

**INTER SCIENCE
INSTITUTE**

944 WEST HYDE PARK
INGLEWOOD, CA 90302
(800) 255-CURE/421-7133
(310) 677-3322

License no. 04-17814-01E

Docket No. 030-13376, Mail control 575728

September 2, 2011

Shirley Xu, License Branch
Division of Materials Safety and State Agreements
Nuclear Regulatory Commission
Office of Federal and State Materials &
Environmental Management Programs
Washington DC 20555-0001

Dear Ms. Xu:

Thank you for your letter dated, August 10, 2011 with respect to ISI's recently submitted renewal. This is submitted in response to the need for additional information.


1. In accordance with 10 CFR 30.33, a copy of ISI's State of California License authorizing possession and use of radioactive materials is enclosed.
2. In accordance with 10 CFR 32.18, ISI confirms that the byproduct material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being.
3. In accordance with 10 CFR 32.18, ISI confirms that the byproduct material is in the form of processed chemical elements, compounds or mixtures, bioassay samples, counting standards, plated or encapsulated sources or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated in to any manufactured or assembled commodity, product, or device intended for commercial distribution.
4. In accordance with 10 CFR 32.18, copies of prototype labels and brochures are submitted for approval as per instructions stated herewith.
5. In accordance with 10 CFR 32.19, ISI confirms that no more than 10 exempt quantities set forth in 10 CFR 30.71. Schedule B shall be sold or transferred in any single transaction.
6. In accordance with 10 CFR 32.19, ISI confirms that each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No

more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

7. In accordance with 10 CFR 32.19, ISI confirms that the immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which both identifies the radioisotope and the quantity of radioactivity, and bears the words "Radioactive Material."
8. In accordance with 10 CFR 32.20, ISI confirms the following:
 - a. Each person licensed under § 32.18 will maintain records of transfer of material identifying, by name and address each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.
 - b. ISI will file a summary report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including being addressed to: ATTN: DOCUMENT CONTROL DESK/EXEMPT DISTRIBUTION.
 1. The report will clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
 2. The report will further indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.
 - c. For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form transferred under the specific license.
 - d. ISI will file the report covering the preceding calendar year on or before January 31 of each year. If transfers occur, the report will include the total quantity of each radionuclide transferred for transfers in prior years if not previously reported to the Commission. Further, should ISI discontinue activities authorized by the license issued under § 32.18, ISI will file a report for the current calendar year within 30 days after ceasing distribution.
 - e. If no transfers of byproduct material have been made, under § 32.18 during the reporting period, the report will so indicate.
 - f. ISI will maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.

Thank you for your assistance in renewing ISI's NRC license. Please do not hesitate to contact me should anything further be required.

Sincerely,



Siegfried R. Krutzik, Ph.D.

Radiation Safety Officer

cc: NRC 2011 Renewal File

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the places(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee	Inter Science Institute	3. License Number	3398-19GL	Amendment Number : 8
2. Address	944 West Hyde Park Boulevard Inglewood, CA 90302	4. Expiration date	December 12, 2014	(3)
Attention:	Matthew C. Urbin, Ph.D. Radiation Safety Officer	5. Inspection agency	Los Angeles County Department of Health Services	

License Number 3398-19GL is hereby renewed in its entirety:

6. Nuclide	7. Form	8. Possession Limit
A. Hydrogen-3	A. RIA kits	A. Not applicable
B. Iodine-125	B. RIA kits	B. Not applicable

9. Authorized Use

- A.-E. To be used for distribution to persons generally licensed pursuant to Section 30192.5(a) of the California Radiation Control Regulation or equivalent provisions of NRC or Agreement States.

LICENSE CONDITIONS

10. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.
11. Each unit of radioactive materials distributed under this license shall bear durable, clearly visible label:
- Identifying the radioactive contents as to chemical form and radionuclides, and indicating that the amount of radioactivity does not exceed 10 microcuries; and
 - Displaying the radiation caution symbol described in the Code of Federal Regulations, Title 10, Part 20, Section 20.1901, and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans and Animals."

RADIOACTIVE MATERIAL LICENSE

License Number: 3398-19GL

Amendment Number: 8

12. The following statement, or a substantially similar statement which contains the information called for in the following statement, shall appear either on a label affixed to each unit of radioactive material distributed under this license or in a leaflet or brochure which accompanies each package of such units:

"This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority."

