725558

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: March 17, 1971

TO: A. Harrison

FROM: E.P. Cronkite, MD E.P. Cronkite

SUBJECT: CIRC Numbers

The following CIRC #s are inactive. Except for completing old records, they should not be used for identifying patient activity until reactivation is formally approved.

Principal Investigator	CIRC #
Dr. Atkins	21
	29
	31
	43
	50
Dr. Cohn	13
	36 B
	36 D (5/22/70)

The Medical Research Center
Brookhaven National Laboratory
Upton, L. I., New York

EPC/ck
cc: Dr. Atkins
Dr. Cohn
CIRC Committee
Mr. Finn
Dr. Dahl

REPOSITORY Records Holding Area Bldg. 494
COLLECTION Committee - Clinical Investigations and use of Radioisotopes
BOX No. 4
FOLDER CIRC #31

1180239

Upton, New York

CONSENT FOR PROCEDURE, STUDY, OR
DRUG UNDER CLINICAL INVESTIGATION

HISTORY NO:
WARD: OPD
DATE:

I understand that the physicians at the Hospital of the Medical Research Center, Brookhaven National Laboratory, are engaged in research and study of the nature of diseases and of new methods of diagnosis and treatment. I have been informed of the anticipated duration of hospitalization and the nature of the procedure, study, or drug under clinical investigation known as:

Technetium-99m labeled diethylenetriaminepentacetic acid (DTPA)

I understand that the nature of this procedure, study, or drug is experimental, and that at the present time no assurance can be given that my participation will be directly beneficial to me. I have been informed that the timing and sequence of these studies may not be revealed to me. I understand that in the opinions of the investigators responsible for this project, and of the review board (Clinical Investigations Committee), I should be informed of the following possible hazards and inconveniences before agreeing to this clinical investigation:

There is the possibility that the material to be injected has not been prepared in a sterile manner. Much higher doses of DTPA (more than 1000 times the amount I will receive) have been known to produce some kidney damage.

I have been informed of the above. I have also been informed of customary procedures. These may, or may not, be used. I have been offered the opportunity for further discussion of this procedure, study, or drug with the attending physician.

I voluntarily consent to participate in the above studies with an understanding of the known possible effects or hazards that might occur in the course thereof, and with the further understanding that not all effects of such procedure, study, or drug are known.

PATIENT'S NAME: _____

SIGNED BY: _____
(Patient or Legal Guardian)

WITNESS: _____

I, the undersigned, herewith affirm that I have explained the above to Mr. (Mrs.) (Miss) _____ and that I am willing to answer further inquiries.

_____ M.D. DATE: _____

DO NOT WRITE IN BINDING MARGIN

FORM NO
UPTON, N.Y.

1180240

The Committee on Clinical Investigations and Use of Radioisotopes hereby approves the program with the following title:

Evaluation of DTPA labeled with ^{99m}TC for use in scanning

CIRC # 31 has been assigned to this program.

George C. Cotzias.

George C. Cotzias, M.D., Chairman

Lewis M. Schiffer

Lewis M. Schiffer, M.D.

James S. Robertson

James S. Robertson, M.D.

Principal investigator

Harold Atkins, M.D.

Robert A. Love

Robert A. Love, M. D.

Donald C. Borg

Donald C. Borg, M.D.

Knud Knudsen

Knud Knudsen, M.D.

Date: 2/7/68

Place: Medical Research Center
Brookhaven National Laboratory
Upton, New York 11973

Committee on Clinical Investigations and Uses of Radioisotopes

Approval Recommended ✓ Date 9 Feb

Disapproval _____ Date _____

E. P. Cronkite

E. P. Cronkite, M.D.
Chairman, Medical Department

1180241

CIRC # 21

DATE:

E. P. Cronkite, M. D.
Chairman

FORM FOR INITIATION OR REVIEW OF CLINICAL

INVESTIGATIVE PROGRAMS

(Submit original only to Department Chairman)

A. Title of the proposal: Evaluation of DTPA labeled with ^{99m}TC for use in scanning

B. Sponsoring physician(s): J. S. Robertson

C. Responsible investigator(s): H. L. Atkins

D. Brief description of the study, including its general goals and purpose, and pertinent information on past studies: (Attach additional sheets if necessary.)

