Council on Dairy Cattle Breeding

Quality Certification Requirements for Genotyping Laboratories

Latest Review: 2025/12/16

Effective: 2017/09/01

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Revision History

2018/05/01 – Update on the “Performance Metrics for Genotyping Laboratories” section, to standardize the documentation with the Genomic Nominator Guidelines.

2018/05/18 – Final version of “Performance Metrics for Genotyping Laboratories” section, merging all sources of information and after receiving input from Laboratories representatives at the 2018 Genotyping Laboratories Workshop.

2019/02/06 – Time limitation introduced for the approval process.

2019/09/24 – Time standards included *related* to genotyping Lab submissions.

2025/12/16 – Update on timelines, links and certification process. Additionally, included new “Collaborator Information Form” as well as process flow diagram.

Purpose

The guidelines for certification requirements for Genotyping Laboratories are established to maintain consistent standards and promote reliability across all aspects of the genomic evaluation program. These requirements help ensure the accuracy and uniformity of all records included in the system so that the impact of contributed resources and the overall efficiency of the program are maximized. By setting clear expectations for data quality, submission procedures, and compliance, the guidelines safeguard the integrity of genomic information and support the generation of trustworthy evaluation results that benefit all stakeholders involved.

Background

A Genotyping Laboratory is a certified organization responsible for submitting and managing genomic data for inclusion in the National Cooperator Database, ensuring the accuracy, quality, and integrity of the data used in CDCB evaluations.

The performance of Genotyping Laboratories is tracked and assessed through CDCB's quality control system, which includes systematic checks and ongoing performance monitoring conducted by CDCB staff.

To perform effectively in this role, it is essential to have a clear understanding of the responsibilities, tasks, and requirements necessary to meet CDCB's expectations. The primary duties of CDCB Genotyping Laboratories include:

i) Producing high-quality genotypic data that meets CDCB's technical standards.

ii) Uploading accurate information for genotyped animals into the CDCB system.

iii) Identifying and resolving issues such as low call rates, parent-progeny conflicts, or genotype duplications.

iv) Maintaining clear and accurate sample identification throughout all laboratory processes.

v) Collaborating with nominators, farms, and other third-party organizations to address issues that may prevent animals from receiving evaluations.

vi) Complying with all CDCB requirements necessary to maintain certified status.

Genomic tests, combined with phenotypic information on individual animals and their relatives, have been proven to be a powerful resource for predicting future performance in dairy cattle at an early age. The accuracy of these predictions relies on the precise and error-free submission of information to the National Cooperator Database (e.g., sampling the incorrect animal, mislabeling samples, switching samples within the laboratory, etc.). To minimize the introduction of such errors into the genetic evaluation program, core requirements and performance metrics—supported by monitoring and quality reporting systems such as the CDCB Genotyping Laboratory Report Card—are essential.

Adherence to Quality Certification Requirements will be monitored by CDCB staff, who will conduct reviews and assess performance to determine certification status as defined below.

A CDCB Quality Certification is required for each genotyping technology used (e.g., Genotyping Laboratories using Thermo Fisher (Affymetrix) and Illumina will require one certification per technology).

Core Requirements for Genotyping Laboratories

Genotyping Laboratories Seeking Certification

Genotyping Laboratories candidates must undergo the CDCB certification process in order to become an Approved CDCB Genotyping Laboratory. Therefore, a prospective laboratory is required to complete the following steps[1]:

1. Submit the completed CDCB Quality Certification for Genotyping Laboratories Application Form.
2. Sign the Material License Agreement (MLA) provided by CDCB. This document outlines the rights and obligations related to data submission to CDCB and CDCB's use of submitted data.
3. Submit the CDCB Laboratory Standard Operating Procedures (SOPs) using the designated CDCB template.
4. Submit the non-refundable CDCB Genotyping Laboratory Application Fee of **$1,000** to CDCB at the beginning of the certification process. A separate fee is required for each certification application. Laboratories applying for multiple certifications must submit the fee for each application individually.
5. Provide a copy of a valid and current accreditation in a recognized quality certification program (e.g., **ISO 17025** or equivalent). The scope of the accreditation must cover all processes involved in generating genomic data submitted to CDCB.
6. Provide a Laboratory Site and Technology Disclosure that lists every site submitting data to CDCB, states the Quality Certification (**ISO 17025** or equivalent) status for each site, identifies the genotyping technology used, and specifies the location of each site.
7. Designate personnel who will be granted access to the CDCB file submission tools, web queries, CDCB-related communications, and who will receive initial training from CDCB Staff. This information must be provided using the CDCB Collaborator Information Form, which will be provided via email, once the application is accepted.

[1] All application materials should be submitted to cdcb-certification-validation@uscdcb.com.

8. Respond to communications from CDCB within **10 business days** during the application process. If delays are anticipated, the Genotyping Laboratory must notify CDCB in advance and provide a rationale.

   Genotyping Laboratories that fail to respond to CDCB communications within the **10-business-day** period on two or more occasions, within the **three-month** certification period, and do not provide prior written notice with reasonable justification, may be moved to the end of the certification queue or have their application process terminated at CDCB's discretion.

9. Submit test files for verification by CDCB Staff (Note: samples and proficiency tests will be distributed and managed separately by CDCB). The CDCB Genotyping Laboratory Application Fee grants Genotyping Laboratories up to **five file review** attempts within the **three-month** period starting from the date of the application fee is received by CDCB.

