	INSTRUCTIONS	I-TE-04/EN
	Instructions and conditions for accepting requests for assays and samples	Version 03 Dated: 25/09/2023

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II. Introduction

The purpose of this instruction is to inform our customers about the analyses that can be performed by the CIRAD ASTRE research unit laboratory, and how to request an analysis. The document includes:

- the instructions for requesting an assay together with conditions for accepting requests and samples
- the procedure for processing non-compliant requests and samples
- the procedure for reporting results (assay report) to the customer

This instruction is addressed to CIRAD ASTRE laboratory staff involved in the assays and to our customers (by extension, the Directorate of Veterinary Services, Departmental Veterinary Laboratories, Departmental Analysis Laboratories, veterinary laboratories, breeders, etc.).

III. Instructions for handing requests for analysis

III.1 Assays performed by CIRAD ASTRE research unit laboratory in Montpellier

Disease	Pathogen	Species	Technique	Sample
Peste des Petits Ruminants (PPR)	<i>Peste des Petits Ruminants Virus (PPRV)</i>	Goats, Sheep	ELISA*	Serum
			Real time RT-PCR	Ocular or nasal swabs, tissues (organs), feces
Rift Valley Fever (RVF)	<i>Rift Valley Fever Virus (RVFV)</i>	Cattle, Goats, Sheep	ELISA*	Serum
			Real time RT-PCR	Serum, blood, organs
Contagious bovine Lumpy Skin Disease (LSD)	<i>Lumpy Skin Disease Virus (LSDV)</i>	Cattle	ELISA*	Serum
			Real time RT-PCR*	Nodules/skin, whole blood, Nasal, oral or ocular swabs
Sheep/Goat Pox	<i>Sheep pox virus & Goat pox virus (SPPV/GTPV)</i>	Sheep or Goats	ELISA	Serum
			Real time RT-PCR	Nodules/skin, whole blood, Nasal, oral or ocular swabs
Contagious Bovine Pleuropneumonia (CBPP)	<i>Mycoplasma mycoides sub-species mycoides</i>	Cattle	ELISA*	Serum
			PCR	Bacterial culture, pleural fluid, lymph nodes, lung
Contagious Caprine Pleuropneumonia (CCPP)	<i>Mycoplasma capricolum sub-species capripneumoniae</i>	Goats	ELISA*	Serum
			PCR	Bacterial culture, pleural fluid, ganglions, lung

CIRAD laboratory works within the framework of a quality management system. It is accredited by COFRAC in compliance with standard NF EN ISO/IEC 17025. Analyses indicated by an asterisk (*) are covered by accreditation "CIRAD N° 1-2207" (scope available at www.cofrac.fr).

N.B. This list of the services offered by the ASTRE laboratory is not exhaustive. Please contact the laboratory for further details (contact details below).

III.2 Requesting the laboratory for an assay and conditions for accepting requests

III.2.1 Requesting assays

Customers can request assays by phone, e-mail, or by post. The analysis request form “Assay request form (Montpellier & Reunion Island)” can be used. It is available on the research unit’s website (<https://umr-astre.cirad.fr/expertises/diagnostics-analyses>).

The assay request must be accepted before samples are dispatched to the laboratory.

Laboratory contact details:

<i>Address</i>	CIRAD - UMR ASTRE TA A-117 / E Phone switchboard: +33 (0) 499 624 893 Campus International de Baillarguet 34398 MONTPELLIER cedex 5 FRANCE	
<i>Import/Export Manager</i>	Denise Bastron/ Clemence Rinaudo	Tel : +33 (0) 467 593 904 ; +33(0)499 624 893 Email: secretariat.astre@cirad.fr
<i>Technical Manager PPR Biologist</i>	Arnaud Bataille	Tel: + 33 (0)467 593 821 Email: arnaud.bataille@cirad.fr
<i>Technical Manager LSD/SPPV/GTPV Biologist</i>	Philippe Caufour	Tel: + 33 (0)467 593 816 Email: philippe.caufour@cirad.fr
<i>Technical Manager CCPP/CBPP Biologist</i>	Lucía Manso-Silván	Tel : +33 (0)467 593 739 Email: lucia.manso-silvan@cirad.fr
<i>Technical Manager RVF Biologist</i>	Catherine Cêtre-Sossah	Tel : +33 4 67 59 38 34 Email: catherine.cetre-sossah@cirad.fr
<i>Quality Manager</i>	Dominique Sionneau	Tel: + 33 (0)467 593 713 Email: dominique.sionneau@cirad.fr