Tagged chelating agents have been used by others for brain scanning (^{68}Ga, ^{113m}In) because of the extracellular fluid distribution and rapid blood disappearance. The use of pertechnetate has some disadvantages because of selective localization in salivary glands and nasal secretions thus interfering with good visualization. The blood levels are also high at the time of scanning. Technetium-99m labeled DTPA clears from the blood rapidly as evidenced by extremely rapid excretion (90% in two hours). This also results in a lowered patient dose. The rapid transit through the kidneys suggests the possibility of evaluating renal function and anatomy with this agent.

E. Reasons why the investigation(s) are to be performed on human subjects.

To be used as a clinical tool.

F. Type of patient in which the study is to be done (including approximate number of subjects, if known; special restrictions or requirements; method of obtaining consent; etc.):

It is planned to study blood levels and urinary excretion patterns on 5 patients without renal disease by using approximately 0.5 mCi intravenously. Following this, patients who have been scanned with pertechnetate and have positive findings will be rescanned as soon as possible with the DTPA compound (12 mCi). If the comparison is favorable after 5 such cases, we will then use the DTPA exclusively.

1180242

G. 1. Are drugs not in the U. S. Pharmacopoeia (USP) or the NNR being used or contemplated for use? Yes X No ____

2. Is an unusual use of a drug(s) accepted by the USP or NNR contemplated? (An example would be the use of an accepted drug in dosages far exceeding the recommended limits or for purposes distinctly different from the usual indications cited.) Yes ____ No X

3. Are any biological products to be administered that do not bear on their containers or labels notation of approval by the Biological Control Division of the National Institutes of Health? Yes ____ No X

4. Is external or internal radiation other than accepted diagnostic or therapeutic procedures to be administered? Yes X No ____

5. Are any (other) unusual procedures being performed or proposed which in your judgment may entail a special hazard - particularly a hazard above and beyond any imposed by accepted diagnostic and therapeutic measures for that patient? Yes ____ No X

6. Are any radioisotopes to be administered to human beings? Yes X No ____

a. If yes, are the radioisotopes to be used solely within the limits of procedures, specifically described in the USP? Yes ____ No X

Describe the radioisotopic preparation(s): ^{99m}Tc-DTPA.

b. Or are the radioisotopes to be used only in accordance with a project previously approved by the former Radioisotope Committee of this Department? Yes ____ No X

Note the project number: _____

IF ANY OF QUESTIONS 1 THROUGH 5 ARE ANSWERED AFFIRMATIVELY, a detailed analysis of the potential hazards must be appended, including pertinent bibliographic citations and other relevant information.

IF QUESTION 6 IS ANSWERED AFFIRMATIVELY, a completed supplementary form for Radioisotope Administration to human beings must be appended. However, this form need not be filed provided that question 6a or 6b is also answered affirmatively. A separate form must be submitted for each radioisotopic species to be administered.

