86	34.7	2.90	14
HUMAN-17	07/29/86	09/25/86	53.7	2.95	10
HUMAN-18	09/09/86	09/22/86	52.7	3.00	4
HUMAN-19	09/16/86	09/22/86	54.7	7.38	4

Table 19. Summary of Quality Control Data: Relative T8-Lymphocytes

Control Name	Begin Date	End Date	Mean (%)	Standard Deviation	No. Observations
HUMAN-01	06/03/85	09/01/86	31.0	2.73	59
HUMAN-02	06/03/85	09/25/86	29.1	2.04	118
HUMAN-03	06/03/85	09/11/86	21.8	1.88	94
HUMAN-04	06/04/85	09/04/86	31.4	2.11	98
HUMAN-05	06/04/85	08/19/86	28.8	1.89	114
HUMAN-06	06/04/85	04/10/86	32.1	1.45	27
HUMAN-07	06/05/85	07/07/86	38.7	4.73	66
HUMAN-08	06/06/85	09/23/86	34.9	4.29	64
HUMAN-09	06/13/85	08/04/86	25.6	1.66	71
HUMAN-10	06/18/85	09/09/86	23.4	1.93	55
HUMAN-11	09/03/85	05/12/86	22.0	1.56	46
HUMAN-12	09/04/85	09/23/86	29.3	3.41	58
HUMAN-13	09/05/85	09/05/85	17.8	0.64	2
HUMAN-14	09/10/85	09/18/85	20.8	1.36	6
HUMAN-15	09/12/85	07/17/86	25.8	2.48	88
HUMAN-16	07/10/86	09/16/86	44.2	1.13	14
HUMAN-17	07/29/86	09/25/86	21.6	3.71	10
HUMAN-18	09/09/86	09/22/86	24.4	1.04	4
HUMAN-19	09/16/86	09/22/86	25.4	2.36	4

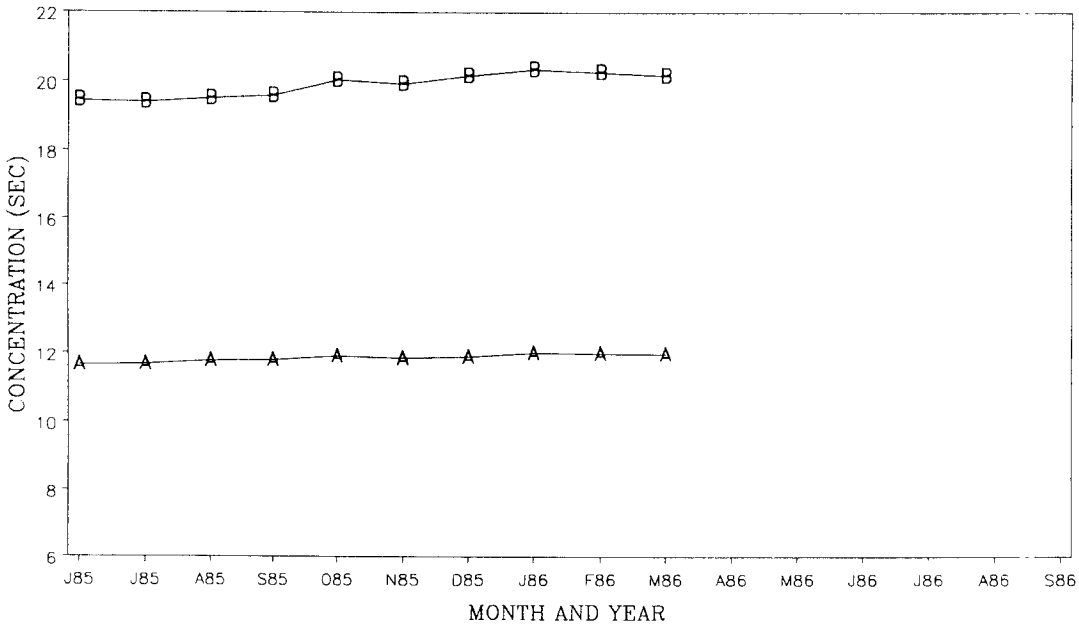
Table 20. Summary of Quality Control Data: T4/T8 Ratio

Control Name	Begin Date	End Date	Mean (Ratio)	Standard Deviation	No. Observations
HUMAN-01	06/03/85	09/01/86	1.3	0.22	59
HUMAN-02	06/03/85	09/25/86	1.8	0.20	118
HUMAN-03	06/03/85	09/11/86	2.0	0.24	94
HUMAN-04	06/04/85	09/04/86	1.5	0.16	98
HUMAN-05	06/04/85	08/19/86	1.9	0.17	114
HUMAN-06	06/04/85	04/10/86	1.4	0.12	27
HUMAN-07	06/05/85	07/07/86	1.1	0.27	66
HUMAN-08	06/06/85	09/23/86	1.5	0.28	64
HUMAN-09	06/13/85	08/04/86	1.8	0.14	71
HUMAN-10	06/18/85	09/09/86	2.2	0.28	55
HUMAN-11	09/03/85	05/12/86	2.7	0.23	46
HUMAN-12	09/04/85	09/23/86	1.5	0.22	58
HUMAN-13	09/05/85	09/05/85	3.3	0.02	2
HUMAN-14	09/10/85	09/18/85	2.7	0.17	6
HUMAN-15	09/12/85	07/17/86	2.1	0.22	88
HUMAN-16	07/10/86	09/16/86	0.8	0.08	14
HUMAN-17	07/29/86	09/25/86	2.5	0.36	10
HUMAN-18	09/09/86	09/22/86	2.2	0.08	4
HUMAN-19	09/16/86	09/22/86	2.1	0.15	4

Table 21. Summary of Quality Control Data Prothrombin Time

Control Name	Lot No.	Begin Date	End Date	Mean (Sec)	Standard Deviation	Coefficient of Variation	No. Observations
CITROL-I	COL1-286	06/03/85	07/24/86	11.9	0.17	1.46	844
CITRL-II	COL2-276	06/03/85	07/24/86	19.9	0.44	2.21	844
CITRL-IA	COL1-313	07/28/86	09/25/86	12.8	0.12	0.92	108
CITRLIIA	COL2-286	07/28/86	09/25/86	20.9	0.36	1.71	108

Figure 1. Monthly Mean Quality Control Values: Prothrombin Time

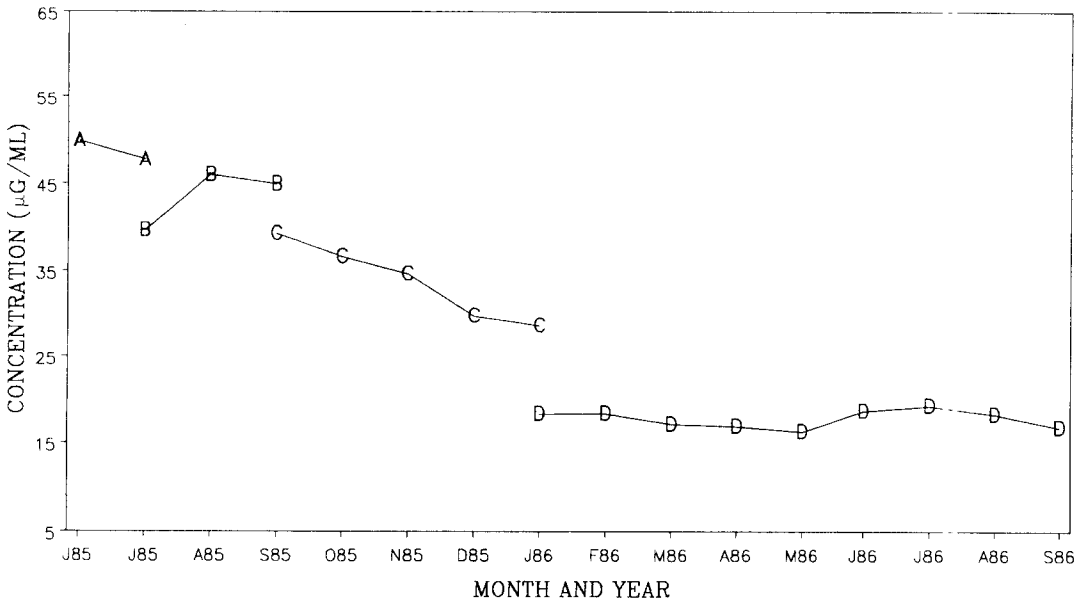


LEGEND: CITROL-I=A CITRL-II=B CITRL-IA=C CITRLIIA=D

Table 22. Summary of Quality Control Data: D-Glucaric Acid

Control Name	Lot No.	Begin Date	End Date	Mean (μg/ml)	Standard Deviation	Coefficient of Variation	No. Observations
D-GLUCAR	POOL-85	06/03/85	07/17/85	49.3	5.97	12.11	44
D-GLUC-2	POOL-85	07/18/85	09/20/85	44.3	5.23	11.81	74
D-GLUC-3	POOL-85	09/23/85	01/16/86	33.6	5.84	17.37	120
U-LYPH-2	07100-86	01/20/86	09/25/86	17.6	2.04	11.59	246

Figure 2. Monthly Mean Quality Control Values: D-Glucaric Acid

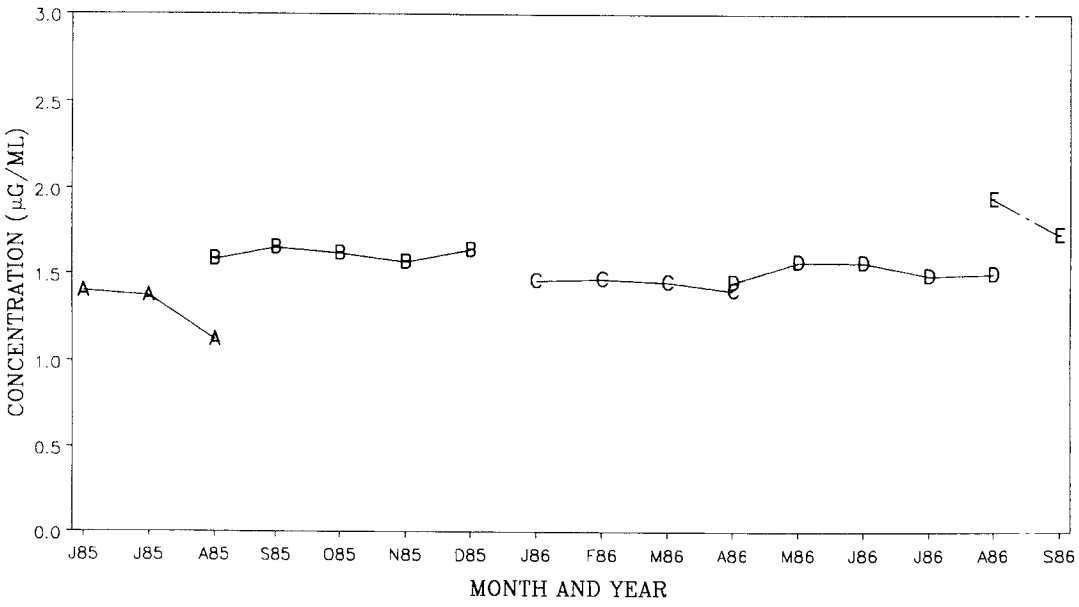


LEGEND: D-GLUCAR=A D-GLUC-2=B D-GLUC-3=C U-LYPH-2=D

Table 23. Summary of Quality Control Data: Porphobilinogen

Control Name	Lot No.	Begin Date	End Date	Mean (µg/ml)	Standard Deviation	Coefficient of Variation	No. Observations
PORPHOBG	POOL-85	06/03/85	08/26/85	1.3	0.28	21.30	83
PORPHBG2	POOL-85	08/26/85	12/19/85	1.6	0.20	12.14	132
PORPHBG3	POOL-85	01/06/86	04/24/86	1.4	0.16	11.35	123
PORPHBG4	POOL-86	04/28/86	08/14/86	1.5	0.17	11.20	93
PORPHBG5	POOL-86	08/18/86	09/25/86	1.8	0.24	13.12	38

Figure 3. Monthly Mean Quality Control Values: Porphobilinogen



LEGEND: PORPHOBG=A PORPHBG2=B PORPHBG3=C
PORPHBG4=D PORPHBG5=E

Table 24. Summary of Quality Control Data: Total Porphyrin Screen

Control Name	Lot No.	Begin Date	End Date	Mean (μg/L)	Standard Deviation	Coefficient of Variation	No. Observations
PORSCR-1	082185	09/23/85	01/09/86	159.3	11.66	7.32	110