Name of manufacturer

13. Each package or radioactive material distributed under this license shall contain or be accompanied by, a copy of the literature titled, "General Rules for Safe Use of Radioactive Materials", enclosed with the letter dated April 28, 2004, signed by Matthew C. Urbin, Ph.D.
14. The authorization stated in Item 9 of this license shall not be valid unless the licensee possesses a currently valid license issued by the Department for manufacture of drugs or devices, in accordance with Section 109875 of the Sherman Food, Drug, and Cosmetic Law (Division 21 of the California Health and Safety Code).
15. The Radiation Safety Officer in this program shall be Matthew C. Urbin, Ph.D.

Prepared By: <i>Frederick T. Toyama</i>	Reviewed By: <i>Lauren Labbe</i>	Issued For the Department of Health Services By: <i>Gary W. Butner</i>
Printed Name: Frederick T. Toyama	Printed Name: Lauren Labbe	Printed Name: Gary W. Butner
Date: <i>5/20/04</i>		Radiologic Health Branch MS 7610, P.O. Box 997414 Sacramento, CA 95899-7414

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the places(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee	Inter Science Institute	3. License Number	1972-19	Amendment Number: 22
2. Address	944 West Hyde Park Boulevard Inglewood, CA 90302	4. Expiration date	December 12, 2014	(3)
Attention:	Matthew C. Urbin, Ph.D. Radiation Safety Officer	5. Inspection agency	Los Angeles County Department of Health Services	

In response to the letter dated July 6, 2004, signed by Matthew C. Urbin, Ph.D., License Number 1972-19 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Hydrogen-3	A. Any	A. Not to exceed 10 millicuries.
B. Iodine-125	B. Any	B. Not to exceed 24 millicuries.

9. Authorized Use

A.-B. To be used for in-vitro clinical testing, and for manufacture of RIA kits for distribution to specific licensees of the NRC or Agreement States. (Iodination procedures are authorized.)

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following location:

(a) 944 West Hyde Park Boulevard, Inglewood, CA.

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

12. Radioactive material shall be used by, or under the supervision of, the following individual:

(a) Matthew C. Urbin, Ph.D.

(b) Siegfried R. Krutzik, Ph.D.

(c) Ruth S. Hilton

(d) Paris Mamikunian

(e) Augustine Okonka

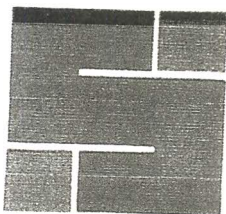
RADIOACTIVE MATERIAL LICENSE

License Number: 1972-19

Amendment Number: 22

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- (a) The renewal application dated November 11, 2000, signed by Alan Kacena with attachments thereto, as modified by the letters with attachments dated April 25, 2003 and June 12, 2003, both signed by Alan Kacena, the letters with attachments dated November 10, 2003 and November 19, 2003, both signed by Matthew C. Urbin, Ph.D., and the letters dated November 18, 2003 and December 4, 2003, both signed by Matthew C. Urbin, Ph.D.
14. (a) The Radiation Safety Officer in this program shall be Matthew C. Urbin, Ph.D.
- (b) The Alternate Radiation Safety Officer shall be Siegfried R. Krutzik, Ph.D.
15. Radioactive materials shall be used by occupational workers in such a manner that the dose limits specified in Title 10, Code of Federal Regulations, Part 20, Subpart C, Sections 20.1201 through 20.1208 are not exceeded.
16. The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).
17. The licensee shall monitor occupational intakes of radioactive material by, and assess the committed effective dose equivalent to, individuals who may have exceeded or are likely to exceed, the limits specified in Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by Section 20.1204.
18. The licensee is authorized to hold radioactive materials with a physical half-life of less than 90 days for decay in storage before disposal in ordinary trash provided:
- (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 7 half-lives.
- (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
19. This license does not authorize distribution of radioactive material pursuant to Title 17, California Code of Regulations, Sections 30180 and 30192 through 30192.6 or equivalent provisions of the U.S. Nuclear Regulatory Commission or Agreement States.

