



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

October 27, 2006

RE: Open Records request

Enclosed are the documents that you requested concerning Covance tuberculosis.

Sincerely,

A handwritten signature in black ink that reads "Martha Loy".

Martha Loy
Budget and Policy Analyst
DATCP, Division of Animal Health
(P) 608-224-4875
(F) 608-224-4903
(e) martha.loy@datcp.state.wi.us

Agriculture generates \$51.5 billion for Wisconsin

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

Dr. Robert G. Ehlenfeldt, State Veterinarian
Division of Animal Health
Wisconsin Department of Agriculture
Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911

June 22, 2006

Dear Dr. Ehlenfeldt,

I am a staff veterinarian at Covance Labs in Madison, WI. I phoned Dr. Jerry Ruch today to report a cynomolgus macaque for a positive tuberculosis skin test. This animal presented with a Grade 4 reaction to the skin test performed last week at 48 hours posttest. The animal was sent to necropsy. Tissue from lung, mediastinal lymph node and two small tan focal lung lesions was sent to Zoologix lab in California to confirm the presence of TB by PCR. That result came back positive for the lesions alone. The assay did not differentiate between *M. tuberculosis*, *M. bovis* or *M. microti*. The lung and lymph tissue was negative.

The room that housed the animal was quarantined after the necropsy showed evidence of lung lesions. There were two other primates that showed equivocal responses to the skin test. The entire colony housed in that room is being sent to necropsy to confirm or deny presence of active infection. Any positive animals will be necropsied to prevent the spread of tuberculosis to other primates in our facility, humans included.

Screening for humans in our facility is biannual but will be repeated due to this outbreak. We will be working hard to eradicate this disease from our facility. Please let me know if I can provide any further information.

Regards,



Jennifer Seeman, DVM
Staff Veterinarian
Lab Animal Medicine
Covance Laboratories, Inc.
3301 Kinsman Boulevard
Madison, WI 53704-2523

(608) 242-2712 ext. 2230

Ehlenfeldt, Robert G DATCP

From: Doris.Olander@aphis.usda.gov
Sent: Monday, July 10, 2006 12:42 PM
To: dr.don.oconnor@datcp.state.wi.us
Cc: paul.mcgraw@datcp.state.wi.us; robert.ehlenfeldt@datcp.state.wi.us;
Jane.E.Mussey@aphis.usda.gov
Subject: Fw: Covance primate TB

Here is the timeline as I have it. Dr. Rush will be in tomorrow. Let us know (Dr. Mussey this week, Dr. Kessenich next) if there is anything else we can do.

Doris Olander, DVM
TSE Coordinator
USDA/APHIS/VS - WI
6510 Schroeder Road, Suite 2
Madison, WI 53711

Tel. 608 270 4000 ext. 4082
Fax 608 270 4001

.... Forwarded by Doris Olander/WI/APHIS/USDA on 07/10/2006 12:33 PM -----

Doris Olander/WI/APHIS/USDA

07/10/2006 08:48 AM

To: Dale.Rush@aphis.usda.gov, "Doris.Olander@aphis.usda.gov",
<Doris.Olander@aphis.usda.gov>, Janet.B.Paveur@aphis.usda.gov,
Jane.E.Mussey@aphis.usda.gov, Jeffrey.T.Nelson@aphis.usda.gov,
Ulysses.J.Lane@aphis.usda.gov

cc

Subject RE: Covance primate TBLink

See corrections -I will thank Jennifer for her corrections without attaching the email.

Doris Olander, DVM
TSE Coordinator
USDA/APHIS/VS - WI
6510 Schroeder Road, Suite 2
Madison, WI 53711

Tel. 608 270 4000 ext. 4082
Fax 608 270 4001

"Seeman, Jennifer" <Jennifer.Seeman@covance.com>

07/10/2006 07:52 AM

To: ""Doris.Olander@aphis.usda.gov" <Doris.Olander@aphis.usda.gov>,
Dale.Rush@aphis.usda.gov
cc Jeffrey.T.Nelson@aphis.usda.gov, Janet.B.Paveur@aphis.usda.gov,
Jane.E.Mussey@aphis.usda.gov, Ulysses.J.Lane@aphis.usda.gov
Subject RE: Covance primate TB

10/4/2006

Hi all,

Please see a few corrections below. I will be contacting Drs. Nelson or Payeur about shipping tissue from Zoologix today. I have already contacted Steve Lloyd from Zoologix to alert him about tissue shipment to NVSL . have not spoken to Dr. Rush, I spoke to Dr. Jerry Ruch originally, I confused the names when discussing with Dr. Olander. Please don't hesitate to call me for more information. My company is concerned about the security of email for this information. We have already had major issues with PETA and wish to avoid email that may not be secure.