Figure 4. Monthly Mean Quality Control Values: Total Porphyrin Screen

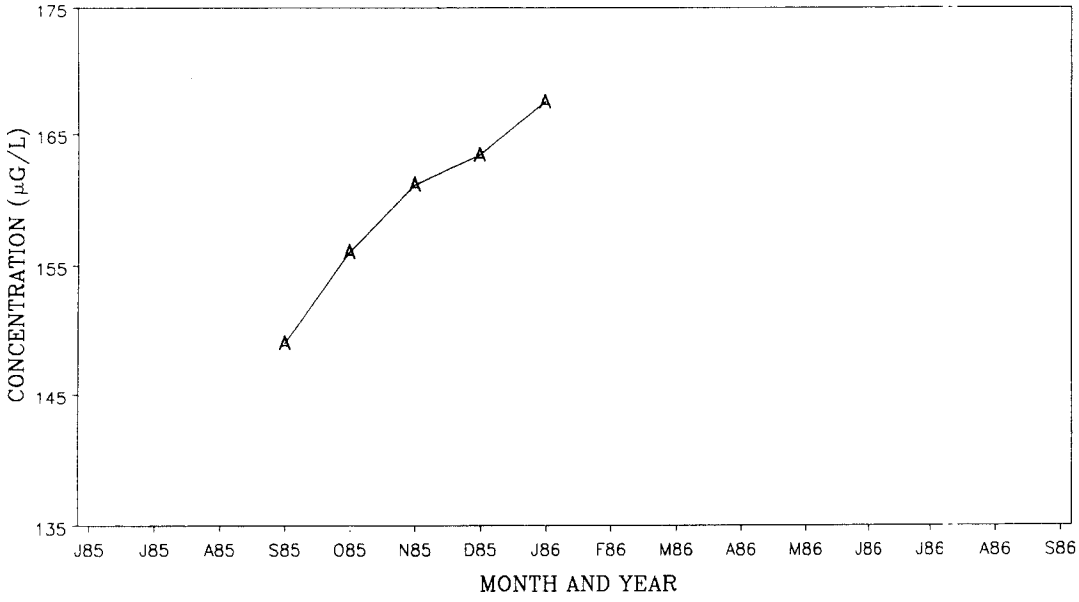
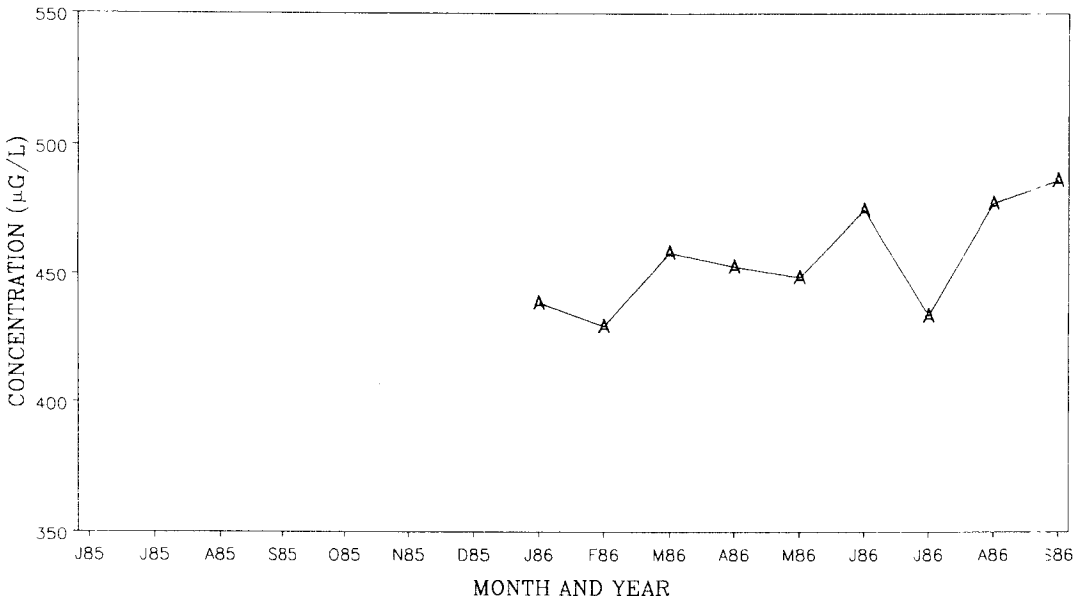


Table 25. Summary of Quality Control Data: Coproporphyrin

Control Name	Lot No.	Begin Date	End Date	Mean (µg/L)	Standard Deviation	Coefficient of Variation	No. Observations
U-LYPH-2	07100	01/06/86	09/25/86	454.1	36.32	8.00	260

Figure 5. Plot Mean Quality Control Values: Coproporphyrin



LEGEND: U-LYPH-2=A

Table 26. Summary of Quality Control Data: Uroporphyrin

Control Name	Lot No.	Begin Date	End Date	Mean (µg/L)	Standard Deviation	Coefficient of Variation	No. Observations
U-LYPH-2	07100	01/06/86	09/25/86	507.0	36.69	7.24	260

Figure 6. Monthly Mean Quality Control Values: Uroporphyrin

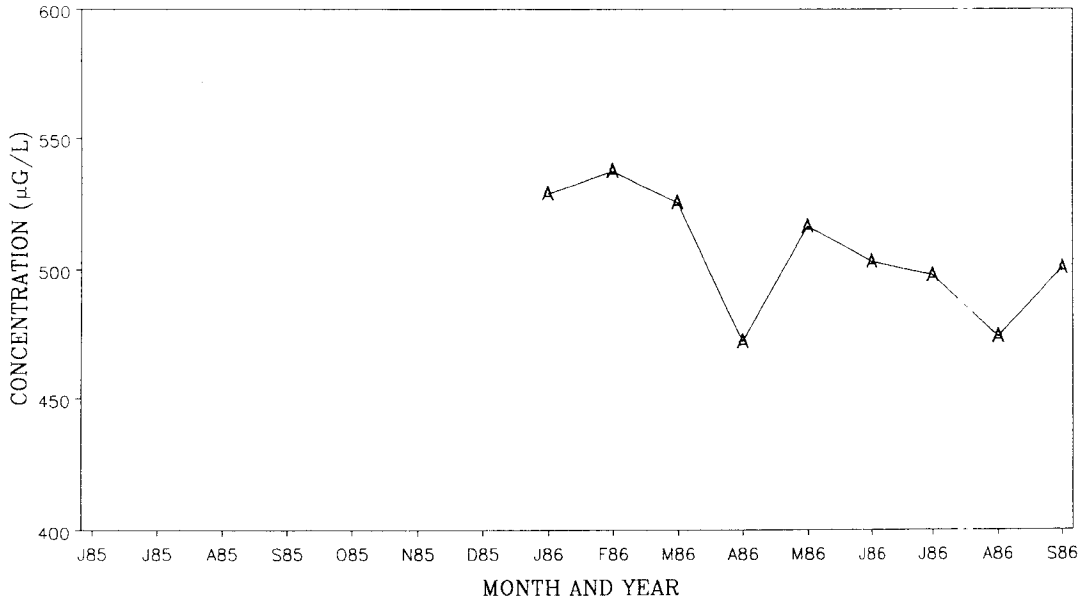
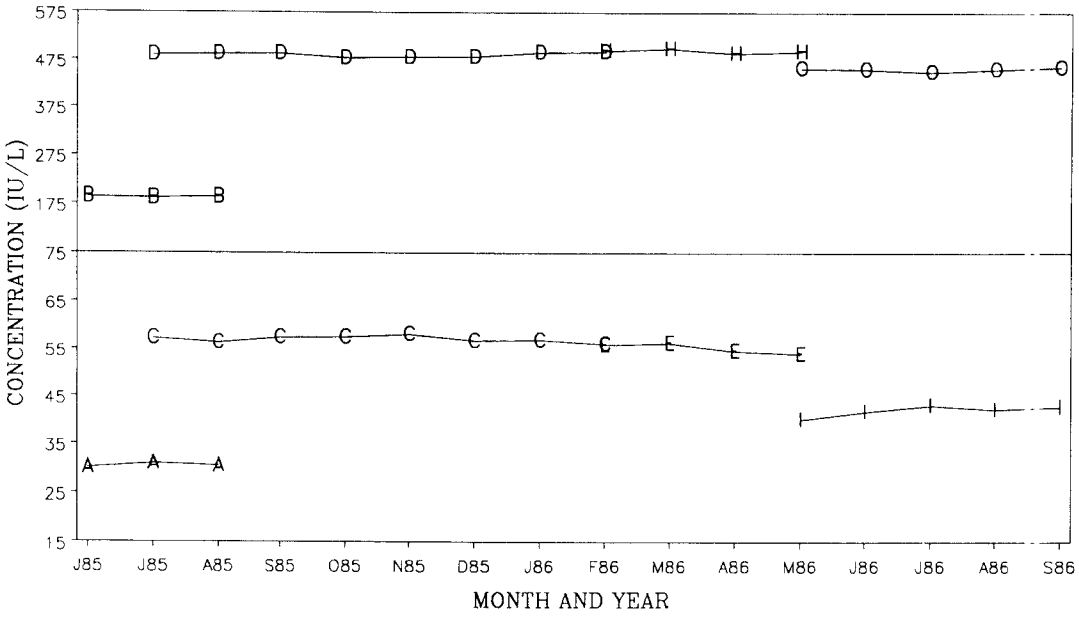


Table 27. Summary of Quality Control Data: Alanine Aminotransferase

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	30.4	1.25	4.10	13
CHMTRK-3	U3-8605B	06/03/85	08/08/85	187.8	2.81	1.50	13
KODAK--1	32401-85	07/29/85	02/13/86	57.0	1.70	2.99	42
KODAK--2	34402-85	07/29/85	02/13/86	485.1	10.39	2.14	42
KODAK-1R	32401-86	02/17/86	05/22/86	55.1	2.18	3.95	21
KODAK-2R	34402-86	02/17/86	05/22/86	493.8	9.36	1.90	21
KODAK-1A	0235401	05/26/86	09/25/86	42.3	2.04	4.83	21
KODAK-2A	0239402	05/26/86	09/25/86	455.3	5.42	1.19	21

Figure 7. Monthly Mean Quality Control Values: Alanine Aminotransferase

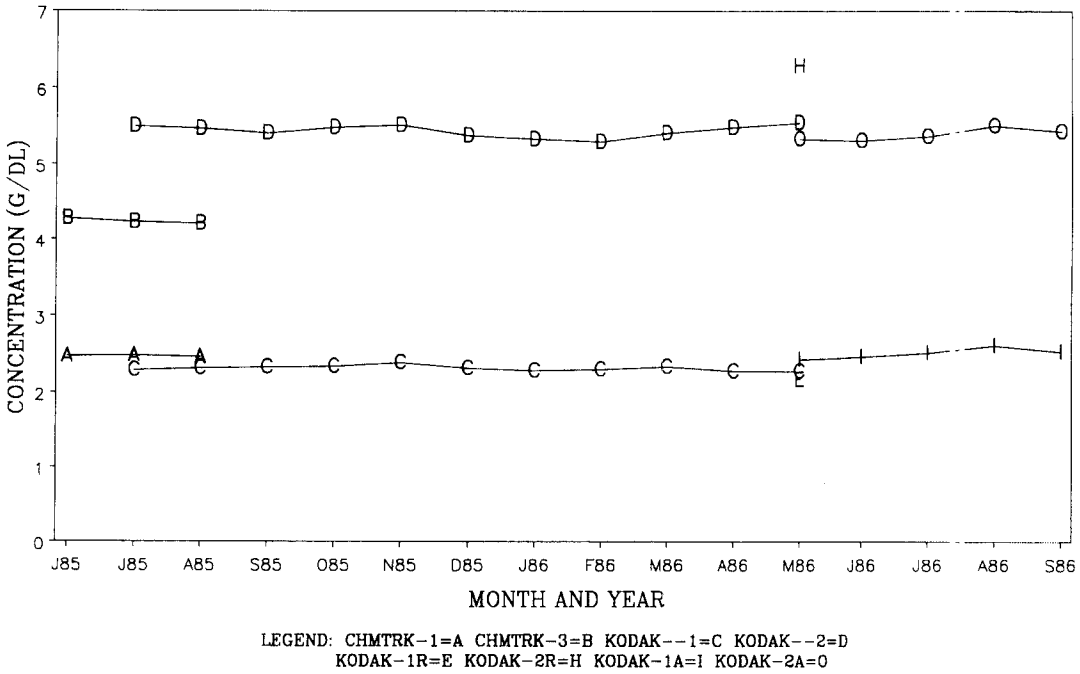


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O

Table 28. Summary of Quality Control Data: Albumin

Control Name	Lot No.	Begin Date	End Date	Mean (g/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	2.5	0.05	2.02	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	4.2	0.10	2.35	136
KODAK--1	32401-85	07/29/85	05/01/86	2.3	0.06	2.38	600
KODAK--2	34402-85	07/29/85	05/01/86	5.4	0.12	2.22	600
KODAK-1R	32401-86	05/05/86	05/22/86	2.2	0.05	2.15	36
KODAK-2R	34402-86	05/05/86	05/22/86	6.3	0.09	1.37	36
KODAK-1A	0235401	05/26/86	09/25/86	2.5	0.07	2.96	212
KODAK-2A	0239402	05/26/86	09/25/86	5.4	0.11	2.07	212

