MPI DMSA Kidney Reagent (Technetium Tc 99m Succimer Kit)

- Localizes in the renal cortex
- Highest target to background ratio of Tc 99m agents
- Low excretion rate
- DMSA is the renal cortical imaging agent of choice. Even in patients with obstructed or dilated collecting systems, an accurate comparison of relative cortical uptake without interfering activity in the pelvocalyceal structures can be made.

For complete prescribing information consult package insert, a summary of which follows:

DESCRIPTION: Each reagent ampul of the kit contains 2-3 ml of a sterile, pyrogen-free aqueous solution containing 1.2 mg of succimer and 0.42 mg of anhydrous stannous chloride in aqueous solution under a nitrogen gas atmosphere. When sterile, sodium chloride-free, pyrogen-free sodium pertechnetate Tc 99m in isotonic saline is combined with the reagent, following the instructions provided with the kit, a complex is formed. Administration is by intravenous injection for diagnostic use.

The succimer component of MPI Kidney Reagent consists of more than 90% meso succimer and less than 10% L isomer.

INDICATIONS AND USAGE: MPI DMSA Kidney Reagent is to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders.

CONTRAINDICATIONS: None known.

WARNINGS: None.

PRECAUTIONS:
As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Succimer afflicts fertility in males or females.

PREGNANCY CATEGORY C: Animal reproduction studies have not been conducted with the MPI DMSA Kidney Reagent either with or without Tc 99m.

It is also not known whether Technetium Tc 99m alone or with Succimer can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be administered to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those electively in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

NURSING MOTHERS: Technetium Tc 99m is excreted in human milk during lactation, therefore, formula feedings should be substituted for breast feedings.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals and whose experience and training have been approved by the appropriate government agency authorized to license the use of radiopharmaceuticals.

MPI DMSA Kidney Reagent should be formulated within 30 minutes prior to clinical use. The product must be used within 30 minutes after preparation. Any unused portion should be discarded after that time.

Some patients with advanced renal failure may exhibit poor renal intake of Tc 99m DMSA. It has been reported that satisfactory images may be obtained in some of these patients by delaying imaging for up to 24 hours.

ADVERSE REACTIONS: Rare instances of syncope, fever, nausea and maculopapular skin rash have been reported.

HOW SUPPLIED: Each kit package contains the following components:

1. Five sealed glass reagent ampouls, each containing 1.2 ml of a sterile, pyrogen-free aqueous solution of Technetium Tc 99m and 0.42 mg anhydrous stannous chloride. The solution is under a nitrogen gas atmosphere.
2. Five sterile and pyrogen-free mixing vials (10 ml).
3. Five mixing vial labels.
4. Five courtesy record labels.
5. One package insert.
Representative Images

R/O Polycystic Kidney Disease

(a) Cortical infarct

(a) EU reported normal

(b) Polycystic kidney disease

(b) Tc-99m DMSA shows solitary lesion L lower pole

(c) Bilateral hypernephroma

(c) Angiogram confirms single cyst

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DIVISION OF TRAVENOL LABORATORIES, INC.
Thallous Chloride TI 201

For complete prescribing information consult package insert, a brief summary of which follows:

**DESCRIPTION:** Thallous Chloride TI 201 is supplied in isotonic solution as a sterile, nonpyrogenic, diagnostic radiopharmaceutical for intravenous administration. Each unit dose contains 1 milliliter and each milliliter contains 2 milliliters of Thallous Chloride TI 201 at calibration time, pH adjusted to 5.0-6.0 with hydrochloric acid and/or sodium hydroxide. Contains no bacteriostatic preservative. Thallium TI 201 is cytotoxic, produces and is essentially nonpyrogenic. Radiolabeled purity at administration time is at least 98.0%, with less than 1.0% Thallium TI 201 1.0% Thallium 203 and 0.2% Lead Pb 203. The concentration of each radiolabeled contaminant changes with time.

**INDICATION AND USAGE:** Thallous Chloride TI 201 may be used in cardiac imaging to define the extent of myocardial infarction. It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

**CONTRAINDICATIONS:** None known.

**WARNINGS:** When studying patients suspected or known to have myocardial infarction or angina, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

**PRECAUTIONS:**

**General:**
Do not use after the expiration time and date (4 days after calibration time) stated on the label.
Discard vial after single use. Do not use if contents are turbid.
The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.
Ideally, examinations using radiopharmaceuticals, especially those effective in nature on a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Thallous Chloride TI 201 as well as other radioactive drugs must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential or mutagenic potential, or whether Thallous Chloride TI 201 affects fertility in males or females.

