



200 Girard Street, Suite 200, Gaithersburg, MD 20877
301-921-0168 Fax: 301-977-0433

Client: 3M MEDICAL DEPARTMENT
3M CENTER
BUILDING 220-2E-02
ST. PAUL, MN 55133-3220
(651) 575-3161
Attention: ANDREW SEACAT

Date Collected: 02/20/1999-02/26/2000
Date Received: 04/18/2000
Date Reported: 05/02/2000

Client No. 1492 Study: 6 MONTH PFOS STUDY Species: CYNOMOLGUS

Accession No.	Spec. ID	Gp	Sex	Age	TSH, SI UIU/ML	CHOLEST MG/DL	HDL-DIR MG/DL	LDL-DIR MG/DL	VLDL MG/DL
A 0098138	I05508M	1			0.45	105	50	53	2
A 0098139	I05519M	1			0.32	145	72	73	0
A 0098140	I05527M	1			0.42	143	44	97	2
A 0098141	I05530F	1			0.43	124	56	68	0
A 0098142	I05531F	1			0.19	116	47	66	3
A 0098143	I05535F	1			0.59	171	42	128	1
A 0098144	I05544F	1			0.80	99	32	65	2
Mean					.457	129	49	78.6	1.4
S.D.					.195	25.4	12.6	25.6	1.1

Group 1

A 0098145	I05514M	2			0.64	115	43	72	0
A 0098146	I05515M	2			0.69	80	37	41	2
A 0098147	I05516M	2			0.49	73	32	36	5
A 0098148	I05521M	2			0.41	67	34	33	0
A 0098149	I05541F	2			0.51	92	48	40	4
A 0098150	I05547F	2			0.43	84	36	48	0
A 0098151	I05550F	2			0.34	82	25	51	6
Mean					.501	84.7	36.4	45.9	2.4
S.D.					.125	15.6	7.5	13.1	2.6

Group 2

Reference Range .2 - 101 - 0 - 0 - 0 -
2.6 240 0 0 0



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A 0098152	I05510M	3			0.83	115	48	66	1
A 0098153	I05518M	3			0.83	98	44	54	0
A 0098154	I05524M	3			0.54	110	37	72	1
A 0098155	I05528M	3			0.60	116	31	76	9
A 0098156	I05532F	3			0.76	91	23	68	0
A 0098157	I05538F	3			0.46	88	32	53	3
A 0098158	I05545F	3			0.34	74	24	50	0
A 0098159	I05548F	3			0.32	74	31	42	1
Mean					.585	95.8	33.8	60.1	1.9
S.D.					.207	17	8.8	12	3

Group 3

A 0098160	I05506M	4			0.73	56	14	42	0
A 0098161	I05507M	4			0.72	25	8	16	1
A 0098162	I05512M	4			1.15	27	11	16	0
A 0098163	I05534F	4			1.25	59	16	40	3
A 0098164	I05536F	4			1.75	53	18	31	4
A 0098165	I05540F	4			0.89	57	16	41	0
A 0098166	I05551F	4			0.86	61	22	35	4
Mean					1.05	48.3	15	31.6	1.7
S.D.					.368	15.4	4.6	11.3	1.9

Group 4

Reference Range .2 - 101 - 0 - 0 - 0 -
 2.6 240 0 0 0



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Accession No.	Spec. ID	Gp	Sex	Age	TSH, SI UIU/ML	CHOLEST MG/DL	HDL-DIR MG/DL	LDL-DIR MG/DL	VLDL MG/DL
A 0098167	I05533F	4R			0.85	117	51	61	5
A 0098168	I05542F	4R			0.60	124	50	46	28
A 0098169	I05511M	4R			0.65	89	45	44	0
A 0098170	I05522M	4R			0.93	106	37	68	1
Mean					.758	109	45.8	54.8	8.5
S.D.					.158	15.3	6.4	11.6	13.2

Group 4 WK52 RECOVERY

Reference Range	.2 - 2.6	101 - 240	0 - 0	0 - 0	0 - 0
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Approved

Page 3 of 3

Date

5/2/00

Andrew M. Seacat, Ph.D.
3M Medical Dept.
3M Center, Building 220-2E-02
St. Paul, MN 55133-3220
Phone: (612) 575-3161
FAX: (612) 733-1773
e-mail: amseacatl@mmm.com

3/6/2000

Peter J. Thomford, Ph.D.
Study Director, Toxicology
Covance Laboratories Inc.
3301 Kinsman Blvd.
Madison WI 53704
Phone: 608-241-7202
Fax: 608-242-2736

Re: 26-week capsule toxicity study with perfluorooctane sulfonic acid potassium salt (PFOS; T-6295) in Cynomolgus Monkeys. Covance Study Number: 6329-223,

Peter,

3M requests information from the study records of 6329-223 for the methods used and the dates of specific hormone determinations conducted by Ani Lytics Incorporated, Gaithersburg, MD. Specifically, we need more information on the methods of determination for T3, T4, free T3, free T4 and TSH. An explanation of the zero values for TSH is requested. What is the limit of detection (LOD) and limit of quantitation (LOQ) for TSH in the method used, and should the zero values be replaced with <LOD or <LOQ. Furthermore, we need to understand the high T3 values reported for the day 37 samples (reference, appendix 6 of Draft interim Report from Covance), for which the T3 values were high in all dose groups. The date that the tests were performed on each sample is also requested. Ani Lytics is being copied on this request in order to expedite the transfer of information.