Figure 8. Monthly Mean Quality Control Values: Albumin

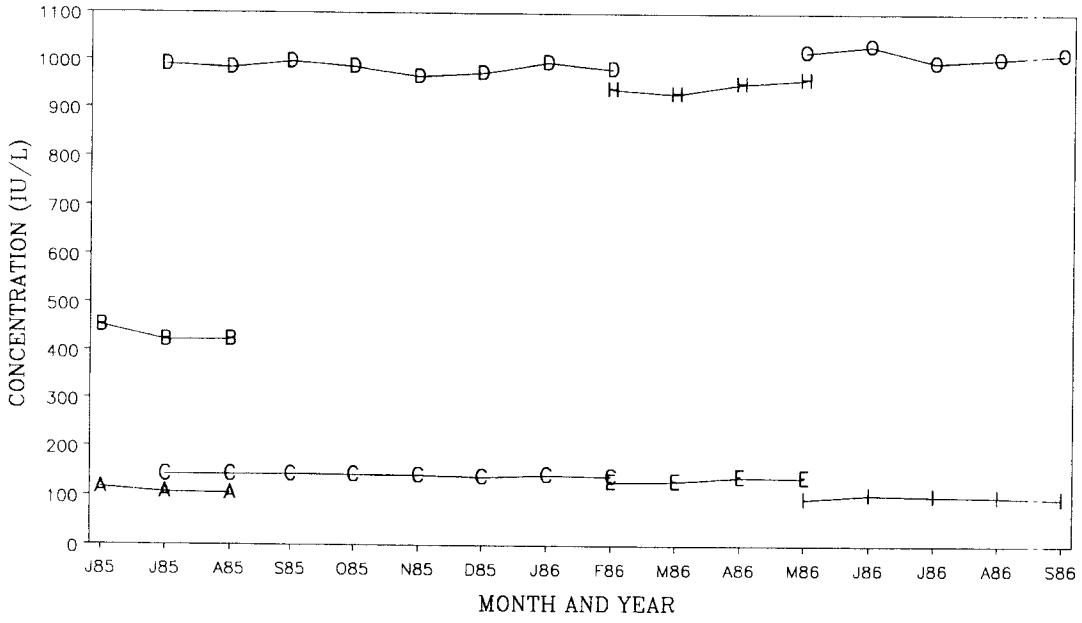


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O

Table 29. Summary of Quality Control Data: Alkaline Phosphatase

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	110.3	6.64	6.02	13(
CHMTRK-3	U3-8605B	06/03/85	08/08/85	435.4	19.42	4.46	13(
KODAK--1	32401-85	07/29/85	02/13/86	141.1	4.80	3.40	42
KODAK--2	34402-85	07/29/85	02/13/86	984.4	25.03	2.54	42
KODAK-1R	32401-86	02/17/86	05/22/86	134.1	5.66	4.22	21
KODAK-2R	34402-86	02/17/86	05/22/86	944.1	25.58	2.71	21
KODAK-1A	0235401	05/26/86	09/25/86	98.5	4.52	4.59	21
KODAK-2A	0239402	05/26/86	09/25/86	1011.9	26.60	2.63	21

Figure 9. Monthly Mean Quality Control Values: Alkaline Phosphatase



LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O

Table 30. Summary of Quality Control Data: Aspartate Aminotransferase

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	61.5	3.72	6.04	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	224.3	8.51	3.80	136
KODAK--1	32401-85	07/29/85	05/22/86	53.0	2.21	4.16	636
KODAK--2	34402-85	07/29/85	05/22/86	576.9	11.71	2.03	636
KODAK-1A	0235401	05/26/86	09/25/86	54.7	2.18	3.99	212
KODAK-2A	0239402	05/26/86	09/25/86	548.8	7.16	1.30	212

Figure 10. Monthly Mean Quality Control Values: Aspartate Aminotransferase

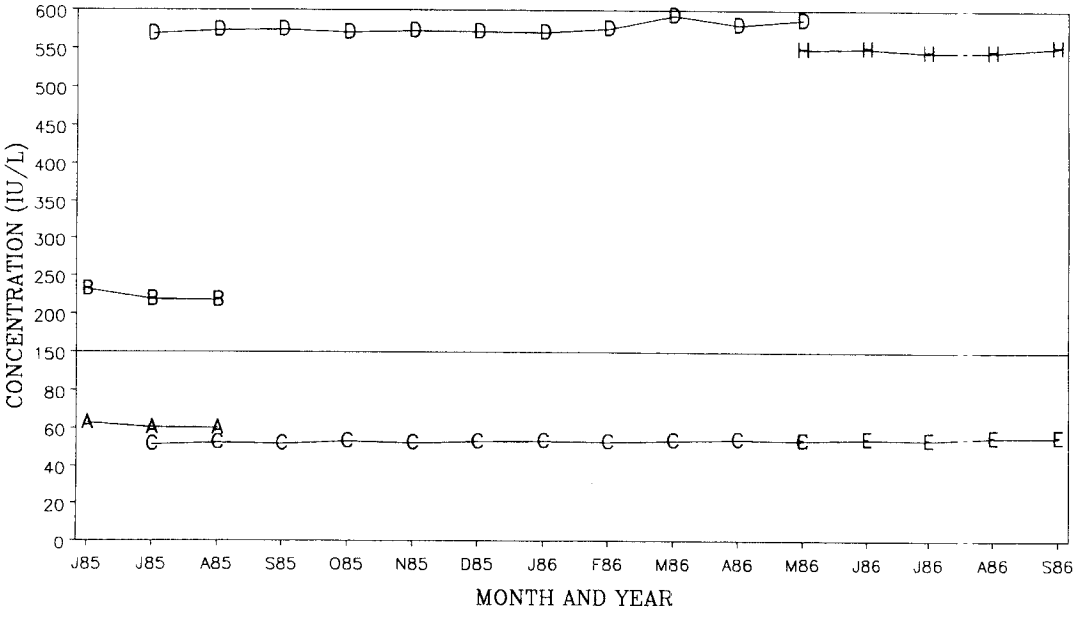
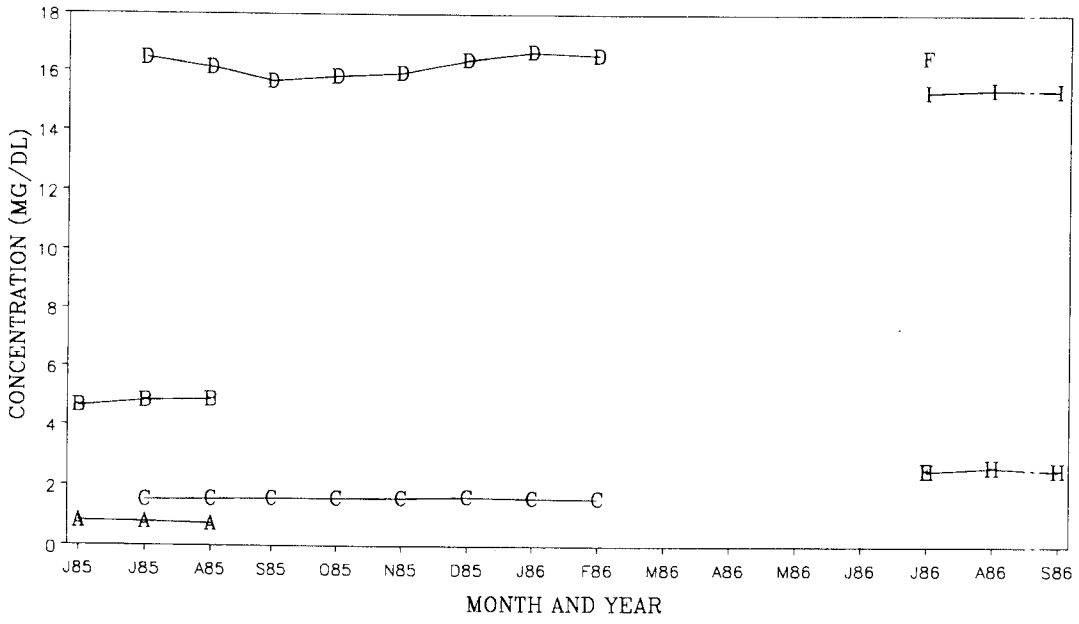


Table 31. Summary of Quality Control Data: Total Bilirubin

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	0.8	0.06	7.57	13
CHMTRK-3	U3-8605B	06/03/85	08/08/85	4.7	0.16	3.42	13
KODAK--1	32401-85	07/29/85	02/13/86	1.6	0.04	2.73	42
KODAK--2	34402-85	07/29/85	02/13/86	16.1	0.49	3.01	42
KODAK-1B	0235401	07/07/86	07/15/86	2.5	0.06	2.52	2
KODAK-2B	0239402	07/07/86	07/15/86	16.5	0.41	2.50	2
KODAK-1C	717NEWSD	07/17/86	09/25/86	2.5	0.08	3.16	12
KODAK-2C	717NEWSD	07/17/86	09/25/86	15.4	0.23	1.52	12

Figure 11. Monthly Mean Quality Control Values: Total Bilirubin

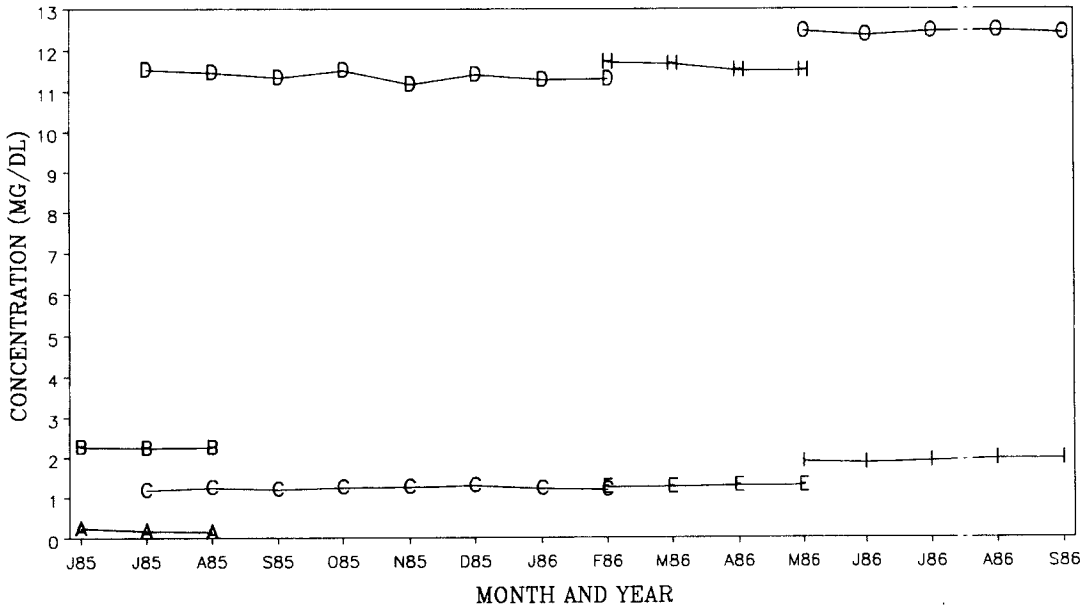


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1B=E KODAK-2B=F KODAK-1C=H KODAK-2C=I

Table 32. Summary of Quality Control Data: Unconjugated Bilirubin

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	0.2	0.07	32.94	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	2.2	0.06	2.68	136
KODAK--1	32401-85	07/29/85	02/13/86	1.2	0.06	4.64	424
KODAK--2	34402-85	07/29/85	02/13/86	11.4	0.20	1.79	424
KODAK-1R	32401-86	02/17/86	05/22/86	1.3	0.04	3.14	212
KODAK-2R	34402-86	02/17/86	05/22/86	11.6	0.22	1.91	212
KODAK-1A	0235401	05/26/86	09/25/86	1.9	0.06	3.40	212
KODAK-2A	0239402	05/26/86	09/25/86	12.4	0.22	1.81	212

Figure 12. Monthly Mean Quality Control Values: Unconjugated Bilirubin

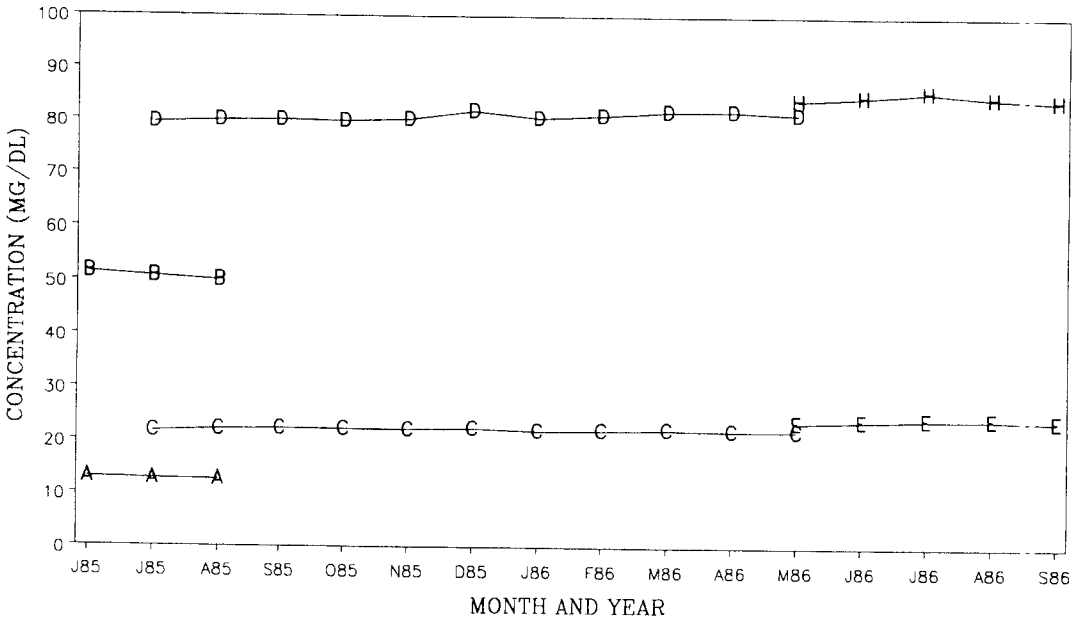


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O

Table 33. Summary of Quality Control Data: Blood Urea Nitrogen

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	12.8	0.24	1.88	13[illegible]
CHMTRK-3	U3-8605B	06/03/85	08/08/85	51.0	0.86	1.69	13[illegible]
KODAK--1	32401-85	07/29/85	05/22/86	22.0	0.37	1.68	63[illegible]
KODAK--2	34402-85	07/29/85	05/22/86	80.8	1.33	1.64	63[illegible]
KODAK-1A	0235401	05/26/86	09/25/86	23.9	0.43	1.82	21[illegible]
KODAK-2A	0239402	05/26/86	09/25/86	84.6	1.30	1.54	21[illegible]

