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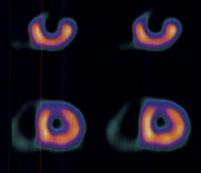
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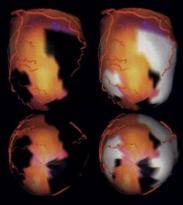
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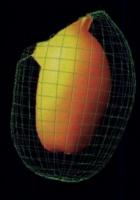




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- Transient adverse effects including dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness were observed in less than 1% of 538 patients during clinical trials.
- Please see the prescribing information for special considerations regarding patients receiving total parenteral nutrition or concurrent octreotide acetate therapy and patients with insulinoma or impaired renal function.

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OCTREO**S**CAN[®]

Kit for the Preparation of Indium In-111 Pentetreotide

Please see adjacent page for brief summary of prescribing information.



Kit for the Preparation of Indium In-III Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION

OctreoScan^e is a kit for the preparation of indium In-111 pentetreotide, a diagnostic rar pharmaceutical. It is a kit consisting of two

- 1) A 10-mL OctreoScan Reaction Vial which contains a hyophilized mixture of 10 µg pentetreotide.
- 2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

Indium In-111 pentetreotide is prepared by combining the two kit components.



INDICATIONS AND USAGE

Indium In-111 pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somalostatin receptors.

CONTRAINDICATIONS

None known

WARNINGS

DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADMIXTURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES; IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OCTREOTIDE

The sensitivity of scintigraphy with indium In-111 pentetreotide may be reduced in patients concurrently receiving therapeutic doses of octreotide acetate. Consideration should be given to temporarily suspending octreotide acetate therapy before the administration of indium In-111 pentetreotide and to monitoring the patient for any signs of withdrawal.

PRECAUTIONS

General

- Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium In-111 pentetreotide.
- The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetreotide and are NOT to be administered separately to the patient.
- Since indium In-111 pentetreotide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.
- 4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetreotide. They should increase fluid intake and void frequently for one day after administration of this drug. In addition, it is recommended that patients be given a mil laxative (e.g., blascody) or lactulose) before and after administration of indium In-111 pentetreotide (see Dosage and Administration section).
- Indium In-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within six hours of preparation.
- 6. Components of the lott are sterile and nonpyrogenic. To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetreotide.
- 7. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetreotide is not expected to cause cholelithiasis.
- As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.
- 9. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been performed with indium In-111 pentetreotide to evaluate carcinogenic potential or effects on fertility. Pentetreotide was evaluated for mutagenic potential in an in vitro mouse lymphoma forward mutation assay and an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

Pregnancy Category C

Animal reproduction studies have not been conducted with indium in-111 pentetreotide. It is not known whether indium in-111 pentetreotide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium in-111 pentetreotide should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium In-111 pentetreotide is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematicorit and hemoglobin.

Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is subtherapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, tabelled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacodyl or lactulose) be given to the patient starting the evening before the radioactive drug is administered, and continuing

for 48 hours. Ample fluid uptake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insulinoma, bowel-cleansing should be undertaken only after consultation with an endocrinologist.

The recommended intravenous dose for <u>planar</u> imaging is 111 MBq (3.0 mCi) of indium In-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for <u>SPECT</u> imaging is 222 MBq (6.0 mCi) of indium In-111 pentetreotide.

The dose should be confirmed by a suitably calibrated radioactivity ionization chamber immediately before

As with all intravenously administered products, OctreoScan should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with applicable regulations.

Aseptic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves should be worn during the administration procedure.

Do not administer OctreoScan in TPN solutions or through the same intravenous line.

Radiation Dosimetry

The estimated radiation doses' to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.'

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide³ to a 70 kg patient

	PLANAR		SPECT	
Kidneys	54.16	5.42	108.32	10.83
Liver	12.15	1.22	24.31	2.43
Spleen	73.86	7.39	147.73	14.77
Uterus	6.34	0.63	12.67	1.27
Ovaries	4.89	0.49	9.79	0.98
Testes	2.90	0.29	5.80	0.58
Red Marrow	3.46	0.35	6.91	0.69
Urinary Bladder Wall	30.42	3.04	60.48	6.05
Gi Tract				
Stomach Wall	5.67	0.57	11.34	1.13
Small Intestine	4.78	0.48	9.56	0.96
Upper Large Intestine	5.80	0.58	11.59	1.16
Lower Large Intestine	7.73	0.77	15.46	1.55
Adrenals	7.55	0.76	15.11	1.51
Thyroid	7.43	0.74	14.86	1.49
Effective Dose ⁴ Equivalent	13.03	1.30	26.06	2.61

- 1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration
- Le.P. Krening, W.H. Bakker, P.P.M. Kooij, W.A.P. Breeman, H.Y.Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reijs, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Rece Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," The Journal of Nuclear Medicine, Vol. 33, No. 5, May 1992, pp. 652-658.
- Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.
- 4. Estimated according to ICRP Publication 53.

