Our vision:
To excel as a science-based regulator, trusted and respected by Canadians and the international community.

Our mission:
Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

Key Aspects

- No single test ante-mortem is sufficient to "rule-out" rabies.
- If onset of symptoms is <7 days, a negative test result does not exclude rabies virus infection as excretion may be intermittent and antibody response may be negligible.
- Additional specimens, collected later in disease progression, may be needed to completely rule-out rabies.

Index:

RABIES TESTING AT THE CFIA: HUMAN SPECIMENS

HUMAN SUSPECT SUBMISSION PROCESS

DISEASE INVESTIGATION—FACTORS TO CONSIDER

- Encephalitis of undetermined cause, rapid deterioration, hospitalization
- Animal bite or contact history
- Travel to a country or area where terrestrial rabies is enzootic e.g. dog rabies in Africa/Asia

CONTACT CFIA RABIES LABORATORY IN OTTAWA

- After consultation with hospital regarding types of samples and urgency of testing, CFIA arranges to have staff available for specialized testing, including overtime, if required
- CFIA provides required documentation to hospital, including Rabies Sample Submission Form (fillable pdf), as well as any special instructions.

ELECTRONIC FORM COMPLETION

- Only one form per patient, even if multiple samples are sent for testing.
- Enter information in the fillable pdf Rabies Sample Submission Form and email it to the laboratory.

PACKAGING AND SHIPMENT TO LAB

- Hospital collects the required samples (nuchal skin biopsy, multiple saliva samples). Package samples, include printed copy of form, and arrange for shipment to the lab.
- Complete and fax or email the notification page (page 9) to inform the lab of shipment details.
- Track shipment until it arrives AND a "Rabies Sample Receipt Notification" email is received from CFIA.

TESTING AND REPORTING OF RESULTS

- When the sample is received at CFIA, an email notification will be sent to the submitter indicating the sample is "Under Test".
- CFIA conducts diagnostic testing (number and type of tests depends on the samples received) and authorizes release of test results.
- CFIA reports results by phone to submitter listed on Rabies Sample Submission form as tests are completed.
- Official "Report of Analysis" for all samples will be emailed to all email addresses provided by submitter on the form as testing is completed.
- If rabies virus is detected, variant typing is conducted and results are communicated to the submitter.
- Hospital notifies OLF if further testing is required (e.g. testing of additional samples; monitoring of viral load in saliva)

Canada

HUMAN RABIES CASES IN CANADA

Rabies in humans is rare in Canada. Since 1924, only 28 cases have been documented. The last reported case of domestically-acquired human rabies caused by a terrestrial mammal occurred in 1967 in Richmond, ON. Since that time, all cases but two were attributed to infection from bats. The remaining two cases (1984 and 2012) were acquired in the Caribbean, the result of dog bites.

Oral vaccination programs and other disease control strategies targeting certain terrestrial wildlife species have been effective in controlling (and in some cases, eliminating) rabies in a number of Canadian provinces. However, not all provinces have wildlife rabies control programs, and rabies control in bat populations is not possible. Even though bats carry their own distinct variants of the rabies virus, infected bats are able to transmit the virus to other mammals. These cases are referred to as "spillover". Several spillover cases from bats into domestic animals are reported each year in Canada, with the potential to transmit the virus to humans. Thus, there is still the risk of exposure to rabies from animals throughout Canada, even in the absence of known epizootics in terrestrial mammals.

In addition to a clinical picture consistent with rabies, examination of other factors is important for evaluating the possibility of rabies. Provide the laboratory with as much information as possible to assist in the selection of appropriate reagents for rabies diagnosis and virus typing.

PRIME CONSIDERATIONS IN SUSPECT RABIES CASES

Patient travel history:

Travel to countries where rabies in endemic, particularly in dogs, should be considered a risk factor for rabies, even in the absence of a known exposure to a rabies vector. As the disease can also be caused by related *Lyssaviruses*, such as Australian bat lyssavirus (ABLV), travel to countries free of rabies virus may still be a risk factor. The CFIA laboratory can provide advice on the distribution of rabies and other lyssaviruses within Canada and worldwide.

Potential rabies exposures:

The incubation period for human rabies is normally between one and three months, but may vary between 10 days to more than a year. Recent or past contact with bats or other mammals is a risk factor for rabies, particularly in rabies endemic-regions. Category III exposure is defined as single or multiple transdermal bites or scratches, licks on broken skin, or contamination of mucous membranes with saliva. Category II exposure is defined as nibbling of uncovered skin or minor scratches or abrasions without bleeding. Both types of exposure can result in transmission of the virus from an infected animal to a person.

