

## REPORT

# A BRIEF REPORT ON ACCREDITATION OF THE KVAFSU-CVA RABIES DIAGNOSTIC LABORATORY IN COMPLIANCE WITH ISO/IEC 17025:2017

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The laboratory is a system, that involves several steps of activity and people. The complexity of this system requires various processes and procedures to be performed properly. Laboratory tests are routine procedures employed to look for changes in the health system of host. Such tests enable the proper diagnosis of health conditions and in turn evaluate the treatments and monitors the disease. As the major decisions on application of the suitable disease treatment / control strategy are based on such laboratory tests, these must be accurate, reliable and reportable on time. In order to achieve such high level of accuracy and reliability, it is essential to apply all laboratory processes and procedures in the best possible manner. Nevertheless, while testing, there is always some amount of inaccuracy. But the challenge is to minimize the level of inaccuracy keeping in view the limitations of the testing systems.

A system that manages the quality issues involving the entire laboratory system is important for achieving good laboratory performance. This situation demands accreditation of a testing laboratory. In brief, this is an assessment carried out by an accreditation institute to ensure and convey to the general public that the laboratory is qualified and competent in carrying out their tasks effectively and that their results are reliable. At present, in India there are two such agencies which assess laboratories for their competence viz., the National Accreditation Board for testing and calibration Laboratories (NABL) and Quality and Accreditation Institute (QAI).

Currently, the accreditation is done as per the International Standard ISO/IEC 17025:2017. This is a system developed for conducting of a test and its implementation. International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. International Electro technical Commission (IEC) details the technical requirements and develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment. 17025 refers to the general requirements for the competence of a testing and calibration laboratory. These policies were last revised in 2017 and thus the present International Standard ISO/IEC 17025:2017.

The accreditation ensures compliance to the regulatory requirements. Further, it elevates the confidence of the customer and satisfaction with the services. It also assures quality at all levels in the laboratory viz., biosafety and biosecurity in handling samples throughout the testing process, the competency of the technical staff, the use of appropriate standard test method, appropriate maintenance of test equipment, measurements and calibrations, traceability of procedures and documents. The reports issued by the laboratory are thus considered precise and accurate.

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Keeping the above in view, the process of accreditation of the KVAFSU-CVA Rabies Diagnostic Laboratory at the Department of Veterinary Microbiology in the Veterinary College, Hebbal, KVAFSU, Bengaluru was initiated during the August, 2019. The hard efforts of the laboratory personnel culminated in its compliance to the ISO/IEC 17025:2017 with effect from February 8, 2020 for a period of two years. The journey through the process of accreditation was indeed a great learning process. Though technically the laboratory was competent enough under the OIE Twinning programme on Strengthening diagnosis of rabies in India, further stringent documentation to ensure its accreditation was mandatory. To proceed with the accreditation, in addition to the ongoing routine technical activities of the laboratory, it needed to have;

- a) A Quality Manual, the top level document of the laboratory which describes the organization / laboratory, its organizational setup, aims and objectives and the quality management system of the laboratory.
- b) A Quality System Procedure which details the procedures of how quality is maintained at each and every level from the point of sample entry until the communication of test results.
- c) Standard operation procedures (SOP) for the tests being done, for the equipments and for all the processes/ activities in the laboratory.
- d) Participation in External quality assessment schemes like Inter laboratory comparisons and proficiency testing to ensure technical competence of the laboratory personnel.
- e) Calibration of all the equipments used in the process to ensure effective functioning of the equipments.
- f) Internal Audit reviews.
- g) Traceability to all the documents and the processes.

Once the laboratory is accredited, it ensured;

- a) Assurance to the customer that the test data is accurate and reliable and in turn increase in sample inflow.
- b) Technical competence of the laboratory.
- c) ISO/IEC 17025:2017 is an international standard, compliance with this gives compliance with international standards and thus acceptance of the test results not only in India but also in other countries.
- d) Accreditation is a pre requisite for the laboratory going in for a Reference laboratory status.
- e) A better control of laboratory operations.

In conclusion, the ISO/IEC 17025 / 2017 accreditation of the KVAFSU-CVA Rabies Diagnostic Laboratory, with the support of the Commonwealth Veterinary Association (CVA) under the 'OIE Laboratory Twinning programme on Rabies' with the CDC, Atlanta and APHA, UK has elevated the laboratory standards in animal rabies diagnosis in the Indian subcontinent. The scope of the accreditation included three tests, namely Direct Fluorescent Antibody Assay (DFA) for detection of rabies viral inclusions in the brain samples, Rapid Fluorescent Focus Inhibition Test (RFFIT) for estimating the anti-rabies vaccinal antibodies in the serum samples and the Polymerase Chain Reaction (PCR) for detection of rabies viral RNA in the clinical samples. Recently, the OIE Biological Standards Commission has approved to designate this laboratory to be the OIE Reference Laboratory for rabies. Once official approval of OIE is completed, the laboratory will play a pivotal role in the South East Asian countries in harmonizing the animal rabies diagnosis, surveillance, providing consultancy services, training in all Quality assurance systems and Knowledge transfer. With these accomplishments, the laboratory dreams of contributing significantly in achieving elimination of 'Canine mediated human rabies by 2030' in the region.

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