HOW SUPPLIED

The OctreoScan kit, NDC 0019-9050-40, is supplied with the following components:

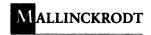
- A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
 10 Jup pentetreotide [N-(diethylenetriamine-N,N,N',N'-tetracetic acid-N'-acetyl)-D-phenylalanyl-L-hemicystyl-L-phenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicys threoninol cyclic (2-*7) disuifide], (also known as octreotide DTPA),
 2.0 mg gentisic acid [2,5-dihydroxybenzoic acid],
 4.9 mg trisodium citrate, anhydrous,
 9.37 mg ctric acid, anhydrous, and
 1.10 mg incritiel

 - (v) 10.0 mg inositol.

Before lyophilization, sodium hydroxide or hydrochloric acid may have been added for pH adjustment. The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

2. A 10-mL vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative

In addition, the kit also contains the following items: (1) a 25 G x 5/8" needle (B-D, Monoject) used to transfer Indium In-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a



Mallinckrodt Inc. Mallinckrodt Nuclear Medicine Division P.O. Box 5840 St. Louis, MO 63134

Termanini B, Gibril F, Reynolds JC, et al. Value of Somatostatin Receptor Scintigraphy: A Prospective Study in Gastrinoma of its Effect on Clinical Management. Gastroenterology 1997;112:335-337.

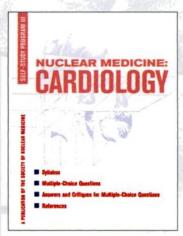
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Topic 2: Pharmacologic Stress (June 1998) Contributors: Mario S. Verani, MD, Jeffrey Leppo, MD, Elias H. Botvinick, MD, Michael W.

Dae, MD and Susan Alexander, MD

ISBN 0-932004-60-1

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Topic 3: Cardiac PET Imaging (September 1998)

Contributors: Richard A. Goldstein, MD, Randall A. Hawkins, MD, PhD, Edward M. Geltman, MD, Carl Hoh,

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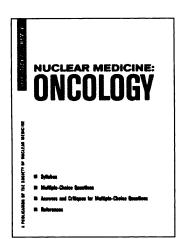
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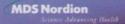
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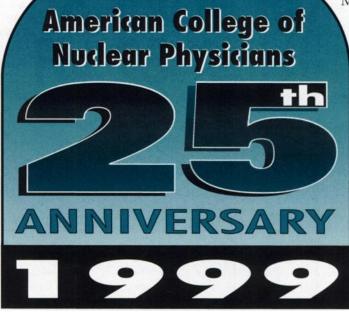
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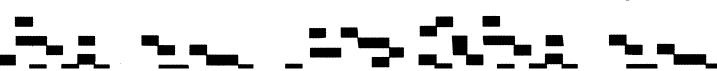
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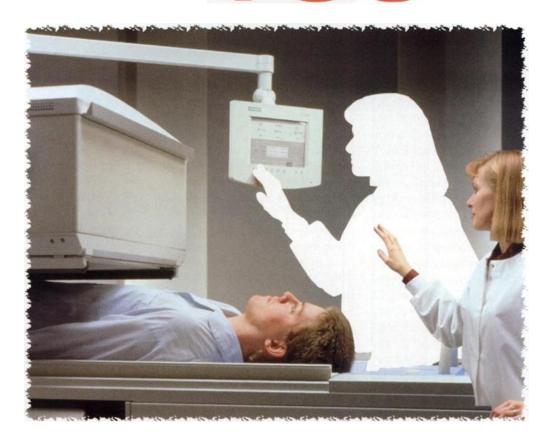
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Participants will be able to compare their facility data with others in the region and with the national (global) averages.

Subscribers may query reports on-line or receive printed reports quarterly via mail. This is a free service. As long as you input your data quarterly, you will be able to obtain data and reports.

All information is confidential.

For more information or to participate in this program, contact UA
Project Coordinator at
(703) 708-9000 x255 or
e-mail: wsmith@snm.org.



ANNOUNCING

The American
Board of
Science In
Nuclear
Medicine
1999
Certification
Examination

The 1999 examination will be given Sunday, June 6,1999 in Los Angeles, CA in conjunction with the 46th Annual Meeting of the Society of Nuclear Medicine.