III.2.2 Conditions for acceptance of assay requests

The assay request must contain the following information:

- customer's name, postal address and e-mail address
- identification of the method to be used
- description and precise identification of the items to be analyzed

NOTE: Where the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Changes to the method will not be made unless they have been documented, justified, authorized and accepted by the customer.

After mutual agreement between the customer and CIRAD (by phone or e-mail, or as defined in the contract or in the technical specifications), a written request for analysis must be issued, in order for it to be formally accepted. Where applicable, that request may serve as a contract.

III.3 Shipping instructions and conditions of admissibility of samples

The client sends the samples to the laboratory (address §III.2.1).

The name of a recipient (the technical manager biologist or other contact person) must appear on the package with the laboratory's address.

ASTRE import/export manager will provide the customer with instructions on how to dispatch the samples and with the corresponding "Advice Sheet" if required. With the customer, the manager will track the package and provide the customer with the import and accompanying documents. No infectious materials shall be shipped without prior agreement between the sender, packer, transporter and consignee regarding regulatory issues (packaging, labelling, declaration, etc.).

III.3.1 Recommendations for sample storage

To maintain the integrity of samples prior to their arrival at CIRAD, conservation conditions to be respected immediately after sampling and during transport are listed in the table below.

In all cases, CIRAD's responsibility begins only on reception of the samples.

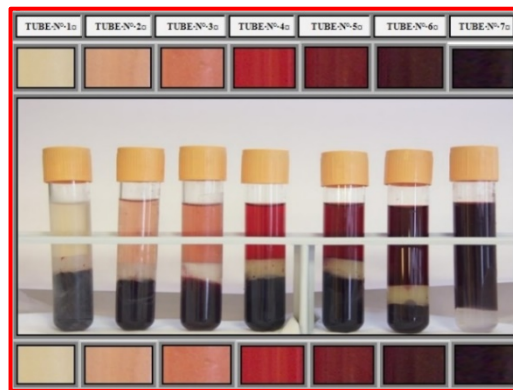
Sample storage and transport conditions

Technique	Recommended samples	Disease	Sample characteristics	Recommended storage prior to delivery	Recommended transportation conditions and times	Storage after delivery
ELISA	Serum	All diseases	Approx. 1 mL	Freeze rapidly at $\leq -16^{\circ}\text{C}$; otherwise, store above freezing (around $+5^{\circ}\text{C}$) ≤ 5 days	Preferably frozen at $\leq -16^{\circ}\text{C}$; ice packs ≤ 3 days	$5 \pm 3^{\circ}\text{C}$ for ≤ 3 days; frozen at $\leq -16^{\circ}\text{C}$ with no time limit
PCR/PCR Real time PCR	Blood	LSD, Sheep pox / Goat pox	At least 1 mL in an EDTA tube	≤ 5 days above freezing (around $+5^{\circ}\text{C}$); otherwise freezing at $\leq -65^{\circ}\text{C}$ (failing that $\leq -16^{\circ}\text{C}$)	Ice packs ≤ 3 days	$5 \pm 3^{\circ}\text{C}$ ≤ 3 days; frozen at $\leq -65^{\circ}\text{C}$ with no time limit
	Serum	RVF	1 ml approx.	Frozen, preferably at $\leq -65^{\circ}\text{C}$, otherwise $\leq -16^{\circ}\text{C}$	Preferably frozen at $\leq -16^{\circ}\text{C}$; ice packs ≤ 3 days	Frozen at $\leq -65^{\circ}\text{C}$ with no time limit $5 \pm 3^{\circ}\text{C}$ ≤ 3 days
	Swab	PPR	After complete drying, placed the swab in a tube with no conservation agent	Frozen, preferably at $\leq -65^{\circ}\text{C}$, otherwise $\leq -16^{\circ}\text{C}$	Dry ice ≤ 5 days	Frozen at $\leq -65^{\circ}\text{C}$ with no time limit
	Feces	PPR	Around 2 mL in a tube with no conservation agent	Frozen, preferably at $\leq -65^{\circ}\text{C}$, otherwise $\leq -16^{\circ}\text{C}$	Dry ice ≤ 5 days	Frozen at $\leq -65^{\circ}\text{C}$ with no time limit
	Tissues	CBPP CCPP, PPR, RVF	Around 2 mL with no conservation agent	Frozen, preferably at $\leq -65^{\circ}\text{C}$, otherwise $\leq -16^{\circ}\text{C}$	Dry ice ≤ 5 days	Frozen at $\leq -65^{\circ}\text{C}$ with no time limit
LSD, sheep pox, goat pox		At least 1 g with no conservation agent	≤ 3 days above freezing (around 5°C); otherwise freeze at $\leq -65^{\circ}\text{C}$ (failing that, $\leq -16^{\circ}\text{C}$)	Ice packs ≤ 3 days	$5 \pm 3^{\circ}\text{C}$ for 2 days. Frozen at $\leq -65^{\circ}\text{C}$ with no time limit	