Pregnancy Category C
Animal reproduction studies have not been conducted with Thallous Chloride TI 201. It is also not known whether Thallous Chloride TI 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride TI 201 should be given to a pregnant woman only if clearly needed.

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 Thallous Chloride TI 201 is administered to a nursing woman.

**ADVERSE REACTIONS:** Adverse reactions related to use of this agent have not been reported to date.

**HOW SUPPLIED:** Thallous Chloride TI 201 is supplied as a sterile, nonpyrogenic, isotonic solution in unit dose vials containing 1 milliliter. Each milliliter contains 2 milliliters of Thallous Chloride TI 201 at calibration time. Contains no bacteriostatic preservative.

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Please see the following page for a brief summary of prescribing information.
INDICATIONS AND USE
OSTEOSCAN-HDP (Technetium Tc99m Oxidronate) is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis.

CLINICAL PHARMACOLOGY
During the 24 hours following injection, Technetium Tc99m-labeled OSTEOSCAN-HDP is rapidly cleared from blood and other non-osseous tissues and accumulates in the skeleton and urine. In humans, blood levels are about 10% of the injected dose at one hour post-injection and continue to fall to about 6%, 4% and 3% at 2, 3 and 4 hours respectively. When measured at 24 hours following its administration, skeletal retention is approximately 50% of the injected dose. OSTEOSCAN-HDP exhibits its greatest affinity for areas of altered osteogenesis and actively metabolizing bone.

CONTRAINDICATIONS
None known.

WARNINGS
This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to hypocalcemia (i.e., alkalosis).

PRECAUTIONS

General
Contents of the vial are intended only for use in the preparation of Technetium Tc99m Oxidronate and are NOT to be administered directly to the patient. Technetium Tc99m Oxidronate should be formulated within eight (8) hours prior to clinical use. Optimal imaging results are obtained one to four hours after administration.

Technetium Tc99m Oxidronate as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patients consistent with proper patient management. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides. To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next four to six hours.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc99m Oxidronate affects fertility in males and females.

Pregnancy — Category C
Animal reproduction studies have not been conducted with Technetium Tc99m Oxidronate. It is also not known whether Technetium Tc99m Oxidronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc99m Oxidronate should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers
Technetium Tc99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Although adverse reactions have not been reported that are specifically attributable to the use of Technetium Tc99m Oxidronate, allergic dermatological manifestations (erythema) have been infrequently reported with similar agents.

DOSAGE AND ADMINISTRATION
General Instructions
The recommended adult dose of Technetium Tc99m-labeled OSTEOSCAN-HDP is 15 mCi with a range of 10 to 20 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results imaging should be done 1–4 hours post-injection.

HOW SUPPLIED
OSTEOSCAN-HDP is supplied as a lyophilized powder packaged in vials. Each vial contains 3.0 mg oxidronate sodium and 0.24 mg stannous chloride as active ingredients, and 0.84 mg gentisic acid as a stabilizer. Kits containing 5 or 30 vials are available. The NDC number for this product is NDC 37000-407-01. The drug can be stored at room temperature prior to and following reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m.

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July, 1982

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OSTEOSCAN-HDP

Technetium Tc99m Oxidronate Kit

This enlarged and updated edition presents a comprehensive, but carefully screened, bibliography of the current literature available in the field of nuclear medicine science. Arranged in outline form, the book contains references chosen for clarity, depth, and availability. General references provide a broad overview of each topic and additional references deal with subjects in greater depth or provide historical insight.

The new edition addresses exciting new areas in the field such as emission computed tomography and nuclear magnetic resonance. Expanded sections include chapters dealing with clinical imaging and nonimaging procedures.

This book provides a valuable reference source for radiopharmacists, radiochemists, physicists, health physicists, clinicians, electronic engineers, computer engineers, and laboratory specialists working or studying in the field.

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$30.50 plus $2.50 postage and handling for each book ordered. Pre-payment required in U.S. funds drawn on U.S. banks only. No foreign funds accepted. For payments made in U.S. dollars, but drawn on a foreign bank, add a bank processing fee of $1.50 for Canadian bank drafts or $20.00 for all other foreign bank drafts. Check or purchase order must accompany all orders. Make checks payable to: The Society of Nuclear Medicine. Prices are subject to change without notice.