_____
Sponsoring Physician

SUPPLEMENTARY FORM FOR RADIOISOTOPE

ADMINISTRATION TO HUMAN BEINGS

A. Radioisotope

1. Species: (Radioisotope or labeled compound, eg. $Na^{24}Cl$ or 1-C^{14}-glucose)
   ^{99m}Tc-diethylenetriaminepentacetic acid (DTPA)
2. Physical characteristics: (Physical half-life; decay scheme (or type, energy and relative frequency of major emissions)
   $T_{\frac{1}{2}}$ = 6 hrs. 99% 140 keV gamma (9.5% int. conv.)
3. Source: (BNL reactor, cyclotron, hot lab., commercial supplier, etc.)
   Hot lab.
4. Preparation: (Target material, quantity, special problems)
   See attached writeup.
5. Specific activity and isotopic purity of administered material:
   Carrier-free ^{99m}Tc, 5 mCi/1-3 mg DTPA
6. Radioassay and calibration procedures: (Include validation to be performed at BNL prior to use)
   At Hot lab.
7. Vehicle and route of administration:
   Intravenous administration in saline.
8. Procedures for control of sterility and pyrogenicity: (Or note that commercially supplied isotopes are certified as ready for administration to human beings.) Pyrogen-free, sterile materials used when possible.
   Final product passed through millipore filter.
9. Extraneous effects, if pertinent: (Such as pharmacological or toxic actions of the parent compound or vehicle, etc.)
   See writeup.

B. Radiation Dosage

1. Biological half-life or half-lives, including slow components:
   $T_{\frac{1}{2}}$ biol. = ~ 25 min.
2. Organ, cellular, or subcellular localization: (Should account for the effects of special drugs or agents on altering the natural distribution of the radioisotope)
   a. Critical or "target" organ(s): Bladder 0.243 rad/mCi; Kidney .000011 rad/mCi
   b. Gonadal exposure: Whole body 0.001 rad/mCi; Gonads 0.0023 rad/mCi

1180244

3. Sample calculations: (Dosage should be calculated for the whole body and for "target" or other separate organs, where indicated.) Summary equations are desired; not extensive calculations. Standard dosage equations from references such as Hine and Brownell's Radiation Dosimetry, National Bureau of Standards Handbook 69, and BNL Hospital Form 1167-A should be used where possible and the reference cited.

Whole-body concentration: 12 mCi/70 mg

Γ = 0.696 rad/mCi/hr at 1 c

$D_g = 0.0346 \times \frac{12}{7 \times 10^1} \times 0.019 \times 0.696 \times 125 = .008$ rad

E_B = 0.015 MeV

$D_B = 73.8 \times \frac{12}{7 \times 10^1} \times 0.015 \times 0.019 = \frac{0.004}{0.012}$ rad "

$T_{\frac{1}{2}}$ biol. = 0.5 hr whole bod

$Teff = \frac{6 \times 0.5}{6+0.5} = 0.46$ hr = 0.019 d

G whole body = 125

Gonadal dose - Bladder as a point source containing 90% inj. activity
Teff = 2 hrs at 5 cm dist

$D = 0.696 \times 10.8 \times \frac{2}{24} \times \frac{1}{25} = .0023$ rad/mCi (females). This can be markedly reduced by having patient void immediately before starting scans and again afterward.

C. Radiological Health Aspects:

1. Hazards to other patients and to personnel from external or internal radiation: None

2. Monitoring procedures, if necessary: -

3. Special procedures for handling waste products, excreta, biological samples, etc., where indicated: Urine disposed of in normal manner.

4. Plan for isotope accountability, if required: -

1180245

1c

E. P. Cronkite, M.D.

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

Date

DATE: January 12, 1968

TO: Clinical Investigation Committee

FROM: Dr. H. L. Atkins

SUBJECT:

[illegible] completed the requirements as set forth by the committee in [illegible] June 15, 1967 with regard to Circ. #31. The following [illegible] the specific recommendation of the memo.

[illegible] not a true physiological basis for using the compound for [illegible] scanning and brain scanning other than the rapid renal [illegible] reduces circulating radionuclide so that the brain scan [illegible] not obscured.

[illegible] 12 mCi of pertechnetate for brain scanning now. The [illegible] like amount of activity of the DTPA compound should be [illegible], since the radiation dose to the patient will be less [illegible] rapid excretion and lack of specific localization.

[illegible] form.

[illegible] FDA write-up, encl. 1.

[illegible] FDA write-up.

[illegible] been recalculated and are estimated as follows:

[illegible] 0.001 rad/mCi

[illegible] 000011 rad/mCi (assuming 3% adm. dose in each kidney)

[illegible] 243 rad/mCi (assuming voiding at 1 hour)

[illegible] 0023 rad/mCi

[illegible] FDA write-up.