Jen

Jen Seeman, DVM
Covance Laboratories
242-2712 ext. 2230

—Original Message—

From: Doris.Olander@aphis.usda.gov [mailto:Doris.Olander@aphis.usda.gov]

Sent: Friday, July 07, 2006 4:21 PM

To: Dale.Rush@aphis.usda.gov

Cc: Seeman, Jennifer; Jeffrey.T.Nelson@aphis.usda.gov; Janet.B.Payeur@aphis.usda.gov; Jane.E.Mussey@aphis.usda.gov; Ulysses.J.Lane@aphis.usda.gov

Subject: Covance primate TB

Dr. Rush, I wanted to update you on our primate problem here in WI. Dr. Seeman at Covance indicated that she has talked to you, but not today. So here we go!

- [Seeman, Jennifer] (6/7/06) - accurate date. 6/15/06 one macaque in a room of 32 has a grade 4 reaction to a skin test (48 hrs) [Seeman, Jennifer] 2 others had equivocal reactions - grade 3
- This animal was necropsied (date uncertain) and lesions were found
- lesion, lung and LN tissue were sent to Zoologix (see below)
- lesion tested positive for TB (not specified) using PCR
- [Seeman, Jennifer] (6/14-16)- accurate date 6/27 & 6/28 the remaining 31 animals in the room were euthanized [Seeman, Jennifer] beginning with skin test + animals.
- The room was cleaned and disinfected
- An additional 4 animals had lesions one with both lung and lymph node lesions
- Tissues from these 4 animals were sent to Zoologix
- All 4 animals tested positive

Epidemiology:

Based on my conversation with Dr. Seeman the index animal does not appear to be the source. When the animal locations were mapped out in the facility, the animal with both lung and LN lesions was at the center of the 4 other positives (the index is included in these). According to Dr. Seeman (she will be faxing the specifics) this animal came from China and entered their faRP)exas. From there it was shipped to Wisconsin. She was unable to provide documentation regarding whether Texas was the port of entry, what animals this animal comingled with in Texas or how long it was there. I am hoping that this information will be available shortly to share as needed (since this involves western region and other agencies I am sending it on to you)

10/4/2006

Communications:

- The state veterinarian (by Dr. Seeman) and the state public health authorities (by the state veterinarian) have both been notified
- The company is cooperating with public health officials
- Dr. Seemans will be requesting that all tissues at Zoologix be shipped to NVSL on Monday
- I spoke with Dr. Nelson regarding this yesterday and he said to keep Dr. Payeur in the loop too so she is cced on this email

Please let me or next week's acting (Dr. Mussey) know what else is needed.

Doris Olander, DVM, MS, DACVPM
TSE Coordinator
USDA/APHIS/VS - WI
6510 Schroeder Road, Suite 2
Madison, WI 53711

Tel. 608 270 4000 ext. 4082

Fax 608 270 4001

Zoologix, Inc.

9811 Owensmouth Avenue

Suite 4

Chatsworth CA 91311

Phone: 818-717-8880

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10/4/2006



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

July 17, 2006

Jennifer Seeman, DVM
Staff Veterinarian
Covance Laboratories, Inc.
3301 Kinsman Blvd.
Madison, WI 53704-2523

Dear Dr. Seeman;

Veterinarians performing tuberculosis testing on any animals in Wisconsin are required to report all results to the department. This can be accomplished by completing form VS Form 6-22 and mailing it to this office within 10 days of the test injection date. In addition, any animals that respond to the tuberculosis test must be reported immediately. Rapid reporting of responding animals permits the department to determine the true status of the animal and protects Wisconsin producer's ability to move animals in interstate and international commerce.

Only accredited and certified veterinarians may perform tuberculosis testing in Wisconsin. Veterinarians performing tuberculosis testing on cattle or farm-raised deer must have additional certification.

I have enclosed two copies of VS Form 6-22. Additional copies can be obtained from the USDA Veterinary Services Office, 6510 Schroeder Rd., Madison, WI 53711; 608-270-4000. If you have any questions on completing the VS 6-22 or any other questions pertaining to tuberculosis please contact Dr. Don O'Connor, Designated Tuberculosis Epidemiologist, 608-224-4882.