Figure 13. Monthly Mean Quality Control Values: Blood Urea Nitrogen

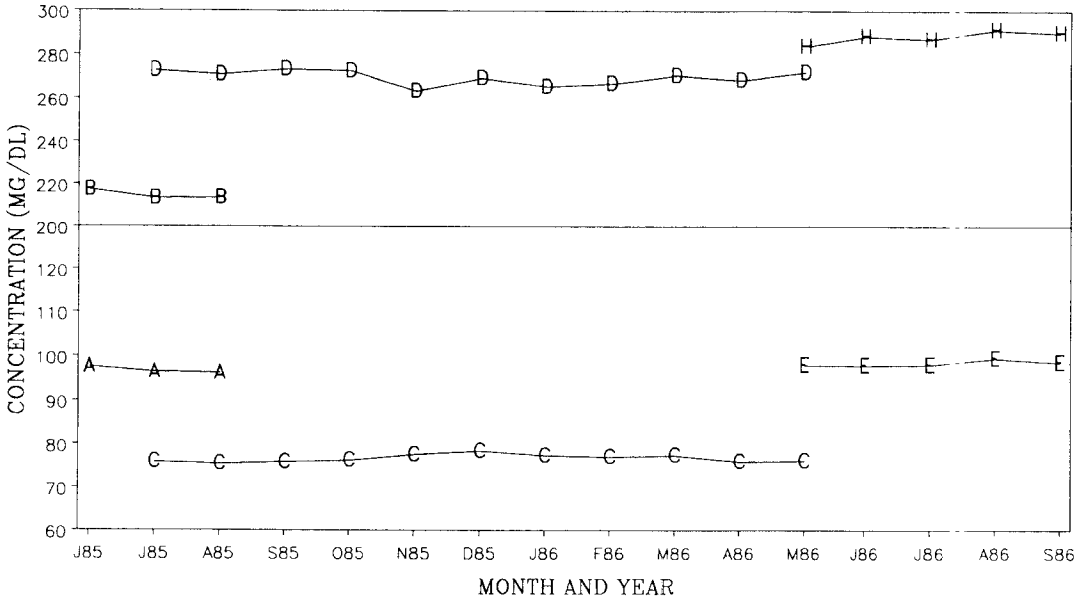


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1A=E KODAK-2A=H

Table 34. Summary of Quality Control Data: Total Cholesterol

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	96.9	1.58	1.63	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	215.3	4.47	2.08	136
KODAK--1	32401-85	07/29/85	05/22/86	76.7	1.40	1.83	636
KODAK--2	34402-85	07/29/85	05/22/86	269.5	4.74	1.76	636
KODAK-1A	0235401	05/26/86	09/25/86	98.4	1.57	1.60	212
KODAK-2A	0239402	05/26/86	09/25/86	288.8	4.37	1.51	212

Figure 14. Monthly Mean Quality Control Values: Total Cholesterol

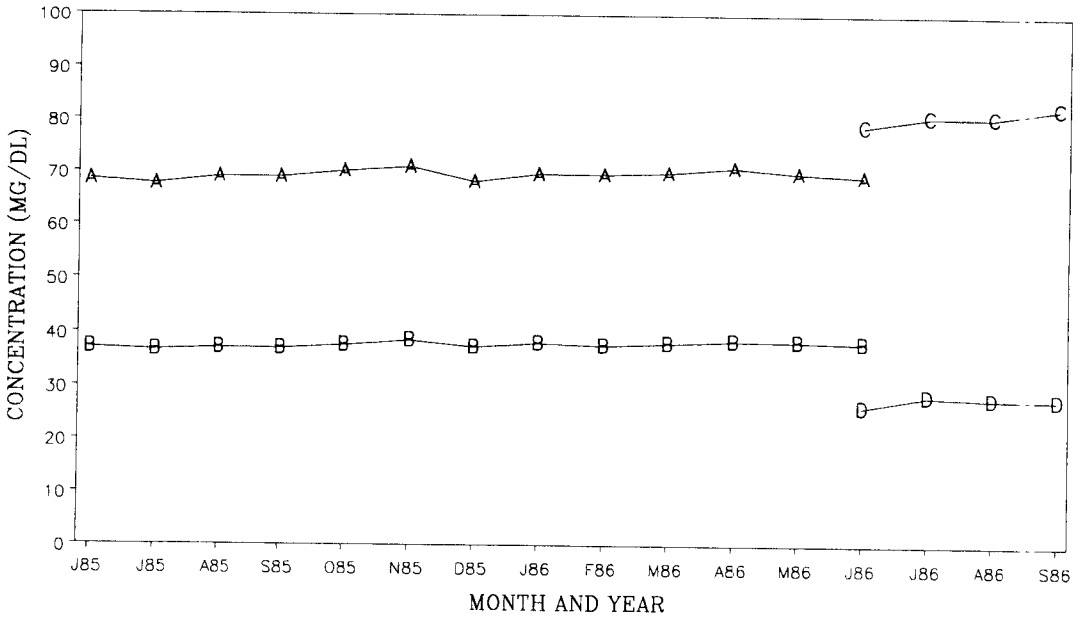


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1A=E KODAK-2A=H

Table 35. Summary of Quality Control Data: High-Density Lipoprotein Cholesterol

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No Observations
SIGMA-HI	84F-6166	06/03/85	06/24/86	69.5	2.04	2.93	80(
SIGMA-LO	84F-6167	06/03/85	06/24/86	37.8	1.09	2.88	80(
SIGMAHIB	95F-6094	06/26/86	09/25/86	81.3	2.13	2.62	15(
SIGMALOB	95F-6095	06/26/86	09/25/86	27.9	1.03	3.69	15(

Figure 15. Monthly Mean Quality Control Values: High-Density Lipoprotein (HDL) Cholesterol

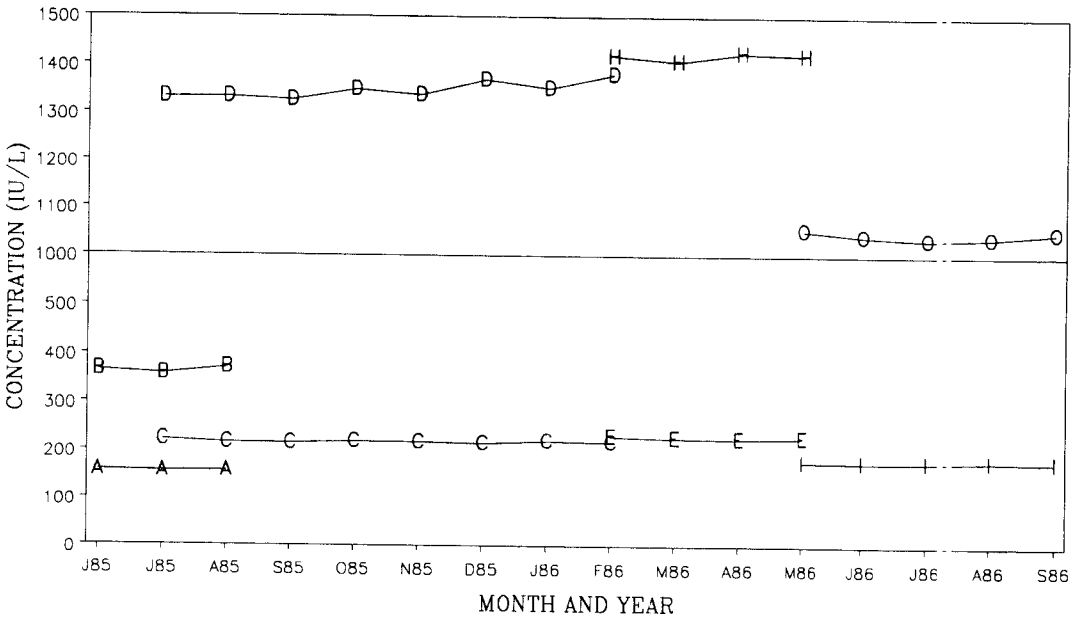


LEGEND: SIGMA-HI=A SIGMA-LO=B SIGMAHIB=C SIGMALOB=D

Table 36. Summary of Quality Control Data: Creatine Phosphokinase

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	156.1	4.87	3.12	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	363.7	14.19	3.90	136
KODAK--1	32401-85	07/29/85	02/13/86	217.3	7.02	3.23	424
KODAK--2	34402-85	07/29/85	02/13/86	1346.8	32.90	2.44	424
KODAK-1R	32401-86	02/17/86	05/22/86	226.6	7.29	3.22	212
KODAK-2R	34402-86	02/17/86	05/22/86	1417.8	36.35	2.56	212
KODAK-1A	0235401	05/26/86	09/25/86	176.2	6.34	3.60	212
KODAK-2A	0239402	05/26/86	09/25/86	1041.7	35.42	3.40	212

Figure 16. Monthly Mean Quality Control Values: Creatine Phosphokinase

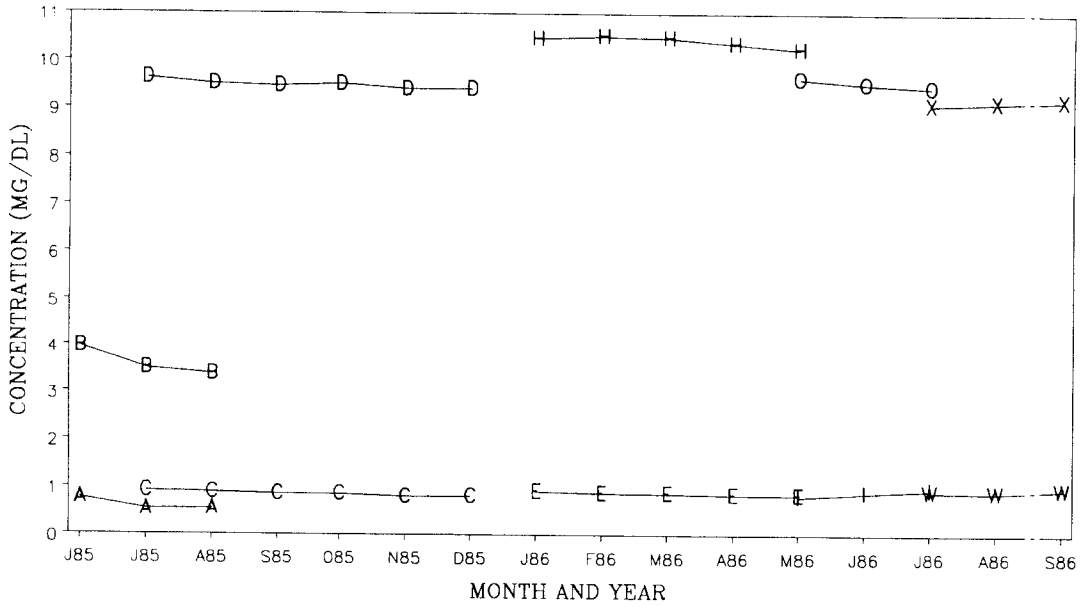


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O

Table 37. Summary of Quality Control Data: Serum Creatinine

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	No Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	0.6	0.17	13
CHMTRK-3	U3-8605B	06/03/85	08/08/85	3.7	0.34	13
KODAK--1	32401-85	07/29/85	12/19/85	0.9	0.08	32
KODAK--2	34402-85	07/29/85	12/19/85	9.5	0.20	32
KODAK-1R	32401-86	01/06/86	05/22/86	0.9	0.08	31
KODAK-2R	34402-86	01/06/86	05/22/86	10.4	0.21	31
KODAK-1A	0235401	05/26/86	07/01/86	0.9	0.09	6
KODAK-2A	0239402	05/26/86	07/01/86	9.5	0.14	6
KODAK-1B	0235401	07/07/86	09/25/86	0.9	0.10	144
KODAK-2B	0239402	07/07/86	09/25/86	9.1	0.18	144

Figure 17. Monthly Mean Quality Control Values: Serum Creatinine

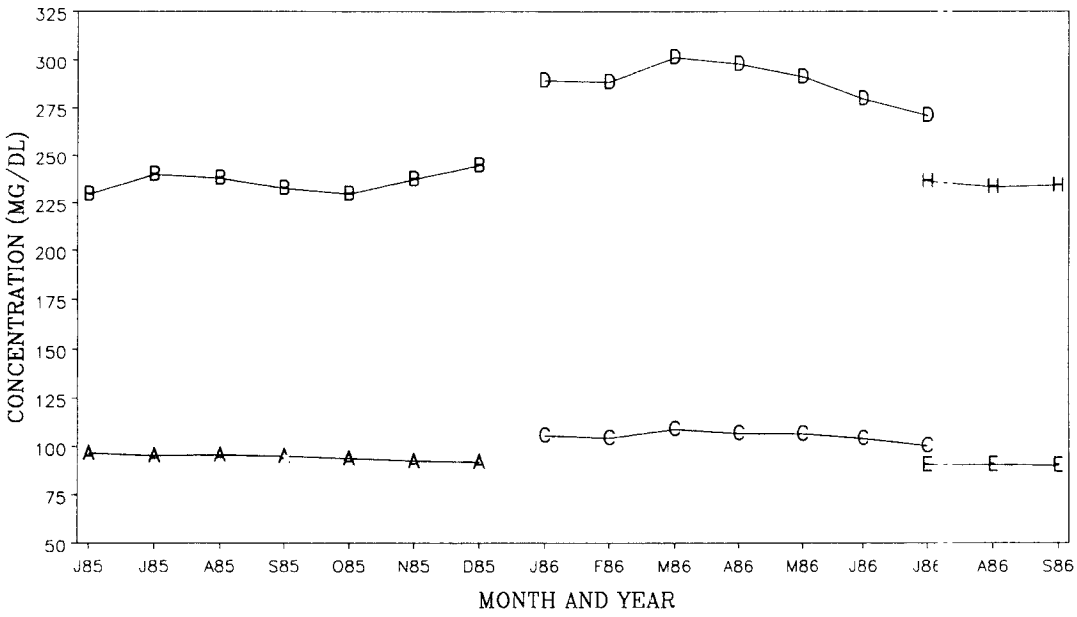


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O
KODAK-1B=W KODAK-2B=X

Table 38. Summary of Quality Control Data: Urine Creatinine

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
U-LYPH-1	07000-85	06/03/85	12/19/85	94.7	3.99	4.22	436
U-LYPH-2	07100-85	06/03/85	12/19/85	235.6	9.03	3.83	436
ULYPH-1R	07000-86	01/06/86	07/01/86	106.3	4.37	4.11	380
ULYPH-2R	07100-86	01/06/86	07/01/86	291.9	11.06	3.79	380
ULYPH-1A	07000-86	07/07/86	09/25/86	90.7	3.04	3.36	144
ULYPH-2A	07100-86	07/07/86	09/25/86	234.8	6.17	2.63	144