[illegible] study as outlined in FDA-1573 and attached reprint of [illegible] DTPA.

1180246

BROOKHAVEN NATIONAL LABORATORY

HOSPITAL OF THE MEDICAL RESEARCH CENTER

Upton, New York

CONSENT FOR PROCEDURE, STUDY, OR DRUG UNDER CLINICAL INVESTIGATION

HISTORY NO:
WARD: OPD
DATE:

I understand that the physicians at the Hospital of the Medical Research Center, Brookhaven National Laboratory, are engaged in research and study of the nature of diseases and of new methods of diagnosis and treatment. I have been informed of the anticipated duration of hospitalization and the nature of the procedure, study, or drug under clinical investigation known as:

Technetium-99m labeled diethylenetriaminepentacetic acid (DTPA)

I understand that the nature of this procedure, study, or drug is experimental, and that at the present time no assurance can be given that my participation will be directly beneficial to me. I have been informed that the timing and sequence of these studies may not be revealed to me. I understand that in the opinions of the investigators responsible for this project, and of the review board (Clinical Investigations Committee), I should be informed of the following possible hazards and inconveniences before agreeing to this clinical investigation:

There is the possibility that the material to be injected has not been prepared in a sterile manner. Much higher doses of DTPA (more than 1000 times the amount I will receive) have been known to produce some kidney damage.

I have been informed of the above. I have also been informed of customary procedures. These may, or may not, be used. I have been offered the opportunity for further discussion of this procedure, study, or drug with the attending physician.

I voluntarily consent to participate in the above studies with an understanding of the known possible effects or hazards that might occur in the course thereof, and with the further understanding that not all effects of such procedure, study, or drug are known.

PATIENT'S NAME: _____

SIGNED BY: _____
(Patient or Legal Guardian)

WITNESS: _____

I, the undersigned, herewith affirm that I have explained the above to Mr. (Mrs.) (Miss) _____ and that I am willing to answer further inquiries.

_____ M.D. DATE: _____

1180247

DO NOT WRITE IN BINDING MARGIN

FORM NO.
UPTON, N.Y.

CIRC #31

Letter for your information

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: June 15, 1967

TO: Members, Clinical Investigation and Uses of Radioisotopes Committee

FROM: See below

SUBJECT: CIRC #31 (copy attached)

The Clinical Investigation Committee met on June 14, 1967 and considered Circ. #31. The committee was impressed most favorably by the scope, the high probability of success, and the importance of the proposed investigation. Therefore the committee suggests that the proposal under consideration deserves the labor necessary to improve it. Specifically it recommends the following improvements:

1) That the common physiological basis for studying both renal function and brain scanning be spelled out.

2) That the use of 12 mCi of Technetium 99m with DTPA be explained.

3) That the consent form be filled out as an example of what the patients will be told.

4) That evidence for the existence of DTPA-technetium complexes be included.

5) That references of the status of DTPA, vis-a-vis the FDA be presented.

6) That kidney and bladder doses be computed.

7) That animal data be described with reference to a) excretion of technetium, b) toxic manifestations.

8) That, perhaps, one tenth of the proposed doses should be used on patients initially to determine whether or not the mouse data constitute a precedent for man.

9) That the new write-up form the basis for obtaining an IND Number from the FDA.

George C. Cotzias

G.C. Cotzias, M.D., Chairman

Herbert Savel, M.D.

Herbert Savel, M.D.

Lewis M. Schiffer

L.M. Schiffer, M.D.

Knud Knudsen

Knud Knudsen, M.D.

1180248

The Committee on Clinical Investigations and Use of Radioisotopes hereby approves the program with the following title:

CIRC # 31 has been assigned to this program.

George C. Cotzias, M.D., Chairman

Lewis M. Schiffer, M.D.

Herbert Savel, M.D.

Knud Knudsen, M.D.