TESTS OFFERED AT OTTAWA LABORATORY FALLOWFIELD—OLF

At the OLF, diagnosis of rabies in humans may be performed by the following tests: fluorescent antibody test (FAT) on nuchal skin biopsy (antemortem) or brain tissue (postmortem) and real-time reverse transcriptase polymerase chain reaction (RT-PCR) on skin, saliva or brain tissue. Virus variant typing by genetic sequence analysis or using discriminatory monoclonal antibody panels is also performed. The CFIA does not carry out serologic tests for rabies virus antibody. For serologic testing, contact Public Health Agency of Canada, National Microbiology Laboratory, Winnipeg, MB.

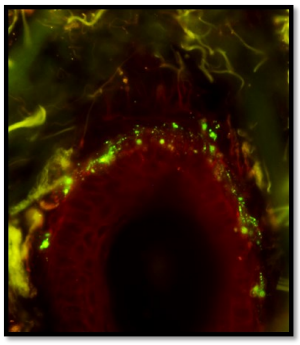
NUCHAL SKIN BIOPSY—ANTEMORTEM TESTING

Skin at the nape of the neck containing many hair follicles is highly enervated. As such, rabies virus antigen may be detectable antemortem by FAT if centrifugal spread from the CNS has occurred.

A full thickness biopsy of at least 5 mm and containing several hair follicles should be taken. Place moistened gauze in a container with the biopsy tissue, but do not wrap the tissue. Store at 4°C or –20°C until ready to ship.

At the lab, the skin is frozen and sectioned using a cryostat. Multiple sections are tested by the FAT. RT-PCR tests may also be performed.

If rabies virus antigen is detected, the remaining skin will be processed to extract viral RNA and the rabies virus variant will be determined by sequence analysis. For these reasons it is important to submit a biopsy of adequate size to provide sufficient tissue for multiple tests.



SALIVA—ANTEMORTEM TESTING

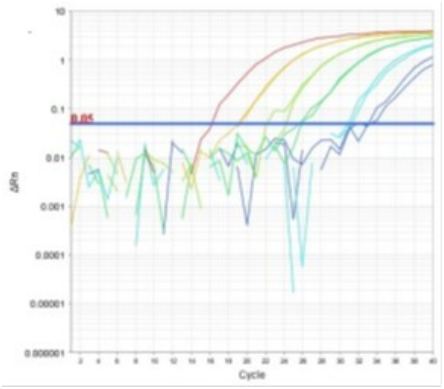


Image of amplification curves of serial 10-fold dilutions of rabies virus in qRT-PCR

Saliva may be submitted for testing by real-time RT-PCR. Collect 2-3 ml of saliva directly into a sterile tube or aspirate and dispense into a sterile, leak-proof container. Do not add preservatives or additional material. Immediately freeze at –20°C, or lower, to prevent degradation of the viral RNA.

Serial samples taken at least 12 hours apart, and preferably 24 hours apart, will increase the sensitivity of the assay as excretion of rabies virus may be intermittent in the early stages of the disease.

The presence of bile or blood may interfere with the testing. However, if the only samples available are thus contaminated, they can still be submitted and the laboratory will attempt to test them.

DIAGNOSED RABIES CASES AND VIRAL LOAD MONITORING

If the patient is receiving medical care in an effort to sustain life, monitoring of the rabies virus load in the saliva may be requested.

Samples should be collected at a frequency of every 24 hours. Clearly mark the date and time of collection on the individual tube.

Results will be expressed as cell culture infectious dose Equivalent Units (EU) per ml of saliva. EU is determined by interpolation of the test result on a standard curve of dilutions of known concentrations of rabies virus.

POSTMORTEM EXAMINATION OF CNS TISSUE

Fresh (not fixed) brain tissue should be submitted for testing. A small section (1 cm x 1 cm x 1 cm) from the brain stem is suitable for diagnosis. Additional tissues such as cerebellum, pons, medulla, hippocampus and spinal cord may also be submitted. Do not submit only cerebrum as it generally has lower levels of rabies virus antigen than other parts of the brain.

Place the tissue into a leak-proof container so it will not be damaged during transit. Store the sample at 4°C or lower until ready to ship.