Figure 18. Monthly Mean Quality Control Values: Urine Creatinine

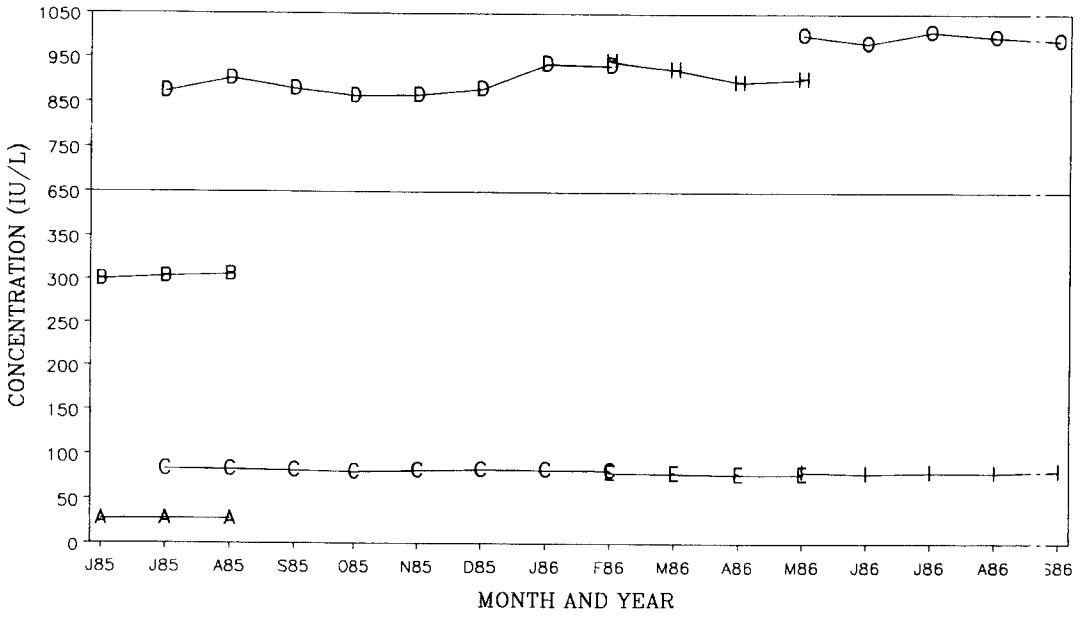


LEGEND: U-LYPH-1=A U-LYPH-2=B ULYPH-1R=C ULYPH-2R=D
ULYPH-1A=E ULYPH-2A=H

Table 39. Summary of Quality Control Data: Gamma Glutamyl Transferase

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	27.7	1.06	3.81	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	302.1	6.57	2.18	136
KODAK--1	32401-85	07/29/85	02/13/86	82.1	2.08	2.53	424
KODAK--2	34402-85	07/29/85	02/13/86	891.3	31.74	3.56	424
KODAK-1R	32401-86	02/17/86	05/22/86	78.2	1.59	2.03	212
KODAK-2R	34402-86	02/17/86	05/22/86	912.6	24.22	2.65	212
KODAK-1A	0235401	05/26/86	09/25/86	80.0	1.68	2.10	216
KODAK-2A	0239402	05/26/86	09/25/86	994.7	19.84	1.99	216

Figure 19. Monthly Mean Quality Control Values: Gamma Glutamyl Transferase

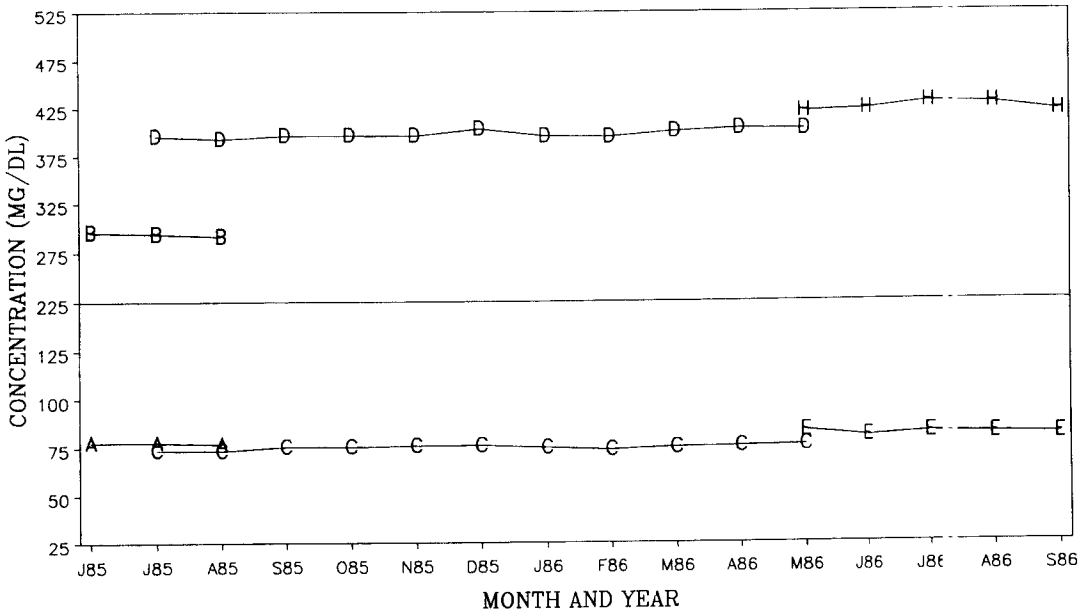


LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1R=E KODAK-2R=H KODAK-1A=I KODAK-2A=O

Table 40. Summary of Quality Control Data: Fasting Glucose

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	77.5	0.85	1.09	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	294.1	2.57	0.88	136
KODAK--1	32401-85	07/29/85	05/22/86	74.7	1.41	1.88	636
KODAK--2	34402-85	07/29/85	05/22/86	397.5	6.87	1.73	636
KODAK-1A	0235401	05/26/86	09/25/86	81.3	1.30	1.60	212
KODAK-2A	0239402	05/26/86	09/25/86	425.3	6.22	1.46	212

Figure 20. Monthly Mean Quality Control Values: Fasting Glucose



LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1A=E KODAK-2A=H

Table 41. Summary of Quality Control Data: Lactic Dehydrogenase

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	915.0	12.97	1.42	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	1461.0	20.24	1.39	136
KODAK--1	32401-85	07/29/85	02/13/86	569.0	19.11	3.36	424
KODAK--2	34402-85	07/29/85	02/13/86	1368.7	30.50	2.23	424
KODAK-1R	32401-86	02/17/86	05/22/86	595.5	13.25	2.23	212
KODAK-2R	34402-86	02/17/86	05/22/86	1401.8	24.16	1.72	212
KODAK-1A	0235401	05/26/86	09/25/86	690.5	9.47	1.37	212
KODAK-2A	0239402	05/26/86	09/25/86	1413.4	18.50	1.31	212

Figure 21. Monthly Mean Quality Control Values: Lactic Dehydrogenase

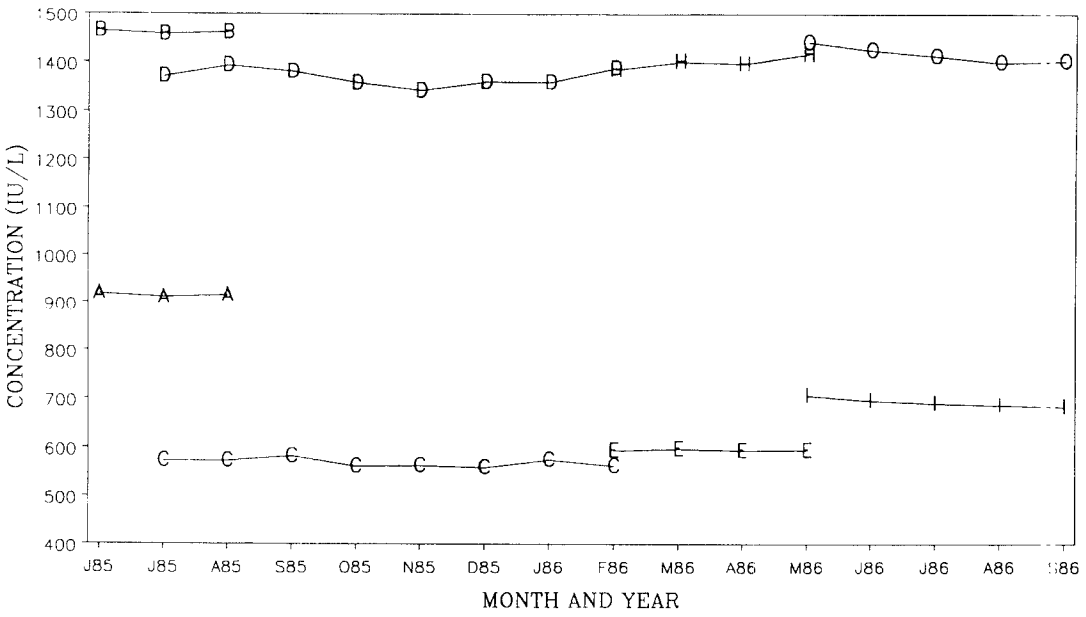
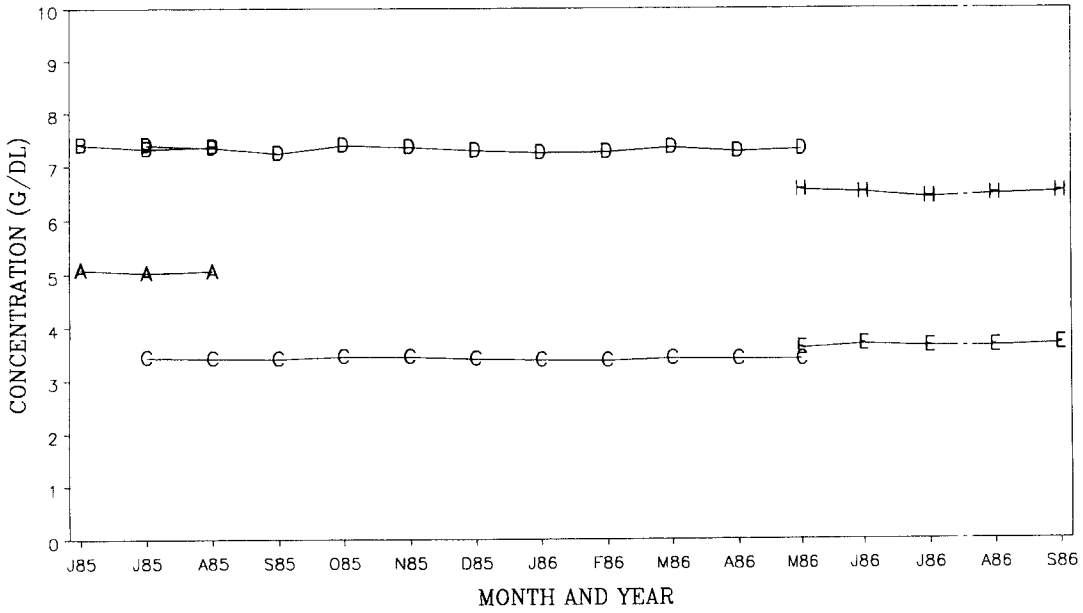


Table 42. Summary of Quality Control Data: Total Protein

Control Name	Lot No.	Begin Date	End Date	Mean (g/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	5.1	0.08	1.63	136
CHMTRK-3	U3-8605B	06/03/85	08/08/85	7.4	0.12	1.59	136
KODAK--1	32401-85	07/29/85	05/22/86	3.4	0.05	1.59	636
KODAK--2	34402-85	07/29/85	05/22/86	7.3	0.12	1.58	636
KODAK-1A	0235401	05/26/86	09/25/86	3.7	0.05	1.41	212
KODAK-2A	0239402	05/26/86	09/25/86	6.5	0.09	1.37	212

Figure 22. Monthly Mean Quality Control Values: Total Protein



LEGEND: CHMTRK-1=A CHMTRK-3=B KODAK--1=C KODAK--2=D
KODAK-1A=E KODAK-2A=H

Table 43. Summary of Quality Control Data: Triglycerides

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	08/08/85	209.4	2.65	1.27	135
CHMTRK-3	U3-8605B	06/03/85	08/08/85	289.3	3.59	1.24	135
KODAK--1	32401-85	07/29/85	05/22/86	92.0	1.86	2.03	633
KODAK--2	34402-85	07/29/85	05/22/86	325.6	6.30	1.93	633
KODAK-1A	0235401	05/26/86	09/25/86	107.2	1.78	1.66	2[illegible]2
KODAK-2A	0239402	05/26/86	09/25/86	341.6	4.74	1.39	2[illegible]2