Date: _____

Place: Medical Research Center
Brookhaven National Laboratory
Upton, New York 11973

Approval recommended _____ Date _____

Disapproval _____ Date _____

V. P. Bond, M.D.
Acting Chairman

1180249

CIRC #31

V. P. Bond, M. D., Acting Chairman

FORM FOR INITIATION OR REVIEW OF CLINICAL

INVESTIGATIVE PROGRAMS

(Submit original only to Department Chairman)

A. Title of the proposal: Evaluation of DTPA labeled with ^{99m}Tc for use in scanning

B. Sponsoring physician(s): J.S. Robertson

C. Responsible investigator(s): H.L. Atkins

D. Brief description of the study, including its general goals and purpose, and pertinent information on past studies: (Attach additional sheets if necessary.)

Tagged chelating agents have been used by others for brain scanning (^{68}Ga, ^{113m}In) because of the extracellular fluid distribution and rapid blood disappearance. The use of pertechnetate has some disadvantages because of selective localization in salivary glands and nasal secretions thus interfering with good visualization. The blood levels are also high at the time of scanning. Technetium-99m labeled DTPA clears from the blood rapidly as evidenced by extremely rapid excretion (90% in two hours). This also results in a lowered patient dose. The rapid transit through the kidneys suggests the possibility of evaluating renal function and anatomy with this agent.

E. Reasons why the investigation(s) are to be performed on human subjects.

To be used as a clinical tool.

F. Type of patient in which the study is to be done (including approximate number of subjects, if known; special restrictions or requirements; method of obtaining consent; etc.):

It is planned to study blood levels and urinary excretion patterns on 5 patients without renal disease by using approximately 1 mCi intravenously. Following this, patients who have been scanned with pertechnetate and have positive findings will be rescanned as soon as possible with the DTPA compound (12 mCi). If the comparison is favorable after 5 such cases, we will then use the DTPA exclusively.

1180250

G. 1. Are drugs not in the U. S. Pharmacopoeia (USP) or the NNR being used or contemplated for use? Yes X No ____

2. Is an unusual use of a drug(s) accepted by the USP or NNR contemplated? (An example would be the use of an accepted drug in dosages far exceeding the recommended limits or for purposes distinctly different from the usual indications cited.) Yes ____ No X

3. Are any biological products to be administered that do not bear on their containers or labels notation of approval by the Biological Control Division of the National Institutes of Health? Yes ____ No X

4. Is external or internal radiation other than accepted diagnostic or therapeutic procedures to be administered? Yes X No ____

5. Are any (other) unusual procedures being performed or proposed which in your judgment may entail a special hazard - particularly a hazard above and beyond any imposed by accepted diagnostic and therapeutic measures for that patient? Yes ____ No X

6. Are any radioisotopes to be administered to human beings? Yes X No ____

a. If yes, are the radioisotopes to be used solely within the limits of procedures, specifically described in the USP? Yes ____ No X

Describe the radioisotopic preparation(s): ^{99m}Tc-DTPA.

b. Or are the radioisotopes to be used only in accordance with a project previously approved by the former Radioisotope Committee of this Department? Yes ____ No X

Note the project number: _____

IF ANY OF QUESTIONS 1 THROUGH 5 ARE ANSWERED AFFIRMATIVELY, a detailed analysis of the potential hazards must be appended, including pertinent bibliographic citations and other relevant information.

IF QUESTION 6 IS ANSWERED AFFIRMATIVELY, a completed supplementary form for Radioisotope Administration to Human Beings must be appended. However, this form need not be filed provided that question 6a or 6b is also answered affirmatively. A separate form must be submitted for each radioisotopic species to be administered.