At the lab, the tissue will be examined by FAT. If rabies virus antigen is detected, the virus will be typed by staining with a panel of specific anti-rabies antibodies or by genetic sequencing.

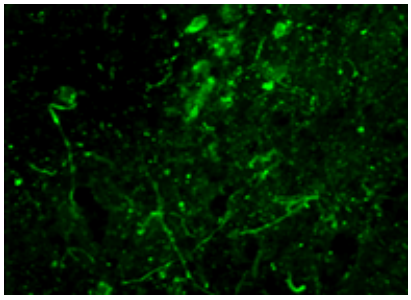


Image of rabies virus antigen in brain tissue detected by FAT

SUMMARY OF SPECIMENS FOR ANTEMORTEM TESTING

- No single test ante-mortem is sufficient to "rule-out" rabies.
- If onset of symptoms is <7 days, a negative test result does not exclude rabies virus infection as excretion may be intermittent and antibody response may be negligible.

Specimen	NUCHAL SKIN BIOPSY	SALIVA	CEREBROSPINAL FLUID
Recommended for Diagnosis?	**YES**	**YES**	**NO**
Collection	Full thickness biopsy, at least 5mm diameter, with several hair follicles.	Multiple collections at least 12 hours apart, 2 to 3 ml each sample.	1 ml
Container	Sterile specimen container with moistened gauze beside tissue DO NOT wrap tissue	Sterile tube/vial No preservatives	Sterile tube/vial
Storage	4 or -20°C	-20°C or lower	-20°C or lower
Tests	√ Fluorescent antibody technique √ Real-time RT-PCR	√ Real-time RT-PCR	√ Real-time RT-PCR
Notes:	Multiple tests are conducted, submit biopsy of adequate size.	Bile or blood may interfere with testing.	Frequently UNFIT due to lack of patient DNA which serves as control for successful sample extraction and amplification. Contact PHAC-NML for serological testing.

LABELS ON PARCEL

For both the shipper and recipient address use a minimum of 16-point font, bold type.

1) SHIPPER: Submitter's name, address and phone number
2) RECIPIENT: R-Unit, Canadian Food Inspection Agency, 3851 Fallowfield Road, Ottawa ON K2J 4S1
   343-212-0340
3) Biological Substance, Category B and UN3373 diamond-on-point
4) 24 hour emergency contact phone number

Ensure the parcel is packaged according to all relevant Transportation of Dangerous Good Regulations.

EXAMPLE SUBMISSION FORM

Go to first empty field | << | < | > | >> | Submit | Clear | Print

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

PROTECTED A when completed

View the Privacy Notice Statement

Rabies Sample Submission

Samples submitted from cattle that test negative for rabies may be tested for other federally regulated diseases.

For Laboratory Use Only

Laboratory Number

Date Form Submitted	Date Shipped (required)	Laboratory (required)	Date Received
	2026-01-01	OTTAWA - 1089	

Animal Sample Information (required)

Animal Species	Specify Species	Sample Identification
HUMAN		ABC123456

Suspect Animal Disease History: (•) Disease Symptoms ( ) Other (Specify in Comments)

Preservative: (•) Fresh ( ) Other (Phone Laboratory)

Animal Sample Location (Georeferenced Coordinates) (required)

Latitude	Longitude	Province	City
45	-75	ONTARIO	HOSPITAL LOCATION OR COUNTRY OF EXPOSURE

Exposure Information (Minimum WHO Category II) (required)

Human Exposure? (•) Yes ( ) No

Type of Exposure (Saliva Contamination): [ ] Bite [ ] Scratch [ ] Open Wound [x] Mucous Membrane

Part of Body Exposed: [ ] Limb [x] Neck/Head [ ] Torso [ ] Other (Specify in Comments)

Domestic Animal Exposure? ( ) Yes (•) No

Exposure: [ ] Evidenced? [ ] Suspected?