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The RADX Ventil-Con II is the only completely functional self-contained mobile xenon gas ventilation unit available anywhere. Ventil-Con retains over 90% of the xenon gas within its internal dry spirometer system, ready for continued use in examination after examination. A bacteriological filter and a CO$_2$ absorber within the spirometer breathing system constantly filter the xenon enriched atmosphere the patient breathes. The patient experiences only 0.2" of water resistance. No disconnects or aborted exams because of breathing resistance.

The xenon gas exhausted from the patient at washout is trapped by a charcoal cartridge pack. If more than 2 uCi/liter attempts to escape, (well below NRC maximum permissible concentration), a built-in alarm alerts the operator. An interface system within the breathing apparatus completely controls the xenon gas flow into the charcoal cartridge. Result: many more examinations can be safely conducted with Ventil-Con II than with any other system.

Ventil-Con II automatically admits oxygen as CO$_2$ is removed. Spirometer volume is held constant, patient comfort is assured. And Ventil-Con's movable arm allows exceptional flexibility in patient positioning while minimizing "dead air space". Radiation shielding of $\frac{1}{8}$" to $\frac{1}{4}$" thickness of lead provides positive containment of radioactivity. A volume meter and a xenon concentration meter inform the operator that the system is operating normally. Provisions for use in cerebral blood flow studies are optionally available.

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56-602B "Clear-Pb" Mobile Barrier ......................... $875.00

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- Standard or Jumbo sizes.

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- Co-57
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- 97.6%
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- 98%
- 99.5%
- 67%
Panel size is 18" high x 1 1/4" thick (1.5 mm lead equiv.) x 12" wide (Standard) or 24" high x 15" wide (Jumbo). Legs are 12" long.

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—Richard L. Witcoski/SI-26
Provides up-to-date information about the effects of low-level radiation exposure on humans. This program examines the difficulties in detecting biological effects at low-dose levels and compares the risks of low-level radiation exposure to other risks of life.
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—William C. Eckelman and Stanley M. Levenson/SI-27
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Consisting of tables, figures, and data obtained from scientific and government agencies such as the NCRP, ICRP, UNSCEAR, and NAS, this volume examines radiation doses received by people from various sources, data on their somatic and genetic effects, comparative risks, and risk perceptions. Information on the effects observed in plant and animal studies is also included.

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Radiation Dosimetry: A comparison of the estimated absorbed radiation dose to the thyroid of an average patient (70 kg) from an oral dose of 100 uCi of BNPI Sodium Iodide 1123 (p. 5n), Commercial (p. 2n) Sodium Iodide 1123 or Sodium Iodide 1131 at Time of Calibration (TOC) is shown below: 1

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Absorbed Dose (rads/100 uCi TOC)</th>
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<tbody>
<tr>
<td>Thyroid</td>
<td>Maximum</td>
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<tr>
<td>Uptake (%)</td>
<td>BNPI</td>
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<td>5</td>
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<td>1.6</td>
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Special Consideration: Radiopharmaceuticals should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

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Volume 24, Number 2
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1984
RESIDENCIES IN NUCLEAR MEDICINE

The Department of Radiology at Harvard Medical School invites applications to its two-and one-year residency programs in nuclear medicine and nuclear radiology for 1984.

Further requests should be directed to S. James Adelstein, M.D., Ph.D., Director, The Joint Program in Nuclear Medicine, Department of Radiology, Harvard Medical School, 25 Shattuck Street, Boston, MA 02115.

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A Nuclear Medicine resident position is available beginning July 1, 1983 for a two-year program at San Francisco General Hospital Medical Center.

The program, approved by the ACGME and satisfying the requirements of the American Board of Nuclear Medicine, includes didactic instruction in radiological physics and mathematics, electronics, radiation safety, dosimetry, and nuclear medicine instrumentation.

Practical experience is provided in performance and interpretation of static and dynamic imaging, computer techniques, radioimmunoassay and other in vitro tests, radiopharmacy, and therapy with radionuclides. Residents participate fully in the integration of these modalities into patient care.

Prerequisite: Prior training in an ACGME-approved program in internal medicine, pathology, pediatrics, or radiology.

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Requests for further information (include CV) should be directed to:

Myron Pollycove, M.D.
Chief, Nuclear Medicine
San Francisco General Hospital Medical Center
San Francisco, CA 94110
HEPATOLITE™
Technetium Tc 99m Disofenin Kit

INDICATIONS AND USAGE: Technetium Tc 99m Disofenin is indicated as a hepatobiliary imaging agent.

CONTRAINDICATIONS: None known.

WARNINGS: The theoretical possibility of allergic reactions should be considered in patients who receive multiple doses.