J. Roberts
Sponsoring Physician

Committee on Clinical Investigations and
Uses of Radioisotopes

Approval recommended _____ Date _____

Disapproval _____ Date _____

_____
V. P. Bond, M. D.
Chairman, Medical Department

1180251

6/25/63
mlk

SUPPLEMENTARY FORM FOR RADIOISOTOPE

ADMINISTRATION TO HUMAN BEINGS

A. Radioisotope

1. Species: (Radioisotope or labeled compound, eg. $Na^{24}Cl$ or 1-C^{14}- glucose)

   ^{99m}Tc-DTPA (Diethylene-triaminepentacetic acid)

2. Physical characteristics: (Physical half-life; decay scheme (or type, energy and relative frequency of major emissions)

   $^{99m}Tc \xrightarrow[T\ 1/2]{6\ hrs} {}^{99}Tc \xrightarrow[T\ 1/2]{2.1x10^5\ yrs} {}^{99}Ru$ (stable)

   γ = 140 kev, 2 kev, 142 kev; β none; 10% Int. convers.

3. Source: (BNL reactor, cyclotron, hot lab.), commercial supplier, etc.)

   Hot lab.

4. Preparation: (Target material, quantity, special problems)

   See enclosed protocol.

5. Specific activity and isotopic purity of administered material:

   Carrier-free $6.7x10^7$ curies/gram

6. Radioassay and calibration procedures: (Include validation to be performed at BNL prior to use)

   At Hot lab.

7. Vehicle and route of administration:

   I.V.

8. Procedures for control of sterility and pyrogenicity: (Or note that commercially supplied isotopes are certified as ready for administration to human beings.) Sterile solutions used throughout, millipore filtration at end of preparation. Four samples have been sent for pyrogen testing and have been found pyrogen-free.

9. Extraneous effects, if pertinent: (Such as pharmacological or toxic actions of the parent compound or vehicle, etc.) Only 1-3 mg DTPA will be injected. This is 1/300-1/1000 of therapeutic dose.

B. Radiation Dosage

1. Biological half-life or half-lives, including slow components:
   Biological half-life is less than 1 hour. In mice 90% was excreted 2 hours after intravenous injection.

2. Organ, cellular, or subcellular localization: (Should account for the effects of special drugs or agents on altering the natural distribution of the radioisotope)

   a. Critical or "target" organ(s): Whole body distribution in extracellular fluid with momentary concentration in kidney during excretion. In mice about 4% was peak concentration in kidney at 1/2 hour with a biological T 1/2 of about 1/2 hour.

   b. Gonadal exposure:

   Gonadal exposure can occur from retained urine in bladder.

1180252

3. Sample calculations: (Dosage should be calculated for the whole body and for "target" or other separate organs, where indicated) Summary equations are desired; not extensive calculations. Standard dosage equations from references such as Hine and Brownell's Radiation Dosimetry, National Bureau of Standards Handbook 69, and BNL Hospital Form 1167-A should be used where possible and the reference cited.

Concentration: 12 mCi/70 kg

Γ = 0.696 rad/mCi/hr at 1 c

$D_g = 0.0346 \times \frac{12}{7\times10^4} \times 0.019\times0.696\times125 = 0.02$ mRad

E_B = 0.015 MeV

$T_{1/2}$ biol. = 0.5 hr whole bo

$D_B = 73.8\times\frac{12}{6\times10^4} \times 0.015\times0.019 =$ 0.004 "

0.024 "

$Teff = \frac{6\times0.5}{6+0.5} = 0.46$ hr = 0.019 c

G whole body =125

Gonadal dose - Bladder as a point source containing 90% inj. activity Teff = 2 hrs at 5 mCi/ist.

$D = 0.696 \times 10.8 \times \frac{2}{24} \times \frac{1}{25} =$ 0.025 Rad (females). This can be markedly reduced by having patient void immediatel before starting scans and again afterward.

C. Radiological Health Aspects

1. Hazards to other patients and to personnel from external or internal radiation: None

2. Monitoring procedures, if necessary: -

3. Special procedures for handling waste products, excreta, biological samples, etc., where indicated: Urine disposed of in normal manner.