The examination is written and consists of two parts —

Part One (3.5 hours) assesses knowledge of basic aspects of Nuclear Medicine Science.

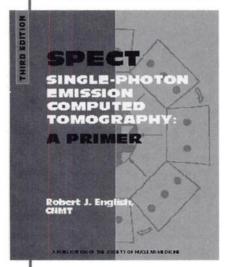
Part Two (2.5 hours) examines in depth the knowledge of a predetermined subspecialty area of the candidate's choice including:

- · Nuclear Medicine Physics and Instrumentation
- Nuclear Pharmaceutical Science and Radiochemistry
- Radiation Protection

Completed Applications must be postmarked by March 12, 1999. The examination fee is \$650 (\$550 refundable if you do not qualify).

For applications and more information, please contact: ABSNM Exam Coordinator
American Board of Science in Nuclear Medicine
c/o The Society of Nuclear Medicine
1850 Samuel Morse Drive, Reston, Virginia 20190-5316
Tel: (703) 708-9000, ext. 227 • Fax: (703) 708-9013

It's Here!



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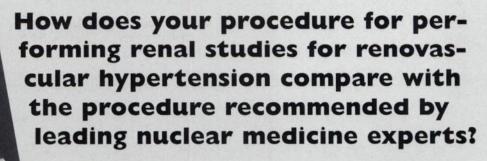
Substantially updated and expanded throughout, the third edition includes even more basic information essential to the technologist working in day-to-day clinical settings.

The new *SPECT Primer* features an enhanced section on Clinical Applications, incorporating the latest and most widely accepted fundamental knowledge in the field, with, three all-new chapters on Acquisition Devices, Processing Devices, and Clinical Indications. And in every chapter, you'll find expanded material to help nuclear medicine professionals who use SPECT perform at peak.

Whether you're a working technologist, teacher, or student, the new edition of *SPECT: A Primer* is a must for your clinical library. No other text available brings together—clearly and authoritatively—the essential information you need to understand and use Single Photon Emission Computerized Tomography.

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Do you know the most effective and efficient way to perform a myocardial perfusion study?



How should you modify your procedures for adult patients when they are performed in pediatric patients?

The answers to these questions and more may be found in the 1997 Society of Nuclear Medicine Procedure Guidelines Manual. This publication will help

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CARDIAC GUIDELINES

Nuclear Medicine

Manual

Procedure Guidelines

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ENDOCRINE GUIDELINES

Guideline for Thyroid Uptake Measurement Guideline for Thyroid Scintigraphy Guideline for Extended Scintigraphy for Differentiated Thyroid Cancer Guideline for Parathyroid Scintigraphy

GASTROINTESTINAL GUIDELINES

Guideline for Hepatobiliary Scintigraphy Guideline for Hepatic and Splenic Imaging Guideline for C-14 Urea Breath Test

GENERAL GUIDELINES

Guidelines for Guideline Development Guideline for General Imaging Guideline for Imaging With Radiopharmaceuticals

GENITOURINARY GUIDELINES

Guideline for Diagnosis of Renovascular Hypertension

INFECTION GUIDELINES

Guideline for Gallium Scintigraphy in Inflammation Guideline for In-III Leukocyte Scintigraphy for Suspected Infection/Inflammation

Guideline for Tc-99m Exametazime (HMPAO) Labeled Leukocyte Scintigraphy for Suspected Infection/Inflammation

NEUROLOGY GUIDELINES

Guideline for Brain Perfusion Single Photon Emission Computed Tomography (SPECT) Using Tc-99m Radiopharmaceuticals

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Guideline for Tumor Imaging Using F-18 FDG Guideline for Bone Pain Treatment

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PULMONARY GUIDELINES

Guideline for Lung Scintigraphy

SKELETAL GUIDELINES

Guideline for Bone Scintigraphy

A Publication of the Society of Nuclear Medicine

DIAGNOSTIC PATTERNS IN NUCLEAR MEDICINE

Authors: Edward B. Silberstein, MD

John G. McAfee, MD Andrew P. Spasoff

This reference book provides a complete list of differential diagnoses for virtually every pattern described in modern nuclear medicine scintigraphy, including the latest findings in nuclear cardiology, PET, antibody and somatostatin receptor imaging. A full list of all diagnostic patterns reported for every organ system is given. Pharmacologic effects on labeling and distribution are fully described.