Figure 23. Monthly Mean Quality Control Values: Triglycerides

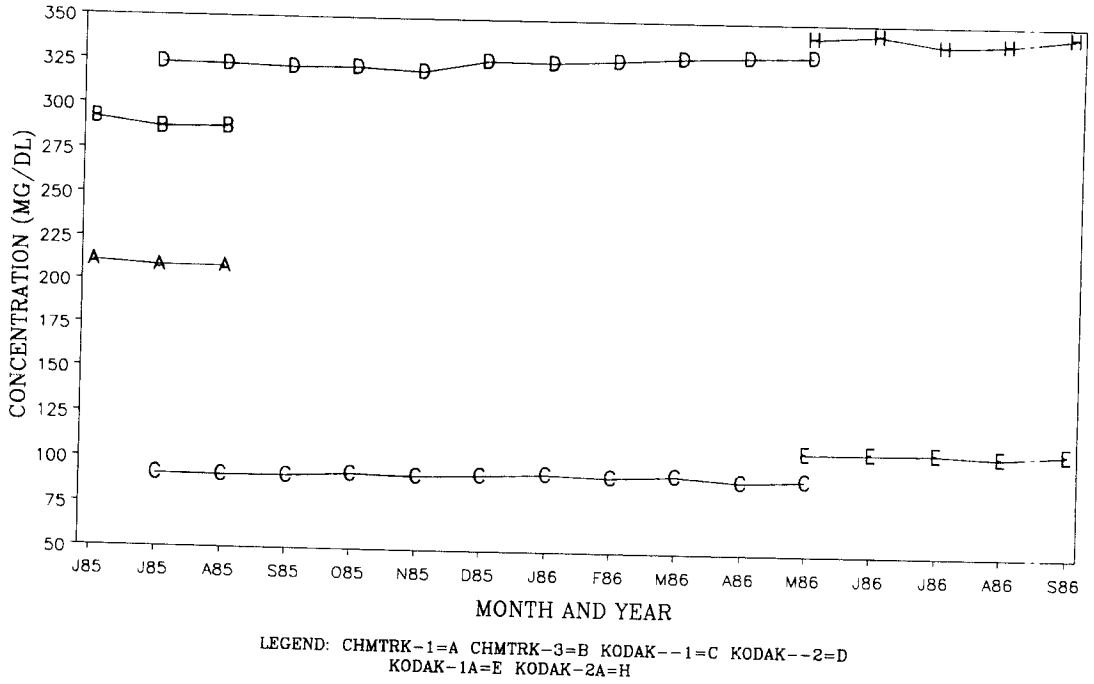
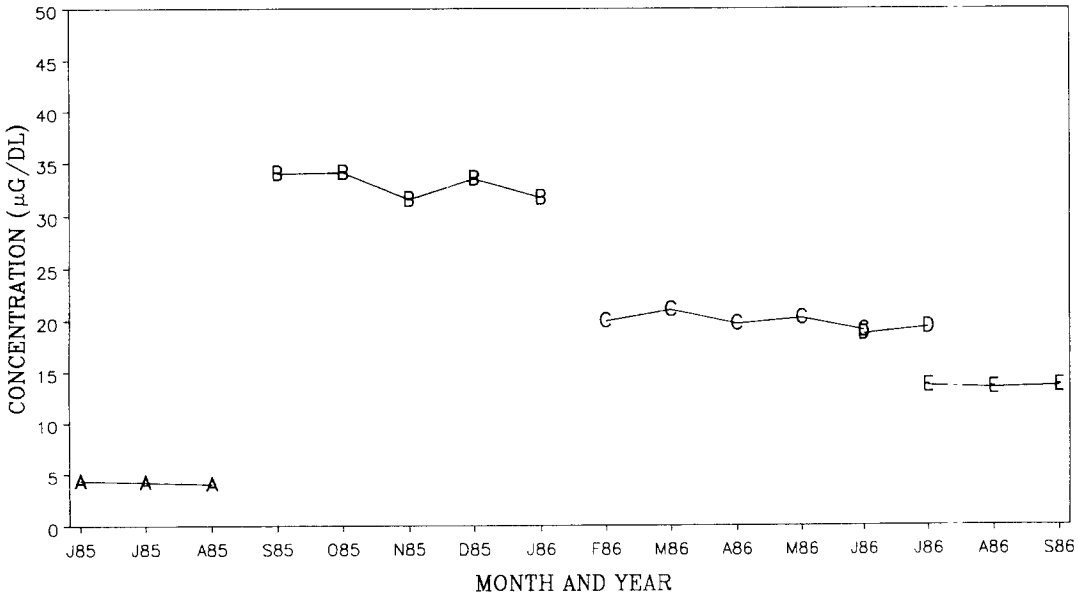


Table 44. Summary of Quality Control Data: δ-Aminolevulinic Acid

Control Name	Lot No.	Begin Date	End Date	Mean (μg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
DELTAALA	POOL-85	06/03/85	08/29/85	4.2	0.39	9.33	92
D-ALA--2	POOL-85	09/03/85	01/30/86	33.0	3.80	11.52	156
D-ALA--3	POOL-86	02/03/86	06/05/86	20.2	2.10	10.43	134
D-ALA--4	POOL-86	06/09/86	07/17/86	19.0	1.38	7.27	36
D-ALA--5	POOL-86	07/21/86	09/25/86	13.6	1.67	12.29	60

Figure 24. Monthly Mean Quality Control Values: δ-Aminolevulinic Acid

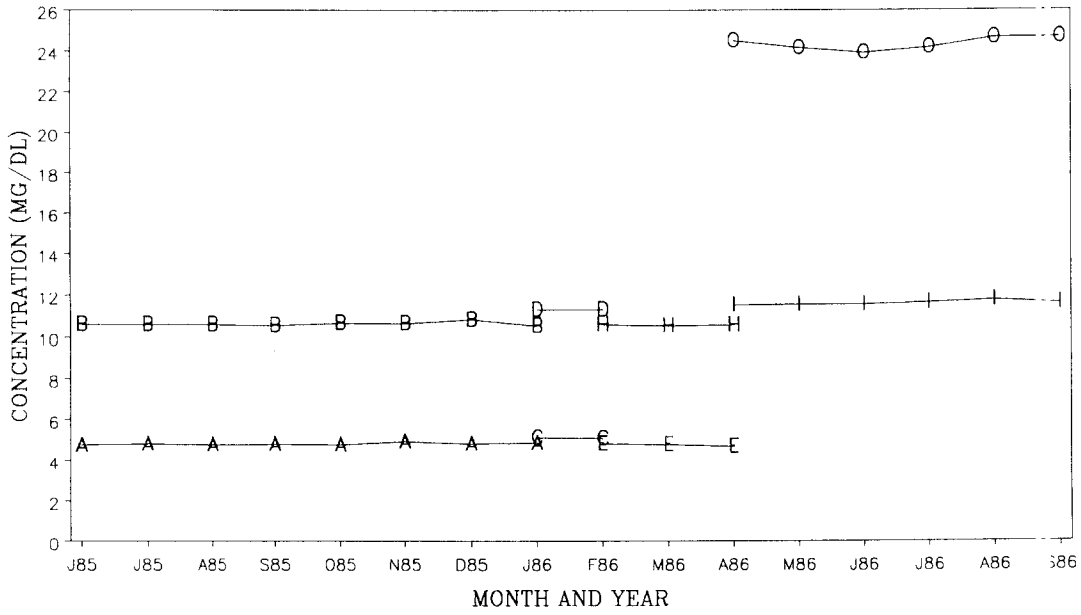


LEGEND: DELTAALA=A D-ALA--2=B D-ALA--3=C
D-ALA--4=D D-ALA--5=E

Table 45. Summary of Quality Control Data: Glycerol Blank

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
CHMTRK-1	U1-8605B	06/03/85	01/09/86	4.8	0.35	7.31	448
CHMTRK-3	U3-8605B	06/03/85	01/09/86	10.6	0.32	2.99	448
CHMTK-1R	U1-8605B	01/13/86	02/13/86	5.1	0.16	3.18	80
CHMTK-3R	U3-8605B	01/13/86	02/13/86	11.3	0.22	1.94	80
CHMTRK1B	U1-8605B	02/17/86	04/28/86	4.8	0.14	2.97	164
CHMTRK3B	U3-8605B	02/17/86	04/28/86	10.6	0.21	1.97	164
CHMTRK1C	U1-8703B	04/29/86	09/25/86	11.6	0.29	2.53	260
CHMTRK3C	U3-8703B	04/29/86	09/25/86	24.3	0.64	2.65	260

Figure 25. Monthly Mean Quality Control Values: Glycerol Blank

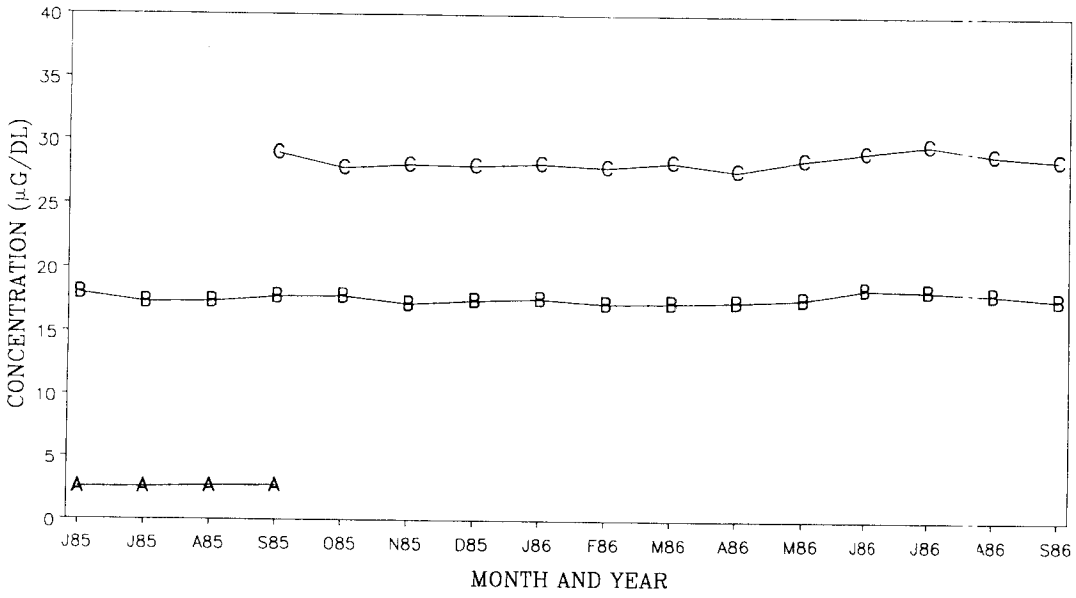


LEGEND: CHMTRK-1=A CHMTRK-3=B CHMTK-1R=C CHMTK-3R=D
CHMTRK1B=E CHMTRK3B=H CHMTRK1C=I CHMTRK3C=O

Table 46. Summary of Quality Control Data: Cortisol (Morning)

Control Name	Lot No.	Begin Date	End Date	Mean (µg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--1	01001-85	06/03/85	09/19/85	2.6	0.22	8.39	114
LYPHO--2	01002-85	06/03/85	09/25/86	17.7	1.00	5.66	476
LYPHO--3	01003-85	09/23/85	09/25/86	28.3	1.64	5.79	362

Figure 26. Monthly Mean Quality Control Values: Cortisol (Morning)

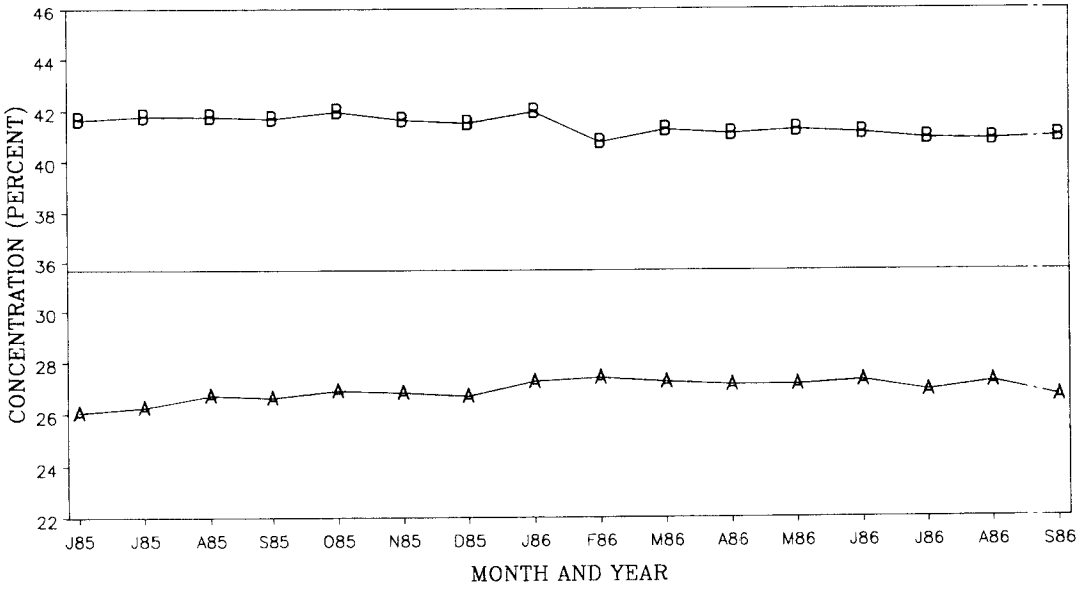


LEGEND: LYPHO--1=A LYPHO--2=B LYPHO--3=C

Table 47. Summary of Quality Control Data: T3 Uptake

Control Name	Lot No.	Begin Date	End Date	Mean (%)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--1	01001-85	06/03/85	09/25/86	26.9	0.69	2.57	476
LYPHO--3	01003-85	06/03/85	09/25/86	41.4	0.93	2.26	476