4. Plan for isotope accountability, if required: -

ak

1180253

June 25, 1963

Preparation of Tc^{99m} Labeled DTPA

A method has been developed for the preparation of a Tc^{99m} complex with the trisodium salt of calcium diethylenetriaminepentaacetic acid (DTPA). This material may be useful in renal function studies and renal scanning. It may also be a useful agent in brain scanning particularly for the localization of low-lying tumors that are frequently obscured in pertechnetate scans due to high backgrounds, due to the more rapid clearance of the DTPA.

Method of Preparation:

1. Milk Tc^{99m} generator with sterile saline solution.
2. Add 10 mg of $FeSO_4 \cdot 7H_2O$ (~2 mg Fe^{++}) to 4 ml of Tc^{99m} solution in a sterilized 50 cc centrifuge tube containing magnetic stirring bar.
3. Stir 5 minutes and add 1 ml of concentrated HCl.
4. Add 10 mg of sterile pyrogen free Ca DTPA (Geigy), and stir for 5 minutes.
5. Adjust the pH to 3.0 $\pm$ 0.1 with NaOH and stir for ~1 minute.
6. Adjust the pH to 5.5 - 6.5 with NaOH.

1180254

Approximately 85-90% of the Tc^{99m} is complexed with the Ca DTPA. The uncomplexed Tc^{99m} as pertechnetate may be removed from the solution by passing through a small (~1.5 - 2.0 cc) Dowex 1 x 8 column that has been well washed with sterile saline solution.

7. Prior to administration the product solution is passed through a sterile 0.22 micron filter into a sterile multi-injection type bottle.

~ 1.5 mg Ca DTPA / ml

4-5-67
PR:gfs

1180255

LEBERCO LABORATORIES

123 HAWTHORNE STREET – ROSELLE PARK, N. J. 07204

DIAL 201 245 1933

1180256

BIOLOGICAL ASSAY
FOR
PYROGENIC SUBSTANCES

DATE: APRIL 11, 1967

SUBMITTED TO: BROOKHAVEN NATIONAL LABORATORY
ASSOCIATED UNIVERSITIES, INC.
UPTON, L.I. NEW YORK

ASSAY NUMBER: 76963

DATE RECEIVED: APRIL 10, 1967

TEST MATERIAL: 4 VIALS CONTAINING YELLOW LIQUID
MARKED 1, 2, 3, 4

METHOD OF ASSAY: U. S. P. XVI (MODIFIED 0.5 ML./KG.)

RESULTS:

Animal Number	Control Temperature	Weight of animal in kilograms	Amount injected in cc	Temperature after injection: One hour	Two hours	Three hours	Change in Temperature
207	39.8	3.3	1.7	40.3	40.3	40.3	0.5
337	39.8	3.0	1.5	40.2	39.8	40.2	0.4
357	39.7	3.6	1.8	40.0	40.0	40.0	0.3

NUCLEAR MEDICINE STATISTICS 1969

	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC	TOTAL	IND #	CIRC
Brain ^{99m}Tc-DTPA	7	6	8	9	1	3	10	5	14	10	18	11	102	4344	31
Brain ^{99m}TcO4	3	2	7	4	5	6	1	7	2		3	3	43	4316	15
Thyroid ^{99m}TcO4	8	5	6	6	10	7	6	16	18	6	12	12	112	"	"
Kidney ^{99m}Tc-DTPA	4	3	3	3	3	4	6	2		1		7	36	4344	31
Kidneys ^{99m}Tc-Fe-Asc.			4	5	3	4				1		2	19	5375	24
Liver & Spleen ^{99m}Tc-S	3	4	4	5	5	3	4	1	1	6	3	1	40	4172	15
Lymph Nodes	3		2		1	1	1	1	1	1	1	1	13	"	"
Liver, Spleen & Marrow ^{99m}TcS	2	2	3	2	4	6	6	5		3	1	4	38	"	
Blood Pool ^{99m}Tc-HSA							1			1			2	DES-IND 29926	27
Bones ^{18}F					3		1				1		5	5623	42
TOTAL	30	22	37	34	35	34	36	37	36	29	39	41	410		

1180257