Domestic Animal Species Exposed:

Submitter Comments: Skin biopsy (Unique ID 1), Saliva 1 (Unique ID 2), Saliva 2 (Unique ID 3), Saliva 3 (Unique ID 4). Describe animal exposure history and travel history

Affected Party (e.g. Domestic Animal Owner, Person Who Reported Wildlife Exposure) (required)

Initials	City	Province
NONE	LOCATION OF HOSPITAL	QUEBEC

Intermediary Party (e.g. Animal Health Laboratory, Hospital, Humane Society, Veterinary Clinic)

Name	City		
LABORATORY OR PUBLIC HEALTH CONTACT			
Province	**Telephone No.**	**Extension No.**	**Email Address**
YUKON TERRITORY	(123) 555-6789		

Submitter Information (required)

Name	Employer		
PHYSICIAN RESPONSIBLE FOR ACTION ON RESULT	HOSPITAL NAME		
Primary Email Address	**Other Email Address 1**	**Other Email Address 2**	
DOCTOR@EMPLOYER.CA	DOCTOR2@EMPLOYER.CA	DOCTOR3@EMPLOYER.CA	

City	Province	Telephone No.	Extension No.	Cellphone No.
MONTREAL	QUEBEC	(123) 555-6698		

For Laboratory Use Only

Sample Condition [ ] Good [ ] Poor — Wildlife Surveillance Sample ( ) Yes ( ) No

Test	Result			Date Phoned	Initials
[ ] Fluorescent Antibody (FAT)	[ ] Positive	[ ] Negative	[ ] Unfit		
[ ] Other (Specify Below)	[ ] Positive	[ ] Negative	[ ] Unfit		

Laboratory Comments

Result Entered	Result Authorized	Reference Number

Canada

CFIA / ACIA 2908 (2024/02)
LSTB-2908-E-V1.2

Canada

COMPLETING THE RABIES SAMPLE SUBMISSION FORM

COMPUTER SYSTEM REQUIREMENTS

☑ Internet connection

☑ Adobe® Reader version 9 or higher. Free download is available at: http://get.adobe.com/reader/otherversions/

☑ Operating System: any operating system, as long as it can run Adobe® Version 9. The hardware requirements are listed at the adobe web site: http://www.adobe.com/ca/products/reader/tech-specs.html

INSTRUCTIONS FOR DATA ENTRY

1) Save the Rabies Sample Submission form provided by the lab to your desktop.
2) Close all internet browsers that are open.
3) Ensure that your Adobe® Reader is configured to open as a separate program, and does not open in your internet browser.
4) Open the file. The form will have certain fields pre-populated. Enter information in all the fields that are in **bold text** below.

Contact your internal IM/IT computer system support if you are unable to open the Adobe® pdf form, if you receive a Firewall warning message or if you are unable to print the form.

Only one form is prepared per patient, even though there may be multiple samples that will be shipped for testing.

Date Shipped
Enter the date that the sample is given to the courier for transport to the laboratory. The format is Year (4 digits) Month (2 digits) Day (2 digits) (e.g. 20140123) or use the calendar box provided.

Sample ID
Enter the unique patient identifier that has been assigned by the hospital. Maximum 20 characters. Character choices are limited to: "A-Z", "0-9", spaces, dashes "-", underscores "_" , and forward slashes "/".

Animal Sample Location: Province
Select the province/territory of the location of the patient from the drop-down list.

Animal Sample Location: City
Enter the name of the City where the hospital is located.

Human Exposure?
Check "Yes", if patient has potentially exposed other people. If "Yes" is selected, you must populate the boxes to describe the "Type of Exposure" and the "Part of Body Exposed".

Submitter Comments
Enter information such as pertinent clinical history (e.g., duration of the illness, description of clinical signs) and the samples that are being submitted. This field is restricted to 234 characters.

Intermediary Party Name (Optional)
Please specify the exact name of the Laboratory, Hospital, etc., if an intermediary was involved in the case. Include physician name, if applicable.

Intermediary Party City (Optional)
Enter city of the intermediary party.

Intermediary Party Province (Optional)
Select the province or territory from the drop-down list.

Intermediary Party Telephone No. (Optional)
Please specify the telephone number if results are to be conveyed this party as well as the submitter. Format is 10 digits with no spaces, dashes or brackets.

Intermediary Party Extension No. (Optional)
Enter telephone extension number.

Intermediary Party Email Address (Optional)
Please specify the email address if results are to be conveyed to this party as **well as to the submitter.**

Submitter Name
Enter the full name of the submitter.

Submitter Employer
Enter the name of your employer, e.g., hospital; Public Health Unit; etc.

Submitter: Primary Email Address
Please specify the email address that will be used for conveying information including results.

Submitter: Other Email Address (Optional)
Two additional email addresses may be entered. The report of analysis will be sent to these addresses as well as the primary address, and the intermediary party, if applicable.

Submitter City
Enter the city of the submitter.

Submitter Province
Select the province or territory from the drop-down list.