Prepared By: <i>Beverly Hill</i>	Reviewed By: <i>Rene Obear</i>	Issued For the Department of Health Services By: <i>Gary Butner</i>
Printed Name: Beverly Hill	Printed Name: Rene Obear	Printed Name: Gary Butner
Date: <i>9/9/04</i>		Radiologic Health Branch MS 7610, P.O. Box 997414 Sacramento, CA 95899-7414



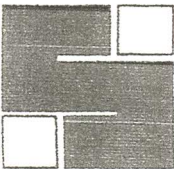





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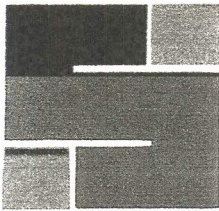
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Sample documents for #4

SAMPLE BOX LABEL

	INTER SCIENCE INSTITUTE 944 WEST HYDE PARK BLVD INGLEWOOD, CA 90302 (800) 255-2873
<hr/>	
	
	
	PROGESTERONE KIT
LOT NO.: 2349056 EXP DATE: 04/30/12	
SEE ACCOMPANYING INSTRUCTION BOOKLET INSIDE	



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Sample documents for #4

SAMPLE BOTTLE LABEL

NDC#44391 -
Exp date: 04/30/12
Lot #: 2349056
Store at 0-4°C.

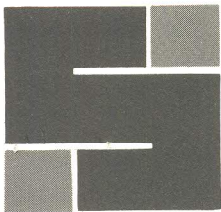
For Radioimmunoassay of
Progesterone
ISOTOPE ^{125}I
I-125
CAUTION: RADIOACTIVE MATERIAL
HANDLE WITH CARE
DO NOT INGEST OR INHALE

For in vitro diagnostic use.
INTER SCIENCE
INSTITUTE
944 WEST HYDE PARK
INGLEWOOD, CA 90302

NDC#44391 -
Exp date: 04/30/12
Lot #: 2349056
Store at 0-4°C.

For Radioimmunoassay of
Progesterone
ISOTOPE ^{125}I
I-125
CAUTION: RADIOACTIVE MATERIAL
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For in vitro diagnostic use.
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License No. 04-17814-01E
Docket No. 030-13376, MC 575728

PROGESTERONE RIA KIT

I^{125} Radioimmunoassay for the Quantitative
Determination of Progesterone in Plasma/Serum

Progesterone RIA (100 determinations)

Store at 2-8° C

Contact Information:

Inter Science Institute (ISI)
944 West Hyde Park Boulevard
Inglewood CA 90302
www.interscienceinstitute.com

(800) 255-2873 or (310) 677-3322
Fax: (310) 677-2846

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PROGESTERONE KIT

Precautions

General Precautions

All biological materials and patient specimens should be considered as potentially biohazardous and be handled with universal precautions. Personal protective equipment (gloves, lab coats and goggles) should be used when handling biohazardous materials. Work areas and equipment used with biohazardous materials should be decontaminated regularly. Biohazardous waste must be disposed of according to state and federal regulations.

Rules and Regulations

A copy of radioisotope license certificate issued to a US customer must be on file with Inter Science Institute before kits or components containing radioactive material can be shipped. These radioactive materials may be acquired by any customer with the appropriate Specific license. Under a General license these radioactive materials may be acquired only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories and hospitals and only for *in vitro* clinical or laboratory tests not involving external or internal administration of the radioactive material or its radiation to human beings or other animals. Its acquisition, receipt, storage, use, transfer and disposal are all subject to the regulations of the U.S. Nuclear Regulatory Commission (NRC) or a State with which the NRC has entered into an agreement for the exercise of regulatory control.

Summary of basic principles of the radiation protection directive

1. Radioactive material may only be stored in its original packing and reserved spaces.
2. Receipt, storage and use of this material must be recorded.
3. Radioactive material may only be handled and used in rooms specified for this purpose (controlled area).
4. Avoid any direct contact with radioactive material by wearing protective clothing and protective gloves.
5. To prevent cross-contamination with other isotopes, ensure that contaminated laboratory equipment and glasses are disposed of as directed.
6. Use the required care and attention to clear up any contamination.
7. Disposal of radioactive material must be carried out in accordance with the respective current directive.

Safety Precautions

The radioactive material should only be used with the following precautions:

Handle radioactive materials according to the requirements of your General or Specific license. To minimize exposure to radiation, the user should adhere to guidelines set forth in the National Bureau of Standards publication on the *Safe Handling of Radioactive Materials* and in subsequent publications issued by State and Federal authorities.

