

ACTIVITY AREA REFERENCE DOCUMENT

CERTIFICATION SERVICES – GENETICS ICAR Accreditation of DNA Data Interpretation Centres

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Author	Martin Burke
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Latest revision author	Martin Burke (for discussion with input from Brian Van Doormaal, Toine Roozen, Andie Dimitriadou, Brian Wickham)
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PURPOSE

ICAR offers two separate areas in Accreditation for Organisations involved in DNA analysis and interpretation ;

- 1) ICAR Accreditation of laboratories (so called wet labs) who analyse biomaterial to produce DNA Genotypes (DNA Data) and is described in ICAR SOP 05_CER_GNTX_0002.
- 2) ICAR Accreditation of **DNA Data Interpretation Centres** who take the DNA Data from the 'wet labs' in 1) above and interpret the data for a number of purposes as is described in this ICAR SOP 05_CER_GNTX_0003.

DNA Data Interpretation covered by this accreditation procedure includes applications for;

1. Parentage verification
2. Parentage discovery
3. Microsatellite imputation from SNPs (will not be part of the initial offering in 2016)
4. Animal identification verification.

For definitions see the 'Terms & Definitions' table below and for further technical background see ICAR Guidelines Section 4 – Guideline B.

SCOPE

This SOP concerns the Organisations involved in DNA analysis and interpretation, the DNA Working Group, the Interbull Centre, the ICAR Secretariat and Service-ICAR. Given that it is a commercial activity, it is also related to area 02_ADM (Admin/Finance).

TERMS & DEFINITIONS

Term	Definition
Animal Identification verification	The process by which a DNA analysis of a tissue sample is used to determine if the sample can be excluded as originating from a particular animal.
DNA Data Handling and Interpretation Test	This is a prerequisite compliance test which each DNA Data Interpretation Centre Applicant has to pass before ICAR Accreditation can be granted. ICAR's reference institute sends a predetermined set of SNPs to the Applicant with a series of accompanying animal and/or parentage analysis tasks to complete. The Applicant is asked to complete the interpretation tasks and return the required answers/results which are then assessed by ICAR's reference institute. Applicants must pass this assessment to gain Accreditation status.
ICAR accreditation	Formal Recognition by ICAR that an organisation has provided sufficient evidence that it has the competency, authority and experience to conduct DNA data interpretation for the purposes outlined in this Standard Operation procedure.
MAF	Minor allele frequency.
Microsatellite	Refer to definition of STR in this table.
Microsatellite imputation from SNPs	The process by which the microsatellite (STR) profiles of an animal may be imputed from SNP genotypes for the purpose of parentage verification.
Parentage discovery	The process by which a set of SNPs from an animal's genotype are compared to a database of SNP genotypes for older animals in order to identify the most likely sire and/or dam, if not already confirmed by Parentage Verification.
Parentage verification	The process by which the genotypes of the recorded parents (sire and/or dam) of an animal are examined relative to the genotype of the animal to determine if one or other does not qualify as a parent.
SI	Service ICAR
SNP	Single nucleotide polymorphism
SOP	Standard Operating Procedure in ICAR
STR	Abbreviation for short-tandem-repeat and commonly referred to as a microsatellite.

RESPONSIBILITIES

Services Executive: Administration of the Accreditation Applications in Service-ICAR for applicant DNA Data Interpretation Centres.

Administration Executive: Contractual and financial transactions between the Accredited DNA Data Interpretation Centres, the Interbull Centre and Service-ICAR.

Information Executive: Maintenance of ICAR web listing of Accredited DNA Data Interpretation Centres.

DNA Working Group (WG): Maintenance of Guidelines, policies as well as review and approval / rejection of Accreditation Applications (including design of the 'DNA Data Handling and Interpretation Test'.

Interbull Centre: Provide SNP database exchange and validation service for 'DNA Data Handling and Interpretation Test'.

PROCEDURE

ICAR Accreditation of Centres Performing DNA Data Interpretation

The DNA Data Interpretation Centre Accreditation process comprises the following steps:

1. Application for accreditation.
2. Review of application.
3. Data handling and interpretation test
4. Granting of accreditation and on-going compliance monitoring.

1. Application

Organisations requesting DNA Data Interpretation Centre Accreditation from ICAR must apply by downloading, filling in and submitting the Application form and administration fee to ICAR. The Application form as found in Annex V Guidelines Section 4, must be filled out accurately and completely, providing necessary documentation as required, and submitted.

2. Review of Application

The form will be evaluated by the Chair and/or nominated members of ICAR's DNA Working Group (WG). The DNA WG will review the application in line with criteria specified in the ICAR Guidelines, specifically in Section 4 Guideline B.

Based on this review and the successful passing of the 'DNA Data Handling and Interpretation Test' therein, the DNA WG shall either approve, request further information or reject the application through a letter from ICAR. In the case of rejection, ICAR advises that no resubmission is allowed within ninety days of the failed application. After the ninety days have elapsed then the Applicant is entitled to submit again.

3. DNA Data Handling and Interpretation Test

The DNA WG will define the DNA Data Handling and Interpretation Test protocol, quantity of SNPs, file exchange rules, pass/fail criteria, etc. This test will be outsourced to and coordinated by the Interbull Centre on behalf of Service ICAR. This test will be detailed as Annex **X** in our Guidelines.

4. Granting of accreditation and on-going monitoring

Notice of successful DNA Data Interpretation Centre Accreditation will be sent to the Organisation by ICAR and the Organisation's name will be added to ICAR's Website listing of Accredited DNA Data Interpretation Centres. The Accreditation will have an expiry date of four years, at the end of which a new application is to be completed and submitted.

To ensure the ongoing compliance of Accredited DNA Data Interpretation Centres, ICAR's reference centre will send, on an annual basis, a version of the DNA Data Handling and

Interpretation Test to each Centre. The Centre will return test files and their results will be assessed and filed as a record of ongoing compliance.

As well as the Annual DNA Data Handling and Interpretation Test, ICAR will require as a routine, a full validation DNA Data Handling and Interpretation Test every four years, to ensure interpretations are still accurate and comparable.

To maintain its Accreditation status, the DNA Data Interpretation Centre must participate in and pass all DNA Data Handling and Interpretation Tests – both annually and at the end of the four years.

Service ICAR Fees for Accreditation of DNA Data Interpretation Centres *(Proposal for discussion)*

Application Fee: Service ICAR will calculate the four-year charges due for the Applicant. The overall four-year figure covers all the DNA Data Interpretation activities that occur in the four-year period as follows;

- Service for ICAR Administration including Web Accreditation Listing maintenance costs
- Cost of the 'Initial' DNA Data Handling and Interpretation Test
- Cost of the three 'On-going Annual DNA Data Handling and Interpretation Compliance' tests

Service ICAR will divide the four-year total charge by four and send an Annual fee. In year five ICAR will start the cycle again with a new Application.

Example:

If a DNA Data Interpretation Centre applies in 2016, it is in effect applying for Accreditation and GenoEx-PSE eligibility, and Service ICAR would set a fee to cover 2016, 2017, 2018 and 2019. Dividing by four, SI would invoice annually. In 2020 the four year cycle would begin again.

RELATED DOCUMENTS

ICAR Guidelines Section 4 – Guideline B.

GenoEx-PSE Service Agreement

05_CER_GNTX_0002 ICAR Accreditation of DNA Analysis Laboratories (Wet Labs)

DNA Working Group Terms of Reference

Application Form Annex V Guidelines Section 4

Data Handling and Interpretation test protocol – Annex X Guidelines Section 4