Submitter Telephone No.
Please specify the telephone number to which results are to be conveyed. Format is 10 digits with no spaces, dashes or brackets. The laboratory will not leave messages on phones that do not have the physician's and/or organization in the recorded message.

Submitter Extension No. (if applicable)
Enter telephone extension.

Submitter Cellphone No. (Optional)
Please specify the cellular telephone number to which results are to be conveyed. Format is 10 digits with no spaces, dashes or brackets.

Once data entry has been completed, and the information has been verified, email the file to: cfia.rabieseast-rageest.acia@inspection.gc.ca. The laboratory will complete the electronic submission on your behalf.

SHIPPING TO OTTAWA LABORATORY FALLOWFIELD-OLF

Day	Air Freight	Courier	Medical Transport
Monday-Friday	Lab will arrange for pick-up from the airport. Provide the following information in advance: Waybill/tracking number, Airline, Flight Number, and the expected date and time of arrival.	Major companies deliver to our site (e.g. Purolator, FedEx, DHL, UPS) once per day. At the present time, Purolator is the only company that routinely makes deliveries to this site before 10 am. Other couriers deliver throughout the day until 4 pm, when our receiving department closes. If you want testing conducted on the day of delivery then we suggest that you use Purolator or upon consultation with the laboratory, alternatively have the sample shipped to the depot (see next section).	The Guardhouse at our location will accept parcels daily between 06:00 am and midnight, including weekends and statutory holidays, year-round.
Saturday	Same as for Monday-Friday.	Some couriers, at special request, will deliver on Saturday. For Saturday delivery, ship to the courier's depot. To expedite processing, the lab will arrange for pick-up from the depot, if notified in advance. √ Change shipping address to **"DEPOT" and include the street address of the courier's depot location**. √ Mark the package **"HOLD FOR PICK-UP"**. √ If shipping on Friday, and to ensure that the sample arrives on Saturday, **CHECK OFF "SAT/SAM"** delivery on the electronic waybill. √ **DO NOT SELECT "DELIVERY BY 9 OR 10 AM"** as this option applies only to Monday to Friday regular delivery service. If selected, this may result in delivery on the next business day and the specimen not being available for pick-up. Use the courier's tracking number to check that the parcel has been picked up at the depot by the CFIA.	Same as for Monday-Friday.
Sunday and Holidays	Check with airline to ensure that the cargo office is open for parcel pick-ups.	There is NO Sunday or holiday service available from any of the couriers for delivery to this location. For the Canadian government holidays (November 11 and Easter Monday) deliveries are not accepted so couriers will not come to the site even though they are open for business. If you wish for a sample to be tested on these days, please refer to instructions for shipping to depot. For the provincial family day holiday in February, the laboratory is open but couriers are closed.	Same as for Monday-Friday

HUMAN SAMPLE SUBMISSION FOR RABIES

If testing is required notify the laboratory at 343-212-0340.

Complete this page and either FAX to 343-212-0202 or email to cfia.rabieseast-rageest.acia@inspection.gc.ca

Complete a "Rabies Sample Submission" form (see pages 6-7) and email to the lab. Enclose a paper copy with the shipment.

Please provide the following information so that we may cross-reference to the form:

Submitter Name:

It is the responsibility of the submitter to select a method of transportation that will ensure the delivery of the specimen. Consult page 8 for details.

Courier Company or Airline:

Tracking Number:

Date and Time of Expected Arrival:

Patient Hospitalized: YES NO Date of Illness Onset:

Animal Exposure History? NO or YES, describe including species and nature of exposure

Travel History outside of home province? NO or YES, list provinces and/or countries

Additional Comments:

Samples Submitted:

Sample Type	Submitted Yes or No	Date/time 1	Date/time 2	Date/time 3	Date/time 4
Saliva					
Nuchal biopsy					
Cerebrospinal Fluid					
Postmortem brain/CNS tissue					

For further information, contact:

R-Unit, Ottawa Laboratory
Fallowfield
Canadian Food Inspection Agency
3851 Fallowfield Road
Ottawa ON K2J 4S1

Mon-Fri 8 am - 4 pm ET

Phone: 343-212-0340
Fax: 343-212-0202
E-mail: cfia.rabieseast-rageest.acia@inspection.gc.ca

We're on the Web
inspection.canada.ca

THE PROBABILITY OF DETECTING VIRUS IN PERIPHERAL TISSUE INCREASES WITH DISEASE PROGRESSION.

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