Radioactive materials should be stored in designated areas. People handling radioactive materials should not eat or drink while using materials. Radioactive materials should not be pipeted by mouth. Protective clothing and gloves should be used by people using radioactive materials. All spills should be immediately and thoroughly cleaned up and decontaminated. Contaminated materials should be disposed of properly according to license requirements.

Disposal

General licensees (holders of NRC Form 483) may dispose of solid radioactive waste as nonradioactive waste, after removing labeling. General licensees may dispose of liquid radioactive waste of the type contained in this product through a laboratory sink drain. Licensees must remove or deface labels from empty containers of radioactive materials before disposal of solid waste.

Specific licensees (NRC Form 313) should refer to Title 10, Code of Federal Regulations, Part 20. Licensees may dispose of small quantities of liquid radioactive waste of the type used in this product through a laboratory sink drain. Refer to the appropriate regulations applicable to your laboratory.

Assay Principle

Progesterone is measured by radioimmunoassay. Progesterone is incubated with patient or standard Progesterone with a specific Progesterone antiserum. The amount of bound/unbound tritiated Progesterone varies inversely with the amount of total Progesterone in the assay tube. A standard curve is prepared producing a dose-response related relationship to determine specific binding characteristics of the assay throughout the measureable range. The antiserum bound Progesterone is separated from the non bound and compared to the standard curve to determine the actual level of Progesterone present in the specimen.

Materials and Equipment (Required but not provided unless noted)

Reagents & Supplies

1. Buffer - 0.01M Phosphate Buffered Saline, pH 7.5. Store refrigerated.
2. Antibody - Rabbit anti-Progesterone serum. Dilute 1:1000 in buffer for use. Store diluted antiserum refrigerated. Store stock antiserum frozen.
3. Isotope - I-125. (Provided in this kit). Store refrigerated.
4. Standards - Progesterone in Methanol. Store refrigerated.
Standards should cover a range of 0 - 1000 ng/dl
5. Ammonium Sulfate - Saturated solution. Store at room temperature.
6. Protein Buffer - 0.01M Phosphate Buffered Saline, pH 7.5 containing 0.1% bovine serum albumin and 0.2% bovine gamma globulin. Store refrigerated.
7. Scintillation fluid - 4 g Diphenyloxazole per liter Toluene. Store at room temperature.
8. Hexane:Ethyl Acetate :: 4:1 ACS grade. Store at room temperature.
9. Controls - A minimum of 2 Controls are recommended with this assay. If possible, Controls should cover a different range of clinical specimens.

Equipment

1. 12 x 75 mm disposable Borosilicate tubes
2. Automatic dispensers with disposable tips
3. Vortex type mixer
4. Centrifuge capable of 1500 - 2000 x g
5. Scintillation Vials with caps (Polypropylene)
6. 16 x 125 disposable Borosilicate tubes for extraction
7. Beta scintillation counter
8. Evaporation apparatus
9. Gamma counter

Storage and Stability

The reagents should be stored at 2 - 8 °C. Do not use components beyond the expiration date shown on the kit labels. Do not mix various lots of any kit component within an individual assay.

Quality Control/Quality Assurance

It is recommended to use control samples according to state and federal regulations. Use controls at both the normal and pathological levels. The commercial controls should fall within established limits.

Procedural Notes And Limitations of the Procedure

The Progesterone procedure quantitatively measures the level of Progesterone found in above specified types of specimens. Patient and specimen preparations should be followed as previously stated. If variations are made in the patient or specimen collection, results may be altered. Medications, therapy or other factors may alter the basal levels of Progesterone or produce compounds that may interfere in the accurate determination of this hormone. These factors need to be taken into account by the physician or investigator requesting the assay to ensure maximal utility of the result. Specimens containing radioactivity may yield inaccurate results.

Reporting Patient Results

Analysis of specimens with results > 1000 ng/dL should be repeated using 250 uL of sample and then multiply result by 4 for reporting. Values less than the sensitivity of the assay (5 ng/dL) should be reported as <5 ng/dL.

Assay Performance Characteristics

Specificity

Cross-reactivity was determined at the 50% inhibition of binding level following the basic procedure. Progesterone = 1.00

<u>Compound</u>	<u>Cross-reactivity</u>
Progesterone	1.00
17-Hydroxy Progesterone	.01
11-Deoxycorticosterone	.02
Other compounds tested	< 0.01

Sensitivity

The sensitivity as determined as the least amount of Progesterone that can be distinguished from zero is 2.0 ng/dl.

