Council on Dairy Cattle Breeding

Genotyping Laboratories Guideline Updates

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Genotyping Laboratories Guidelines

- The CDCB GENLAB working group

    - Ezequiel Nicolazzi (Coordinator) - **CDCB**
    - George Wiggans – **CDCB**
    - Michael Cowan – **Genetic Visions**
    - Wim Van Haeringen – **VHL**
    - Emily Piper – **Zoetis**
    - Jiansheng Qiu – **Geneseek**
    - Michael Bishop **– Illumina**

- **Official activity: Apr 6th – June 21st** (unofficial activity still open if required)

- Organized as 4 virtual meetings and email interaction between meetings.
- Each meeting had the main objective of discussing one main topic.

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GENLAB WG objectives

- i) Definition of standard operating procedures (SOPs) for labs.
- ii) SNP chip validation process
- iii) Review of the CDCB lab certification process
- iv) Auditing certified labs

- The final objective of the working group was to **validate current CDCB procedures** that have direct influence/impact on partner Genomic Laboratories (objectives ii and iii), and to finalize a document that includes the **quality certification requirements** for genotyping labs (objectives i and iv).

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Review of CDCB practices on SNP chip validation and genomic laboratories (objectives ii and iii)

- Discussion on current CDCB practices on SNP chip validation and genomic laboratories certification processes
- GENLAB WG participants agreed that these procedures were complete
- A “genotyping test” for all genomic laboratories was strongly suggested
  - Later on, agreed to restrict this test to new laboratories
    - Already accredited labs have get evaluated on each submission
  - After many attempts to push this forward, the complexity of the procedure made it inapplicable.
  - Test of new genotyping labs will continue to occur requesting at least a submission of 96 genotypes including animals related to animals already genotyped in our system.

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Quality certification requirements for G-labs

- A drafted Quality certification requirement document was shared with the WG participants
- The document was reviewed and discussed over all 4 virtual meetings.
- Main changes to the original version:
  - Requirement of ISO-17025 certification (or equivalent)
  - The introduction of the one-time certification fee
  - New set of metrics for Genotyping laboratories QC
  - The introduction of an annual auditing done by CDCB staff.
  - Annual face-to-face workshop, similar to the CDCB nominators (hi!)

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ISO-17025 (or equivalent)

- All WG participants agreed that ISO-17025 was a a desired requirement for all labs (even if not all participant labs *had* an ISO17025 at the moment)
- Allows documenting and certifying each step of the procedure leading to the genotyping data shared with CDCB
- CDCB audit restricted to the quality of data received and the capacity of the lab to interact with its systems.
- No need of “dual” certification on practices.
- This excluded the need of a “Quality Certification Requirements for Genomic Laboratories” task force, as no actual audit would be conducted on the genotyping process (covered by the ISO certification)

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ISO-17025 (or equivalent)

- GENLAB WG proposal is that ISO certification requirement is applied immediately.
- A tolerance 2-year period to be applied to already CDCB certified laboratories without ISO certification, with proven progress after the first year.
- After 2 years from the approval of the document, any genomic laboratory not ISO (or similar) certified will be discredited.
  - Year 1 is 09/01/2018 – termination of accreditation for non ISO labs in 09/01/2019.

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SOP clarifications

- Does not require extensive details on the techniques. A description of the procedures (can copy/paste from ISO certification).
- Required to understand criticalities in the data received.
- Same as for nominator SOP, CDCB is not allowed to share any content received from gentoyping labs with ANY party.
- Available in Redmine (doc document)
- Required for the auditing process. Will communicate deadline.

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THANK YOU FOR YOUR ATTENTION

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