III.3.2 Conditions of admissibility of samples

On receipt, the laboratory will check that samples comply with the following:

- The sample is accompanied by an assay request
- The provenance of the sample is clearly identified
- The sample matches the information on the work request form (nature, number, transit time, etc.).
- The sample must be in an appropriate intact tube or flask
- Quantity of sample should be sufficient to perform at least two assays
- Quality of sample must be compatible with the test procedure:
 - The sample must not display any obvious bacterial or fungal contamination, or have the smell/appearance of putrefaction
 - Samples for serological analyses shall not be decomplemented or display high hemolysis (> hemolysis tube 6 below).



Special cases:

- For LSD and sheep pox/goat pox analyses by PCR in real time using whole blood, the sample should not be placed in a heparinized tube (due to the risk of PCR inhibition). Another anticoagulant, such as EDTA, should be used instead.

III.4 Procedure for handling non-compliant requests and samples

If the above-mentioned conditions for acceptance are not met, the laboratory will contact the customer to complete/clarify the request, or alternatively, to cancel it.

The laboratory assesses the relevance of the request on a case-by-case basis before carrying out the test (e.g. when the sample set is of unsuitable nature or quality).

If only some samples are unacceptable, the action taken will depend on the nature of the request:

- When the tests concern only one animal, any non-compliance of the sample will affect the results and must be discussed with the customer.
- When the tests concern a herd, the customer shall only be contacted if the items sent for analysis (e.g. the minimum number of samples required for testing) make it impossible to fulfil the request.

All discussions with the customer are recorded in writing and kept with the request.

III.5 Reporting results by CIRAD

III.5.1 Timelines

Results will be sent to the customer within the requested time limit, the time limit mentioned in the technical instructions received from the customer or the urgency associated with the samples processed.

If the laboratory is unable to provide analyses that comply with the standard and with its own internal criteria within the allotted time, the customer will be contacted. If the time needed to provide conforming tests is too long, the customer may cancel the work request.

III.5.2 Reporting test results

A status is given to each result: for instance, a sample may be declared “positive” or “detected”, “negative” or “undetected”, or even “dubious” in certain methods, depending on the criteria used to interpret the results of the method used. For PCR, a qualitative result is reported for each sample in the test report. As far as possible, ELISA results are reported in numerical form and the positivity threshold for the corresponding method is clearly indicated in the report.

For each accredited ELISA assay, the laboratory defines its measurement uncertainty at based on an "internal reference material (IRM) positioned around the positivity threshold. Based on that uncertainty, a sample may also be declared “positive close to the threshold”, “negative close to the threshold”, if the measurement uncertainty associated with the result overlaps the threshold established for the method. In these cases, the measurement uncertainty established by the laboratory for the ELISA method used is specified in the assay report.

III.5.3 Opinions and interpretations/expert appraisal

The laboratory does not issue opinions and interpretations under standard ISO/IEC 17025. However, as part of its remit as a reference laboratory, it can provide an expertise report (not under accreditation), independently of the assay report.