Recovery

Specimens were spiked with a known quantity of Progesterone and measured to determine the amount of recovery .

<u>Specimen</u> (ng/dl)	<u>Amount added</u> (ng/dl)	<u>Amount measured</u> (ng/dl)	<u>Recovery</u> (%)
18	20.0	36	95
18	100.0	101	99
18	1000.0	1002	100

Intra-Assay Variability

The mean, standard deviation and coefficient of variation for three controls assayed 20 times in one run are listed below.

<u>Mean</u> (ng/dl)	<u>Coefficient of Variation</u> (%)
18	11.7
125	5.1
976	6.6

Inter-Assay Variation

The mean, standard deviation, and coefficient of variation for three controls assayed in 20 different runs are listed below.

<u>Mean</u> (ng/dl)	<u>Standard Deviation</u> (ng/dl)	<u>Coefficient of Variation</u> (%)
19	2.0	10.5
128	5.9	4.6
896	79	8.0

Reportable Range: 0 - 1000 ng/dL

Life Threatening Values: None

Procedure

Sample Extraction

1. Use Accessioning program to print out worksheet containing list of patient specimens to be analyzed.
2. Set up a 16 x 125 mm extraction tube for each specimen or control to be assayed. Include a water blank.
3. Perform usual examination of specimen. Report unusual findings to supervisor and record on worksheet (such as gross lipemia, hemolysis, specimen not consistent with its matrix, ID mismatch, etc).
4. Add 1 ml distilled water to water blank tube. Add 1 ml specimen or control to specimen and control tubes.
5. Add 5 ml extraction solvent (Hexane:Ethyl Acetate :: 4:1) to all tubes. Vortex tubes thoroughly and let stand for five minutes to allow layers to separate.
6. Label 12x75mm tubes in duplicate if using blank controls and specimen, pipet 250 uL of extract (top layer) into respective tubes.

Standard Curve

7. Set-up 10 tubes for standard curve (12x75mm glass tubes). Tubes for total counts (T) and S₀ (methanol) should be set up in duplicate. Serial dilution tubes S₁ to S₆ should be single tubes.
8. Add 100 uL Methanol to tubes S₁ to S₆.
9. To S₆ tube add 100 uL of standard Progesterone and mix (1000 ng/dL standard).
10. Pipet 100 uL from S₆ tube and add to S₅ tube and mix (500 ng/dL standard).
11. Pipet 100 uL from S₅ tube and add to S₄ tube and mix (250 ng/dL standard).
12. Pipet 100 uL from S₄ tube and add to S₃ tube and mix (125 ng/dL standard).
13. Pipet 100 uL from S₃ tube and add to S₂ tube and mix (62 ng/dL standard).
14. Pipet 100 uL from S₂ tube and add to S₁ tube and mix (31 ng/dL standard).
15. Pipet 100 uL from S₁ tube and discard (leaving 100 uL in the tube).

Immunoassay

16. Add 20 uL of Progesterone tracer to all tubes. Vacuum dry for 30 minutes at 25 psi. (shake the rack to see if some tubes are not dry). Allow to cool for 2 minutes.
17. Pipet 200 uL anti Progesterone Ab (1:1000) titer to each tube [except the T tubes].
18. Pipet 200 uL PBS buffer into T tubes.
19. Add 200 uL BSA-BGG to all tubes. Mix (briefly vortex) and incubate for 1 hour at room temperature.
20. Add 500 uL of saturated ammonium sulfate to each tube. Vortex.
21. Transfer tubes to centrifuge cups, balance and spin for 8 minutes at 1500 x g 20°C.
22. Pour supernatant of each tube to appropriately labeled scintillation vial, and then add 2.5 mL of scintillation fluid.
23. Mix contents of vials and wait at least 1 hour before counting.

Calculations and Reporting Results

The gamma counter software can perform data reduction and calculation of results. Results are then printed out.

SOFTWARE CALCULATION PARAMETERS

Coding

2 TOTAL
2 STD = 0
1 STD = 31
1 STD = 62
1 STD = 125
1 STD = 250
1 STD = 500
1 STD = 1000
2 UNKN

Factors

Unit = ng/dL