Figure 27. Monthly Mean Quality Control Values: T3 Uptake

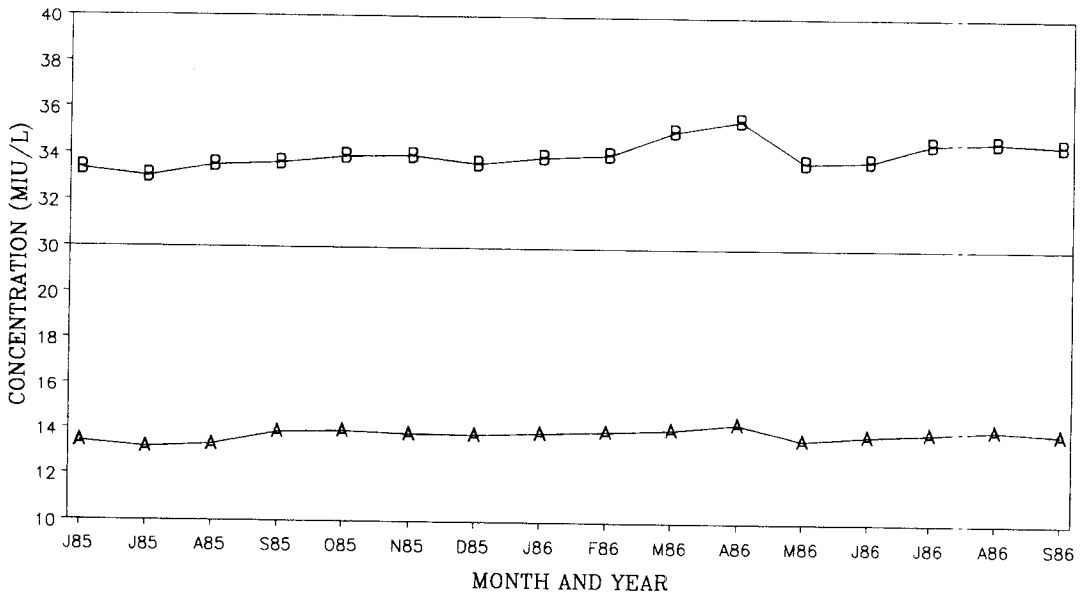


LEGEND: LYPHO--1=A LYPHO--3=B

Table 48. Summary of Quality Control Data: Thyroid-Stimulating Hormone

Control Name	Lot No.	Begin Date	End Date	Mean (mIU/L)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--2	01002-85	06/03/85	09/25/86	13.8	0.62	4.47	480
LYPHO--3	01003-85	06/03/85	09/25/86	34.1	1.18	3.47	480

Figure 28. Monthly Mean Quality Control Values: Thyroid-Stimulating Hormone

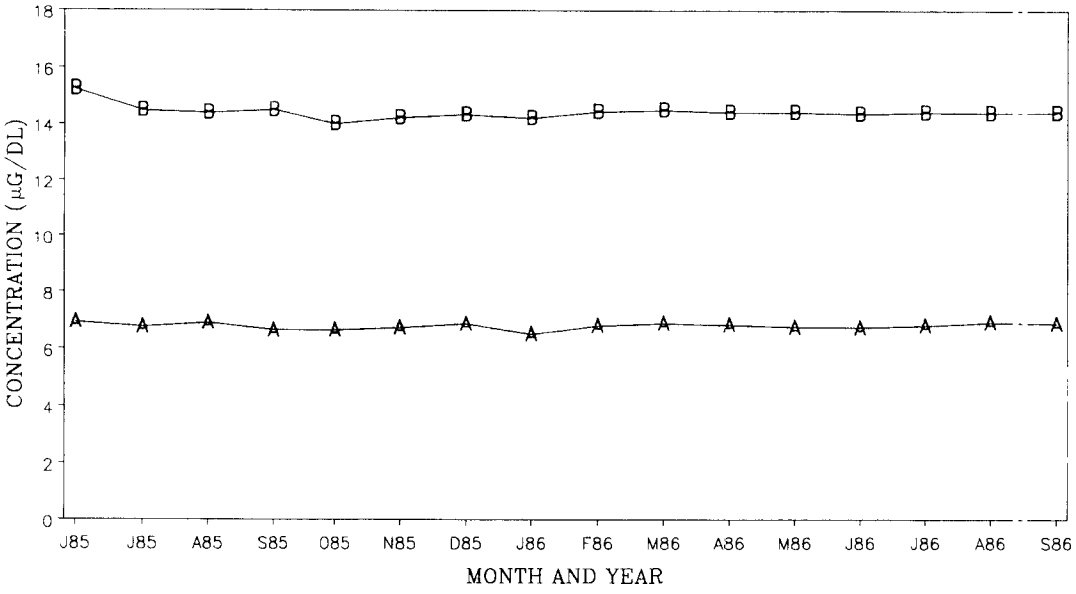


LEGEND: LYPHO--2=A LYPHO--3=B

Table 49. Summary of Quality Control Data: Thyroxine-T4

Control Name	Lot No.	Begin Date	End Date	Mean (µg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--2	01002-85	06/03/85	09/25/86	6.8	0.37	5.51	48
LYPHO--3	01003-85	06/03/85	09/25/86	14.4	0.63	4.35	48

Figure 29. Monthly Mean Quality Control Values: Thyroxine-T4

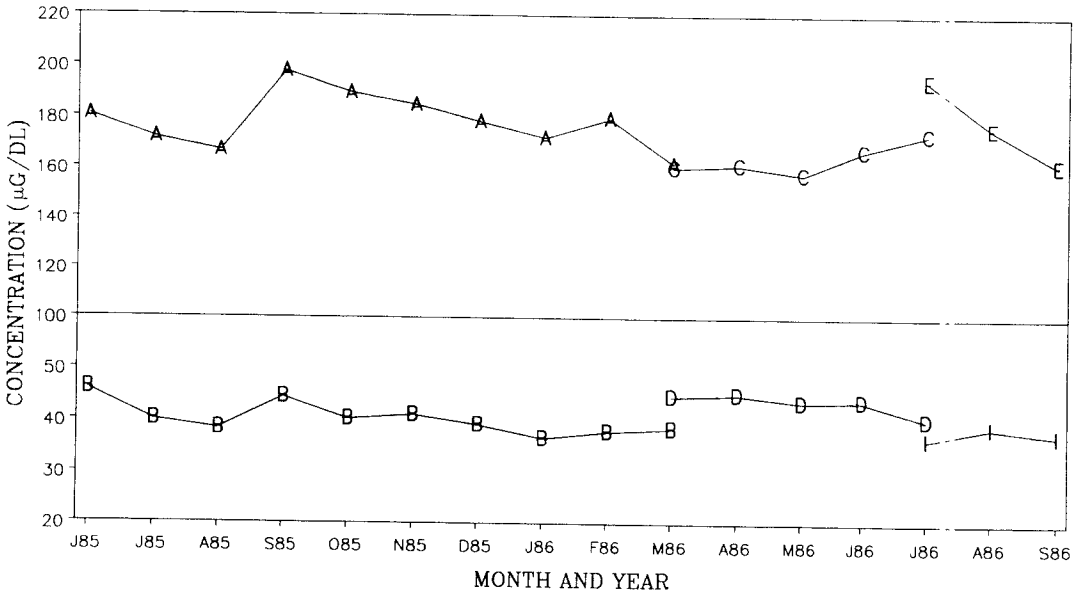


LEGEND: LYPHO--2=A LYPHO--3=B

Table 50. Summary of Quality Control Data: Dehydroepiandrosterone-SO_4

Control Name	Lot No.	Begin Date	End Date	Mean (µg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--2	01002-85	06/03/85	03/06/86	180.0	18.52	10.29	292
LYPHODIL	01004-85	06/03/85	03/06/86	40.4	4.67	11.55	292
LYPHO-2A	01002-86	03/10/86	07/29/86	163.8	12.22	7.46	140
LYPHODLA	01004-86	03/10/86	07/29/86	43.8	3.91	8.93	140
LYPHO-2B	01002-86	07/31/86	09/25/86	169.9	17.69	10.41	50
LYPHODLB	01004-86	07/31/86	09/25/86	38.0	3.35	8.82	50

Figure 30. Monthly Mean Quality Control Values: Dehydroepiandrosterone-SO_4

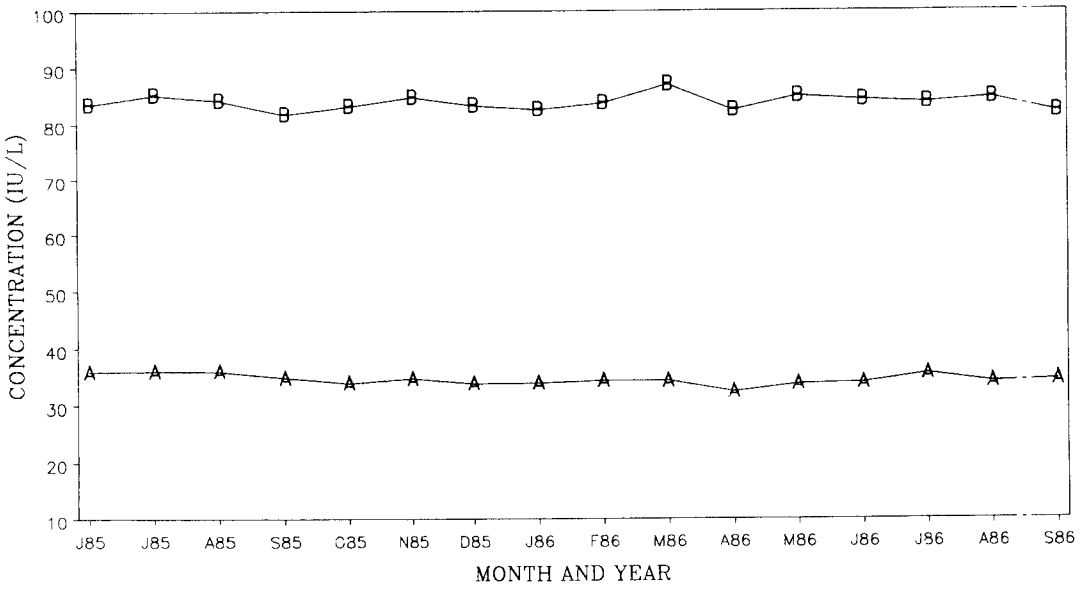


LEGEND: LYPHO--2=A LYPHODIL=B LYPHO-2A=C
LYPHODLA=D LYPHO-2B=E LYPHODLB=I

Table 51. Summary of Quality Control Data: Follicle-Stimulating Hormone

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No Observations
LYPHO--2	01002-85	06/03/85	09/25/86	34.5	2.14	6.21	48
LYPHO--3	01003-85	06/03/85	09/25/86	83.8	5.91	7.06	48

Figure 31. Monthly Mean Quality Control Values: Follicle-Stimulating Hormone

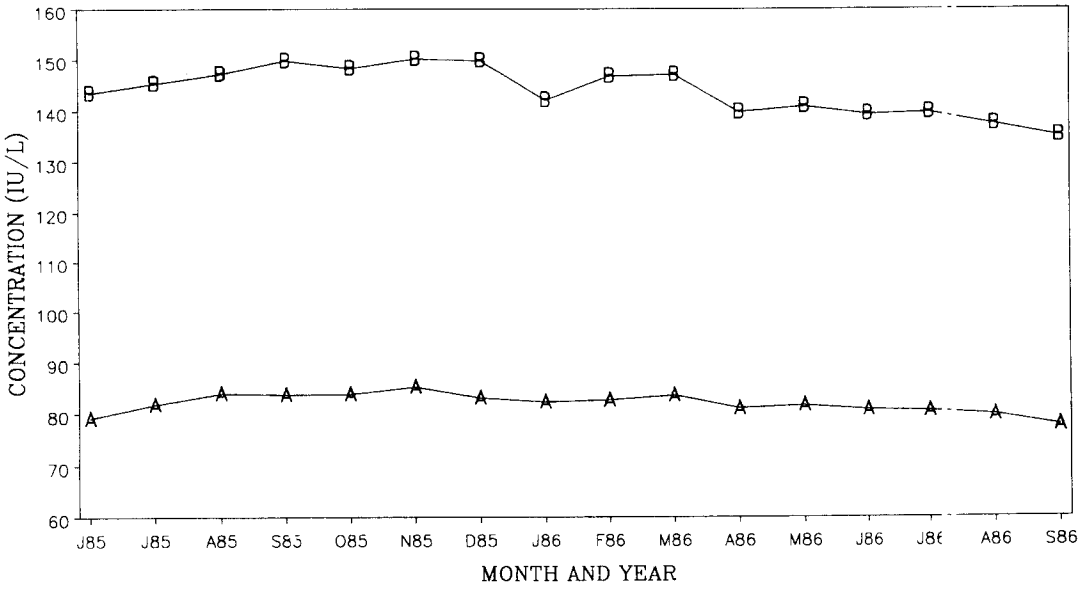


LEGEND: LYPHO--2=A LYPHO--3=B

Table 52. Summary of Quality Control Data: Luteinizing Hormone

Control Name	Lot No.	Begin Date	End Date	Mean (IU/L)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--2	01002-85	06/03/85	09/25/86	82.0	5.50	6.70	484
LYPHO--3	01003-85	06/03/85	09/25/86	144.1	10.54	7.32	484