Sincerely,

Robert G. Ehlenfeldt, DVM
State Veterinarian, Administrator
Division of Animal Health

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O'Connor, Dr. Don DATCP

From: Donald.M.Rush@aphis.usda.gov
Sent: Monday, July 24, 2006 4:58 PM
To: Don O'Connor
Subject: Re: TB testing and reporting of primates

Don, we don't need reports on non-program species. Any accred or non-accred vet can perform tests as we don't control this program. Dept of Public Health in the city of concern or Animal Care (possibly) would take action on positive non-program species.

Sent from my BlackBerry Wireless Handheld

-----Original Message -----

From: "O'Connor, Dr. Don DATCP" [Dr.Don.Oconnor@datcp.state.wi.us]
Sent: 07/24/2006 05:01 PM
To: Donald.M.Rush@aphis.usda.gov
Subject: TB testing and reporting of primates

Covance, a research facility hee in Madison, recently tested primates, several were reactors on the skin test, necropsied with lesions and the tissues sent to a laboratory in California. The PCR was positive, **but** they never cultured it and the PCR was for mycobacteria, not specific for mamalian or avian TB. **They** wre suppose to forward the tissues on to NVSI from California. Dr Olander was handling the follow up as she **was** acting AVIC at the time. Now the question is, who is qualified to TB test primates? According to the UM&R, tuberculin injectins are to be given by an accredited Vet. Is this true with primates? Are they suppose to report all tuberculin tests to the DTE? Who actually regulates this area of the program for non-program animals? Aren't all tuberculin tests to be reported even in non-program animals? I'm asking them to report ail tests, is this acceptable? D O'Connor

7/25/2006



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

July 25, 2006

Jennifer Seeman, DVM
Staff Veterinarian
Covance Laboratories, Inc.
3301 Kinsman Blvd.
Madison, WI 53704-2523

Dear Dr. Seeman:

This letter is to clarify the testing and reporting requirements for tuberculosis. Regulatory oversight and reporting requirements for tuberculosis testing of both program and non-program animals tend to differ depending on the species involved. After consultation with the Eastern Regional Tuberculosis Epidemiologist and Wisconsin's Designated Tuberculosis Epidemiologist, the following protocol is to be followed in Wisconsin.

First, all tuberculin tests are to be conducted by a licensed veterinarian. This requirement is for program and non-program animals, including primates in accordance with Part II section B of the Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1, 2006, governing the testing and eradication of mammalian tuberculosis.

Second, it is not required to report negative screening tests conducted on primates to the Department of Agriculture, Trade and Consumer Protection, since primates are considered non-program animals by the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services. However, all positive reactions must be reported to the Designated Tuberculosis Epidemiologist at the Division of Animal Health, with necropsies conducted under the auspices of a Regulatory State or Federal Veterinarian experienced in identifying tuberculous lesions. Granulomatous lesions, indicative of tuberculosis must be submitted to the National Veterinary Services Laboratory for histopathology and PCR examination. This allows for the diagnosis of either mammalian tuberculosis or avian tuberculosis. The results will be reported to the Wisconsin Department of Health and Family Services.

If you have any other questions pertaining to tuberculosis, please contact Dr. Donald O'Connor, Designated Tuberculosis Epidemiologist at 608-224-4882 or at the address below.

Robert G. Ehlenfeldt, DVM
State Veterinarian
Division of Animal Health

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Ehlenfeldt, Robert G DATCP

From: Ehlenfeldt, Robert G DATCP
Sent: Monday, August 07, 2006 3:49 PM
To: 'Doris.Olander@aphis.usda.gov'; McGraw, Paul J DATCP; Ehlenfeldt, Robert G DATCP
Cc: O'Connor, Dr. Don DATCP
Subject: RE: Covance result
Attachments: seeman tb 2r.doc

I'm not sure we can go anywhere. I think Dr. Seeman should handle the next one correctly.

From: Doris.Olander@aphis.usda.gov [<mailto:Doris.Olander@aphis.usda.gov>]
Sent: Sunday, August 06, 2006 9:40 PM
To: paul.mcgraw@datcp.state.wi.us; robert.ehlenfeldt@datcp.state.wi.us
Subject: Covance result

Not sure where to go from here? There are two more test results exactly like this.