PRECAUTIONS: Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Disofenin and are NOT to be administered directly to the patient. Technetium Tc 99m Disofenin as well as other radiopharmaceuticals must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also care should be taken to minimize radiation exposure to the patient consistent with proper patient management. Technetium Tc 99m Disofenin should be formulated within six (6) hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Disofenin affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Disofenin. It is also not known whether Technetium Tc 99m Disofenin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m should be given to a pregnant woman only if clearly needed.

Ideally examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of Technetium Tc 99m Disofenin have been reported.

DOSAGE AND ADMINISTRATION: The suggested dose range for V administration after reconstitution with oxygen-free sodium pertechnetate Tc 99m injection should be employed in the average patient (70kg) is:

- Non-Jaundiced patient
  - 1-5mCi
  - Patients with serum bilirubin level greater than 5mg/dl
  - 3-8mCi

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation in situ. Do not backflush the syringe. Slow injection is recommended. Radiochemical purity should be checked prior to patient administration.

The patient should be in a fasting state. 4 hours is preferable. False positives (non-visualization) may result if the gall bladder has been emptied by ingestion of food.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration wherever solution and container permit.

HOW SUPPLIED: NEN HEPATOLITE™ Technetium Tc 99m Disofenin Kit is supplied in kits of five (5) and thirty (30) vials, sterile and pyrogen-free, each vial containing in lyophilized form:

- Disofenin
- Stannous Chloride (SnCl2) - 2H2O (Minimum) 20mg
- Total Tin, Maximum (as stannous chloride. SnCl2) - 2H2O 0.24 mg
- Sodium Hydroxide (NaOH) (Minimum) 0.69g
- Sodium Hydroxide (NaOH) (Maximum) 0.86g
- The pH is adjusted to between 5.5-6.5 with hydrochloric acid and/or sodium hydroxide solution prior to lyophilization. The contents of the vial were lyophylized under nitrogen. Store at room temperature (15°-30°C) before and after reconstitution. Protect from light. The lyophilized drug product is light sensitive. Technetium Tc 99m Disofenin contains no preservatives Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels
- The components of the Technetium Tc 99m Disofenin Kit are supplied sterile and non-pyrogenic. Asptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during addition of pertechnetate solution and the withdrawal of doses for patient administration.
- Technetium Tc 99m Disofenin is prepared by adding no more than 100 milliliters of additive-free sterile, non-pyrogenic sodium pertechnetate Tc 99m solution in 2-3 ml (20-50mCi) to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Disofenin.

Catalog Number NRP-475 (5 vial kit)
Catalog Number NRP-475C (30 vial kit)

November 1982

New England Nuclear
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Volume 24, Number 2

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HEPATOLITE™
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“DISIDA [Hepatolite] has been extremely effective in distinguishing medical from surgical jaundice...with the bilirubin ranging from 1.1 to 24.5 mg%.”
Weissmann et al

Superior liver uptake and washout

“Visually and computationally, DISIDA [Hepatolite] was superior to other IDA agents in terms of relative uptake in the liver and liver washout.”
Hernandez and Rosenthal

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“During the first hour after injection (the critical time for imaging), disopropyl-IDA [Hepatolite] had the highest rate of biliary excretion (76.2%), which should result in the best visualization of the biliary system...”
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“We were able to clearly identify the intrahepatic ducts in 46 of the 54 patients imaged with PRIDA [Hepatolite] whereas we were not able to identify them clearly in any of the 21 patients imaged with BIDA.”
Read et al

The only agent you need to stock

“Tc-99m DISIDA [Hepatolite] appears to incorporate the best properties of all the currently available IDA analogs... it is the only IDA derivative that a “hot lab” would need to stock.”
Weissmann et al

References
The "best universal agent" for hepatobiliary imaging

**Hepatolite**

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**Bilirubin: 24.5 mg/dl.** This normal Hepatolite study demonstrates biliary tract patency—suggesting that the patient's hyperbilirubinemia is due to parenchymal disease. Note the shielding of intestinal activity on the 90-minute study. (Reproduced with permission from reference 6.)

**HIDA**

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**Bilirubin: 23.0 mg/dl.** In this patient who presented with painless jaundice, cholescintigraphy with \(^{99m}\text{Tc-HIDA}\) was nondiagnostic. Note the absence of significant liver uptake throughout the study—only persistent renal excretion and blood background. CT revealed a mass in the head of the pancreas. (Reproduced with permission from reference 6.)
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