Diagnostic Patterns in Nuclear Medicine assists in image interpretation by providing complete diagnoses for every scintigraphic pattern. All entries are documented by published references. Organization by organ system provides an easy-to-find, detailed differential diagnosis.

The clinician simply looks up any scintigraphic finding to determine possible causes of that finding, ranked in order of probability, making *Diagnostic Patterns in Nuclear Medicine* the most complete referenced diagnostic guide available.

ISBN: 0-932004-69-5

Price: \$45 (members); \$63 (nonmembers).

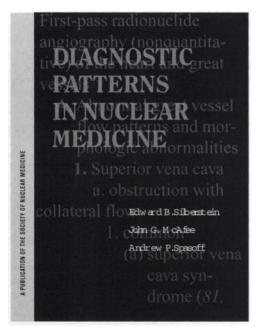


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Part IX: Peri-Diaphragmatic Disease

Part X: Pulmonary System
Part XI: Skeletal System

Part XII: Tumor/Inflammation Imaging (Non-

Gallium, Non-Leukocyte)

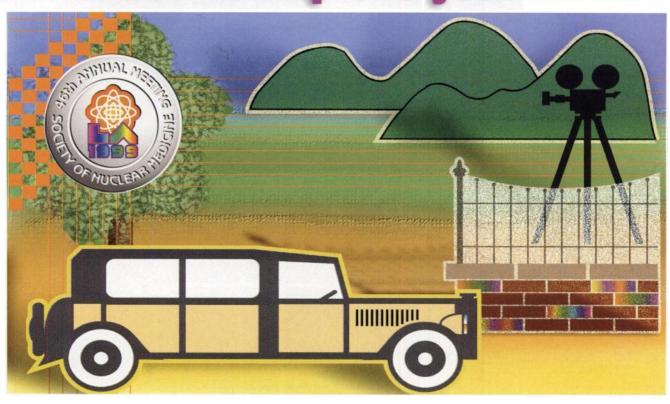
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The Technologist Section

educational program will follow the theme of disease management.

Continuing education sessions and categorical seminars offer attendees approximately 33 credit hours of AMA Category 1 CME for physicians, ACPE for continuing pharmaceutical education for pharmacists, and CEH through the VOICE program for technologists (for courses offered Saturday, June 5 through Thursday, June 10, 1999).

Join us!

June 6-10, 1999

Join 7,000 attendees from around the world at the Society of Nuclear Medicine's 46th Annual Meeting

For further information contact the Department: Meeting Services, 703-708-9000 ext. 229, fax on demand at 888-398-7662 or visit us at our website www.snm.org

Educate Your Patients

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As a clinician, you know nuclear medicine procedures are safe and effective. But you also know that patients are sometimes uneasy about them. Give your patients peace of mind by providing them with concise and thorough information. Whatever your most commonly ordered procedure, you'll find an SNM Patient Pamphlet that will address your patient education needs.



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Faculty Position-Northeast Florida

The University of Florida Health Science Center/Jack-sonville seeks MD, BC/BE in Diagnostic Radiology, with Special Competency or BC/BE in Nuclear Medicine. Fringe benefits are excellent, salary is negotiable. This is a full-time faculty position in the Department of Radiology, with academic rank based on training, background and experience. Send CV and references to Chairman, Search Committee, Radiology Department, 655 W. 8th St., Jacksonville, FL 32209. Fax: (904) 549-3382. EOE/AAE.

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Nuclear Medicine Service Department of Veterans Affairs Medical Center Dallas, TX 75216

Applications are being sought for a full-time Nuclear Medicine Staff Physician, Veterans Affairs Medical Center, Dallas, TX. The position includes an academic appointment in the Department of Radiology, University of Texas Southwest Medical School.

Applications must be board eligible or board certified in Nuclear Medicine. Cardiac, Therapeutic and SPECT experience as well as strong research capabilities required.

Responsibilities include teaching Radiology and Nuclear Medicine residents. A CV and 3 letters of reference should be sent to: Ana Mello, MD, Chief, Nuclear Medicine Service, Veterans Affairs Medical Center, 4500 Lancaster Rd., Dallas, TX 75216.

NO TELEPHONE CALLS ACCEPTED.

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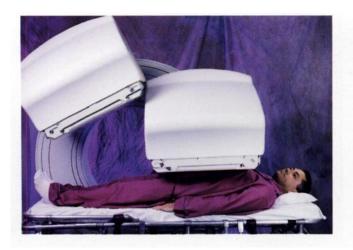
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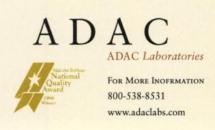
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