Doris Olander, DVM
TSE Coordinator
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6510 Schroeder Road, Suite 2
Madison, WI 53711

Tel. 608 270 4000 ext. 4082
Fax 608 270 4001

Forwarded by Doris Olander/WI/APHIS/USDA on 08/06/2006 09:38 PM

National Veterinary Services Laboratories
1800 Dayton Road Ames, Iowa 50010
Phone (515) 663-7266 Fax (515) 663-7397
Tuberculosis Laboratory Test Report Page 1 of 1

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish)
1-800-877-8339

Accession: 446392 Date Received: 7/14/2006
Establishment No.: WISEEM Referral Number: 06WIJLS0707
SEEMAN, DR. JENNIFER Owner: COVANCE LABS
3301 KINSMAN BLVD. City: MADISON
State: WI
MADISON, WI 53704
Fax: 6082427989

Preservation:

Retain Tag: Species: Monkey

NVSL ID Case # Sample ID Animal ID

10/4/2006

1504462 0608533 606270073 IM052774/C17526
Mycobacteria Isolation
Diagnosis: Not Processed

Specimen Submitted
DNA

Sample unsuitable for testing. Specimen is DNA extracted from animal tissue

DISTRIBUTION:

Submitter
7/20/2006

Approved By: Jeffrey T. Nelson
National Veterinary Services Laboratories

10/4/2006

Ehlenfeldt, Robert G DATCP

From: Doris.Olander@aphis.usda.gov
Sent: Thursday, September 14, 2006 10:54 AM
To: paul.mcgraw@datcp.state.wi.us; robert.ehlenfeldt@datcp.state.wi.us
Subject: Covance (neg) TB result from July

Doris Olander, DVM
TSE Coordinator
USDA/APHIS/VS-WI
6510 Schroeder Road, Suite 2
Madison, WI 53711

Tel. 608 270 4000 ext. 4082
Fax 608 270 4001

.... Forwarded By **Doris Olander/WI/APHIS/USDA on 09/14/2006 10.53 AM**—

National Veterinary Services Laboratories
1800 Dayton Road Ames, Iowa 50010
Phone (515) 663-7266 Fax (515) 663-7397
Tuberculosis Laboratory Test Report Page 1 of 1
FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish)
1-800-877-8339

***** This is a confidential report for official use only. *****

Accession: 446391 Date Received: 7/14/2006

Establishment No.: WISEEM Referral Number: 06WIJLS0707
SEEMAN, DR. JENNIFER Owner: COVANCE LABS
3301 KINSMAN BLVD. City: MADISON
State: WI

MADISON, WI 53704
Fax: 6082427989

Preservation:

Retain Tag: Species: Monkey

NVSL ID Case # Sample ID Animal ID

1504417 0608532 606270064 IM051966/C16680

Mycobacterial Isolation
Diagnosis: No Isolation Made

Specimen Submitted
THYMUS MASS

10/4/2006

DISTRIBUTION:

Submitter
9/13/2006

Approved By: Jeffrey T. Nelson
National Veterinary Services Laboratories

10/4/2006

Ehlenfeldt, Robert G DATCP

From: Doris.Olander@aphis.usda.gov
Sent: Friday, October 20, 2006 11:05 AM
To: paul.mcgraw@datcp.state.wi.us; robert.ehlenfeldt@datcp.state.wi.us
Cc: Thomas.J.Varty@aphis.usda.gov
Subject: Convance

looks like they may finally be able to get an isolate..

Doris Olander, DVM
TSE Coordinator
USDA/APHIS/VS - WI
6510 Schroeder Road, Suite 2
Madison, WI 53711

Tel. 608 270 4000 ext. 4082
Fax 608 270 4001

Forwarded by Doris Olander/WI/APHIS/USDA on 10/20/2006 11:03 AM

National Veterinary Services Laboratories
1800 Dayton Road Ames, Iowa 50010
Phone (515) 663-7266 Fax (515) 663-7397
Tuberculosis Laboratory Test Report Page 1 of 1
FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish)
1-800-877-8339

***** This is a confidential report for official use only. *****

Accession: 446393 Date Received: 7/14/2006

Establishment No.: WISEEM Referral Number: 06WIJLS0707
SEEMAN, DR. JENNIFER Owner: COVANCE LABS
3301 KINSMAN BLVD. City: MADISON
State: WI

MADISON, WI 53704
Fax: 6082427989

Preservation:

Retain Tag: Species: Monkey

NVSL ID Case # Sample ID Animal ID

1504419 0608534 606270080 IM053021/C17600

Identification
Diagnosis: Mycobacterium tuberculosis

Mycobacterial Isolation

10/20/2006

Diagnosis: Acid Fast Organism Isolated

Specimen Submitted
LN-MEDIASTINAL

DISTRIBUTION:

Submitter
10/19/2006

Approved By: Janet Payeur
National Veterinary Services Laboratories

10/20/2006