Figure 32. Monthly Mean Quality Control Values: Luteinizing Hormone

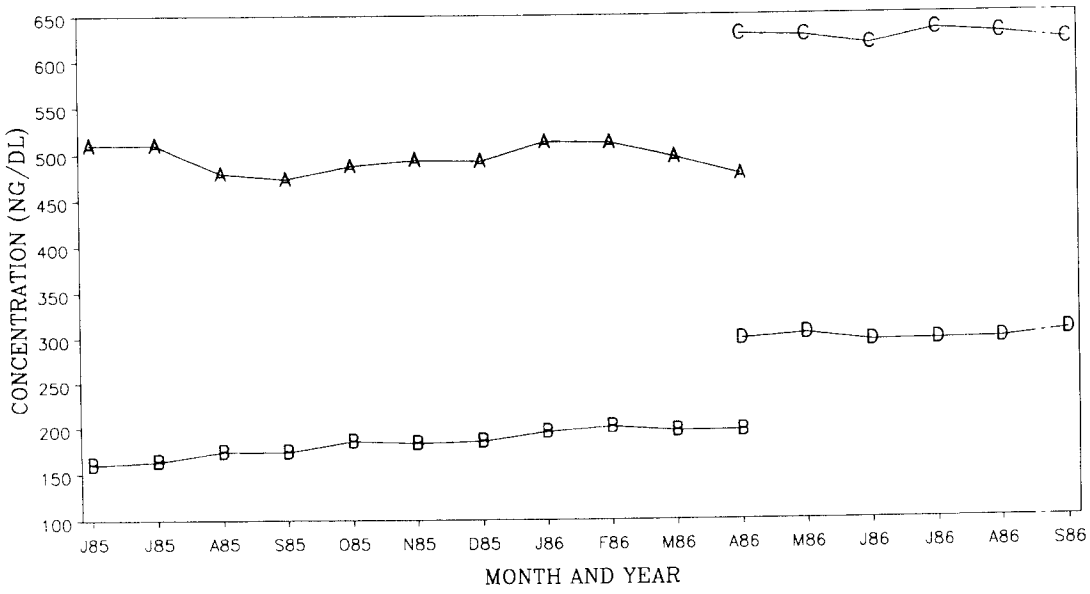


LEGEND: LYPHO--2=A LYPHO--3=B

Table 53. Summary of Quality Control Data: Testosterone

Control Name	Lot No.	Begin Date	End Date	Mean (ng/dl)	Standard Deviation	Coefficient of Variation	No. Observations
LYPHO--2	01002-85	06/03/85	04/08/86	495.1	27.96	5.65	338
LYPHODIL	01004-85	06/03/85	04/08/86	182.1	17.69	9.72	338
LYPHO-2A	01002-86	04/09/86	09/25/86	625.6	28.44	4.55	154
LYPHODLA	01004-86	04/09/86	09/25/86	299.4	13.45	4.49	154

Figure 33. Monthly Mean Quality Control Values: Testosterone

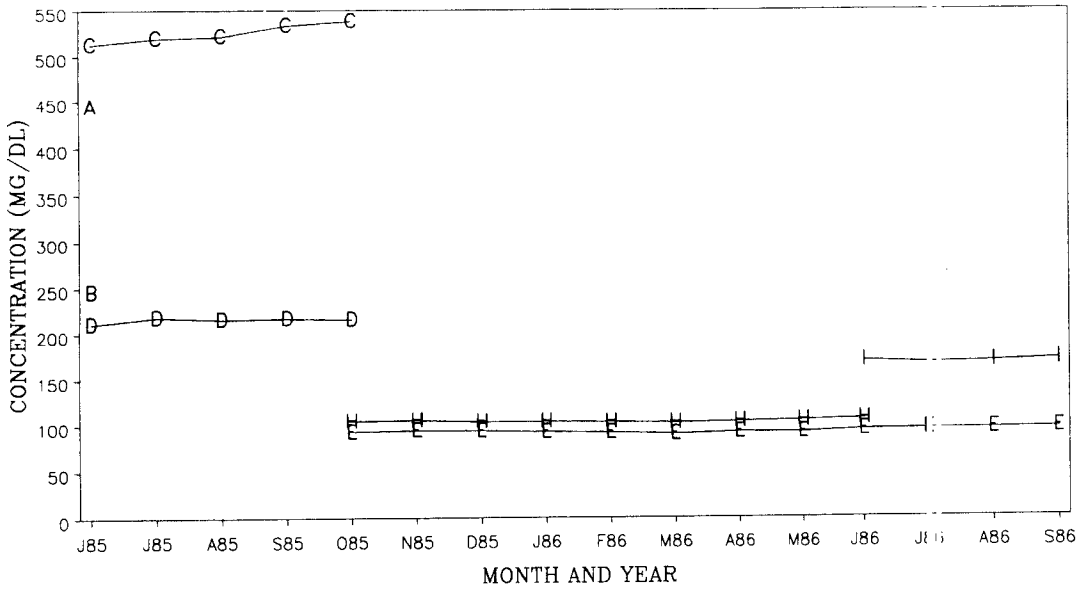


LEGEND: LYPHO--2=A LYPHODIL=B LYPHO-2A=C LYPHODLA=D

Table 54. Summary of Quality Control Data: Immunoglobulin A

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
ELEV	POOL-85	06/03/85	06/17/85	444.6	36.25	8.15	18
NORM	POOL-85	06/03/85	06/17/85	245.7	15.80	6.43	18
H-NORPAR	21855B	06/18/85	10/09/85	524.6	20.34	3.88	120
N-NORPAR	55A220	06/18/85	10/09/85	215.8	7.47	3.46	120
HIGHPOOL	POOL-85	10/10/85	09/25/86	93.1	3.25	3.49	344
NORMPOOL	POOL-85	10/10/85	06/19/86	103.9	3.54	3.41	260
NORPOOLB	POOL-86	06/23/86	09/25/86	168.9	4.05	2.40	84

Figure 34. Monthly Mean Quality Control Values: Immunoglobulin A (IgA)

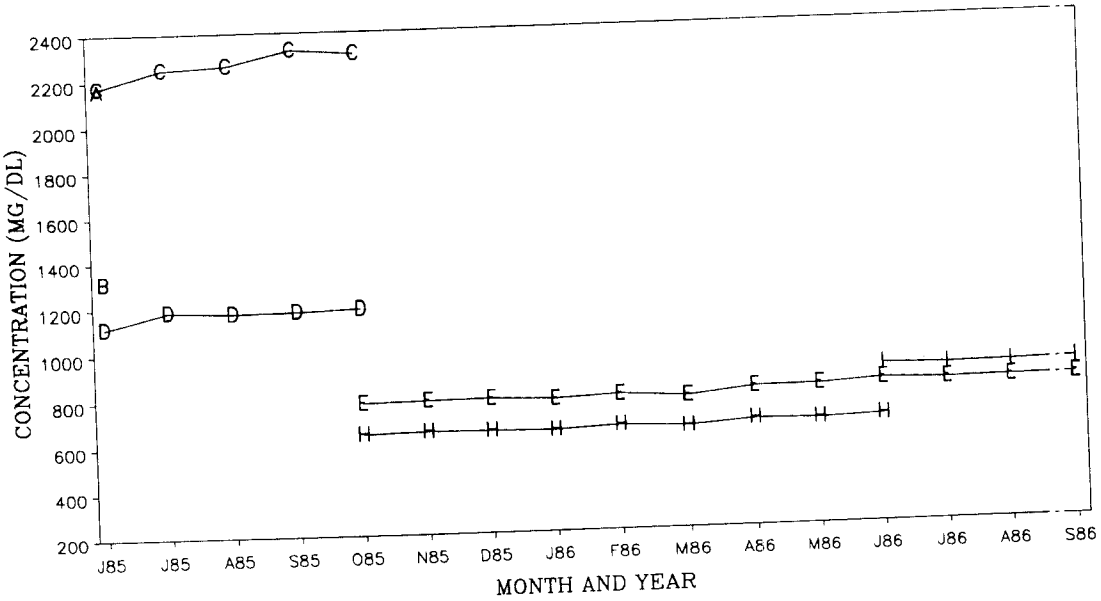


LEGEND: ELEV=A NORM=B H-NORPAR=C N-NORPAR=D
HIGHPOOL=E NORMPOOL=H NORPOOLB=I

Table 55. Summary of Quality Control Data: Immunoglobulin G

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
ELEV	POOL-85	06/03/85	06/17/85	2159.8	93.50	4.33	18
NORM	POOL-85	06/03/85	06/17/85	1310.7	107.97	8.24	18
H-NORPAR	21855B	06/18/85	10/09/85	2269.8	120.70	5.32	120
N-NORPAR	55A220	06/18/85	10/09/85	1171.3	50.47	4.31	120
HIGHPOOL	POOL-85	10/10/85	09/25/86	795.7	29.98	3.77	344
NORMPOOL	POOL-85	10/10/85	06/19/86	651.3	26.13	4.01	260
NORPOOLB	POOL-86	06/23/86	09/25/86	879.7	25.32	2.88	84

Figure 35. Monthly Mean Quality Control Values: Immunoglobulin G (IgG)

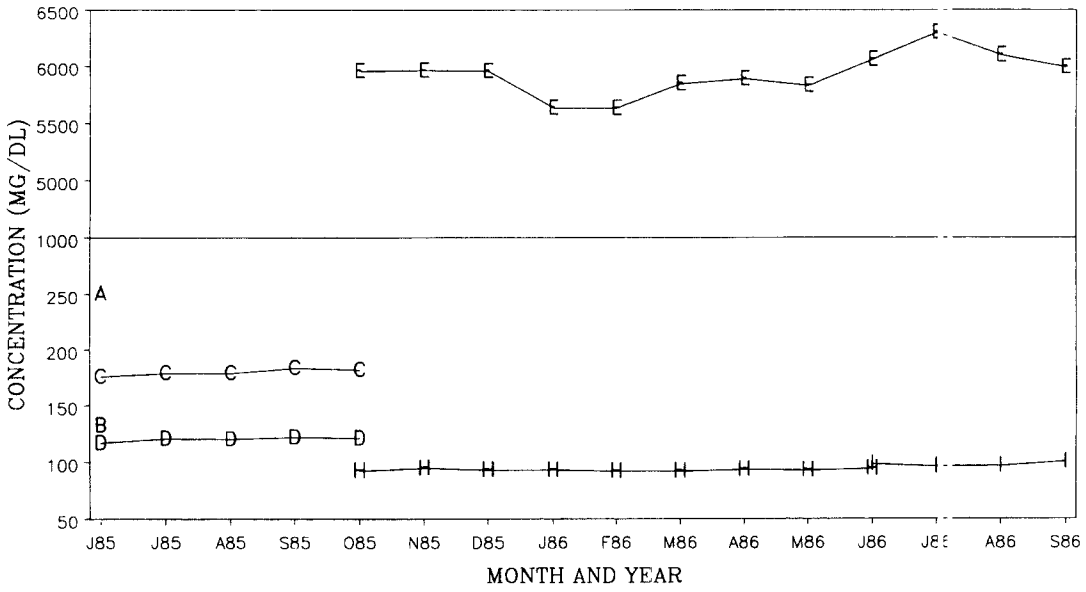


LEGEND: ELEV=A NORM=B H-NORPAR=C N-NORPAR=D
HIGHPOOL=E NORMPOOL=H NORPOOLB=I

Table 56. Summary of Quality Control Data: Immunoglobulin M

Control Name	Lot No.	Begin Date	End Date	Mean (mg/dl)	Standard Deviation	Coefficient of Variation	No. Observations
ELEV	POOL-85	06/03/85	06/17/85	260.4	34.89	13.40	18
NORM	POOL-85	06/03/85	06/17/85	132.5	11.08	8.37	18
H-NORPAR	21855B	06/18/85	10/09/85	180.3	6.63	3.68	120
N-NORPAR	55A220	06/18/85	10/09/85	120.2	3.94	3.28	120
HIGHPOOL	POOL-85	10/10/85	09/25/86	5915.1	292.79	4.95	346
NORMPOOL	POOL-85	10/10/85	06/19/86	93.1	2.98	3.20	262
NORPOOLB	POOL-86	06/23/86	09/25/86	97.7	3.55	3.63	84

Figure 36. Monthly Mean Quality Control Values: Immunoglobulin M (IgM)



LEGEND: ELEV=A NORM=B H-NORPAR=C N-NORPAR=D
HIGHPOOL=E NORMPOOL=H NORPOOLB=I

Table 57. Summary of Quality Control Data: Semen Analysis

Sperm Measure	Control No.	Control Name	Mean	Standard Deviation	Coefficient of Variation	No. of Observations
Concentration, million cells/ml	1001	LOW-CONTROL	16.7	1.11	6.62	20
	1002	MID-CONTROL	62.1	3.82	6.15	20
	1003	HIGH-CONTROL	134.7	5.59	4.15	18
Motile cells, %	1001	LOW-CONTROL	50.6	4.85	9.59	20
	1002	MID-CONTROL	53.5	5.44	10.17	20
	1003	HIGH-CONTROL	80.3	3.04	3.78	18
Mean linear velocity, μm/sec	1001	LOW-CONTROL	54.2	3.49	6.45	20
	1002	MID-CONTROL	53.2	4.17	7.84	20
	1003	HIGH-CONTROL	30.8	1.44	4.67	18
"Normal" shaped cells, %	2001	NOR-CONTROL	72.7	8.11	11.15	92
Mean cell area, μm^2	2001	NOR-CONTROL	8.4	0.53	6.35	92
Mean cell perimeter, μm	2001	NOR-CONTROL	11.5	0.42	3.62	92
Mean length/width ratio	2001	NOR-CONTROL	1.5	0.04	2.74	92
Mean major axis length, μm	2001	NOR-CONTROL	4.0	0.14	3.54	92