Such expert appraisal reports are based on the following:

- authoritative scientific publications in the field
- prescribed texts (e.g. OIE manual of diagnostic tests and vaccines for terrestrial animals)
- knowledge of disease epidemiology
- staff members’ personal experience of the disease in question

In the event of positive results for a pathogen subject to OIE compulsory notification, the laboratory will remind the customer of their responsibility to contact the OIE to declare them.

III.5.4 Procedure for sending assay reports and conditions for affixing the COFRAC logo

The assay report will be sent by e-mail to the e-mail address(es) supplied by the customer using the CIRAD messaging service.

The COFRAC logo is affixed to the report when it contains at least one result for a sample covered by COFRAC accreditation. The results for samples not covered by the accreditation are clearly identified in the report.

Any reproduction of the test report by the client requires prior written authorisation from CIRAD. Clients are not authorised to reproduce the CIRAD UMR117 Montpellier accreditation mark. Any reference to the CIRAD UMR117 Montpellier accreditation must mention: "COFRAC Accreditation Tests, CIRAD n° 1-2207, implementation and scope available at www.cofrac.fr". The laboratory must inform the client and COFRAC of any erroneous or unauthorised use of the CIRAD UMR117 Montpellier accreditation mark by the client.

III.5.5 Reporting of non-compliant results

Any anomaly or divergence from the customer's request (for instance, any addition, difference or suppression in the methods used) shall be recorded and passed on to the customer in the assay report.

With the customer's agreement, the laboratory may issue an assay report including non-conforming results provided they are clearly identified as "not covered by accreditation" and the anomaly or deviation, along with any possible impact on the results and conclusions, are clearly detailed. In such cases, the following words shall be included in the test report: "The sample results that do not conform with the requirements specified by CIRAD are subject to reservations".

In cases where all the samples are considered non-conforming, the words "assay performed subject to reservations" shall be included in the assay report.

III.5.6 Re-issuing of an assay report

If an assay report has to be re-issued by the laboratory:

- The number of the new report shall be followed by the incrementation number + 1
- The new report shall bear the words "supersedes assay report No.—dated—"
- The reason for the recall and the possible impact on the results and conclusions shall be mentioned in the new report, and any modification made shall be traceable
- The e-mail accompanying the new report shall remind the clients of their responsibility to destroy the report it replaces or to return it to CIRAD
- The laboratory shall keep the original report that has been re-issued

III.6 Subcontracting assays

The CIRAD laboratory does not sub-contract assays.

III.7 Fate of samples

Unless otherwise stated by the customer, samples will be kept for one month after the assay report is sent to the customer. Thereafter, the samples shall be destroyed, or placed in a sample bank (unless the customer states otherwise). The same conditions apply if the customer cancels the request.

III.8 Confidentiality

CIRAD is bound by the confidentiality concerning information that comes to its knowledge in connection with any assay requests received. If a general agreement has been signed between CIRAD and the customer, other confidentiality conditions may be added to the procedures laid down in the present document.

Within the scope of our accreditation, auditors (internal and external) are required to consult test reports. This consultation is covered by the confidentiality clause to which the auditors have committed themselves.

The security of the CIRAD information system is guaranteed by regularly updated software packages, in accordance with the CIRAD IT charter (available on request).

III.9 Customer satisfaction

When the assay report is dispatched, a link is sent to the customer to access the “customer satisfaction” survey form and the “claims” form.




IV. References

- Assay request form (Montpellier & Reunion Island)
- Advice sheets: instructions for the transport of biological materials

IV. Abbreviations

CBPP: Contagious bovine peripneumonia
CCPP: Contagious caprine pleuropneumonia
DAL: Departmental Analysis Laboratory
DVL: Departmental Veterinary Laboratory
ELISA: Enzyme-linked immunosorbent Assay
GTPV: Goat pox virus
LSD: Contagious bovine lumpy skin disease
PPR: Peste des Petits Ruminants
RVF: Rift Valley fever
SPPV: Sheep pox virus
VSA: Veterinary Services Authority

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Date:	21/09/2023	21/09/2023	21/09/2023

Signature			
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