Sincerely,

Andrew M. Seacat Ph.D.
Study Monitor

cc: Dr. Saroj Das
Ani Lytics
200 Girard Street, Suite 200
Gaithersburg, Maryland 20877
Telephone No.: 301-921-0168
Facsimile No.: 301-977-0433



200 Girard Street, Suite 200, Gaithersburg, MD 20877
301-921-0168 800-237-2815

05 April 2000

Andrew Seacat, Ph.D.
3M Medical Department
3M Center, Building 220-2E-02
St. Paul, MN 55133-3220

Dear Dr. Seacat,

REF: Fax dated 3/20/00
TSH analysis in Cynos

I want to bring to your attention that primate TSH analysis at Ani-Lytics, Inc. has always been performed using anti-human TSH polyclonal antibody. During our telephone conversation I told you that as of 1998 all human TSH testing is being done using monoclonal antibody, therefore these test reagents can not be used in primates. For this reason we initiated an inhouse TSH assay procedure utilizing polyclonal antibody. The reagent source and other information on each of the assays mentioned in your letter along with result reporting policy are inclosed.

As I indicated to you, primates in general have quite low TSH levels. Therefore it will be necessary to increase the specimen volume in the TSH test system. At least 0.5ml but preferably 1.0ml serum will be good.

Sincerely,

Saroj R. Das, M.S., Ph.D.
Director

cc: Peter J. Thomford, Ph.D.
Study Director, Toxicology
Covance Laboratories, Inc.
3301 Kinsman Blvd.
Madison, WI 53704



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RESULT REPORTING POLICY

Linear regression curve correlation coefficient of 0.99 or greater accepted.

Results observed over the highest calibrator concentration repeated on appropriate dilution.

Lowest limit of quantitation is the lowest calibrator concentration. Values below this concentration are computer generated based on the standard curve. These values are reported. In some assays the exact calibration range is kit lot number specific.

A zero value indicates that the counts bound for the sample/s were same as or close to or > zero standard counts.



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ANALYTE: NonHuman Primate
Thyroid Stimulating Hormone (TSH)

PROCEDURE: Double Antibody RIA
Inhouse Procedure

REAGENTS:

Human TSH standard (Ref WHO standard 68/38)
Sigma-Aldrich Inc. Cat. #T-4651

Rabbit-anti human TSH (polyclonal)
Sigma-Aldrich Inc. Cat. #T-4651

Radiolabeled HTSH
Covance Laboratories, Inc., Vienna, VA

CALIBRATION RANGE: 0.4 to 50 mIu/ml. (Low end sensitivity is
dependent upon the integrity of the iodinated hormone.)

RESULTS: mIu/ml
Computer generated values reported below low end sensitivity of the
curve.

COMMENT: Overall TSH levels in NHP are extremely low so it is
difficult to know if this test offers significant clinical
information.



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ANALYTE: Free T4

PROCEDURE: Coat-A-Count RIA

REAGENT SOURCE: Diagnostic Products Corporation, CA.

CALIBRATION RANGE: 0.1 to 10 ng/dl (kit lot # specific)

RESULTS: ng/dl
Computer generated values reported below the standard.



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ANALYTE: Total T4

PROCEDURE: RIA Coated Tube Assay

REAGENT SOURCE: DPC, CA.

CALIBRATION RANGE: 1 to 24 ug/dl

RESULTS: ug/dl
Computer generated values reported below 1 ug/dl.



200 Girard Street, Suite 200, Gaithersburg, MD 20877
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ANALYTE: Free T3

PROCEDURE: Coat-A-Count RIA

REAGENT SOURCE: DPC, CA.

CALIBRATION RANGE: 0.5 - 42 pg/ml (kit lot # specific)

RESULTS: pg/ml
computer generated values reported below the lowest
standard curve calibrator concentration.



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ANALYTE: Total T3

PROCEDURE: Radioimmunoassay (RIA)
Coated Tube Assay

REAGENT SOURCE: Diagnostic Products Corporation (DPC), CA.

CALIBRATION RANGE: 20 to 600 ng/dl

RESULTS: ng/dl
Computer generated values reported below 20 ng/dl