   If a Genotyping Laboratory is unable to fully comply with CDCB requirements within **three-month** period or within the file review limit (**five file reviews**), CDCB reserves the right to terminate the certification process. In such an event, the Genotyping Laboratory will be required to restart the process, including repayment of the CDCB Genotyping Laboratory Application Fee.

10. Successfully conclude the certification process within **three months** from the date the Genotyping Laboratory Application Fee is received by CDCB.

Certified Genotyping Laboratories

Once the Laboratory has been certified, the following requirements apply:

1. Maintain a valid accreditation in a recognized quality certification program for standard laboratory processes (e.g., **ISO 17025** or equivalent).

   1.1. **All Laboratory sites** submitting data to CDCB must maintain a valid accreditation in a recognized quality certification program for standard laboratory processes (e.g., **ISO 17025** or equivalent).

   1.2. Inform CDCB through an updated Laboratory Site and Technology Disclosure if a laboratory site that submits genotypic data to CDCB loses its accreditation. Additionally, this site must immediately stop submitting data to CDCB. Submission privileges may resume only after the site regains accredited status.

   1.3. Genotyping Laboratories that plan to open a new site from which data will be submitted to CDCB must notify CDCB in advance. Evidence of pursuing accreditation and a written request for temporary submission approval must be submitted to CDCB. CDCB will review the request and determine whether interim submission privileges are appropriate. Only laboratories that complete this process may be eligible for temporary submission without full quality certification accreditation (e.g., **ISO 17025** or equivalent).

2. Provide an updated Laboratory Site and Technology Disclosure each year that lists every site submitting data to CDCB, states the quality certification status (**ISO**

17025 or equivalent) for each site, identifies the genotyping technology used, and specifies the location of each site.

3. Obtain a CDCB Quality Certification for each genotyping technology used (e.g., Genotyping Laboratories using Thermo Fisher (Affymetrix) and Illumina will require one certification per technology). **All Laboratory sites** that submit data to CDCB must use only the genotyping technologies for which they have been certified and that are reported in their Laboratory Site and Technology Disclosure.
4. Submit genotypes regularly to facilitate performance assessment. Genotyping Laboratories must submit a minimum of **one genotype per month** for at least **seven months**, with no gaps exceeding **three months**. For Genotyping Laboratories certified after the date of implementation of this guideline, **1,000 genotype submissions per year** is required.
5. Confirm the appropriate manifest format with the manufacturer/owner prior to starting the CDCB Certification Process. CDCB is not responsible for assigning or managing the manifest file format used by each organization.
6. Verify the nomination of samples before genotype submission to CDCB.
7. Ensure that genotypes are not submitted on behalf of other Laboratories, especially if the other Laboratories are not certified by CDCB.
8. Ensure that the same genotypes are not resubmitted to the CDCB collaborator database. Genotypes must be submitted exclusively by the certified Genotyping Laboratory that produced the genotype and holds responsibility for it.
9. Submit genotypes in the required format and provide the corresponding sample sheet to CDCB. For details on the accepted genotype file formats, refer to: CDCB Accepted Genotype File Formats.
10. Genotyping Laboratories must verify the quality of submissions prior to upload, following the instructions described in the Genomic Flow for Genotyping Laboratories.
11. Eliminate low-call-rate samples (<90%) before uploading.
12. Demonstrate proficiency in investigating and resolving SNP genotype issues, including low call rates, abnormal proportions of heterozygous genotypes, or excessive parent-progeny conflicts. For details on metrics and thresholds, refer to Performance Metrics for Genotyping Laboratories.
13. Coordinate with the Genomic Nominator(s) to ensure genotype submissions are accurately linked to valid animal identification, fee codes, and pedigree information.
14. Comply with the Performance Metrics for Genotyping Laboratories.

15. Actively participate in CDCB's quality control and certification program, which includes:

    15.1. Responding to monthly Report Cards on failed metrics within **one week** of issuance; refer to *Performance Metrics for Genotyping Laboratories* below.

    15.2. Updating the SOPs when there are Genotyping Laboratory and/or CDCB process changes. SOP documents must be submitted annually before the established due date.

    15.3. Participating in the Annual Review Call for Genotyping Laboratories.

Performance Metrics for Genotyping Laboratories

CDCB issues a monthly **Genotyping Laboratory Report Card** containing statistics on observed performance related to the quality of submitted data. Additionally, CDCB provides graphs and statistics available in WebConnect under "Performance Metrics" in the "Special Section". The monthly Genotyping Laboratory Report Card includes key performance metrics and flags for non-compliance[2].

Within **one week** of the date the Report Card is issued, Genotyping Laboratories are expected to respond to the Report Card ticket. (As stated in the monthly Report Card: *"Also note that CDCB expects your feedback on each one of these failures within a week"*). The Genotyping Laboratory's response should address the reasons for the non-compliance(s) and outline the actions intended to improve metric performance. Complete information on QC metrics and thresholds can be found in the Redmine Portal.

Procedural Flow of the Certification Process

A detailed diagram of the systematic procedures for the Genotyping Laboratory Certification Process is available at https://redmine.uscdcb.com/documents/425

[2] Failure to meet the required metrics does not automatically result in de-certification. CDCB will review the Genotyping Laboratory's Report Card and provide a reasonable timeframe for compliance or justification of unmet standards. If there is no evidence of improvement after the designated timeframe, the CDCB staff will formally notify the Genotyping Laboratory of the non-compliance.

Certification Process

Genotyping Laboratories may apply for certification at any time throughout the year. Upon demonstrating the ability to provide data in accordance with the standards set forth in this document — *Quality Certification Requirements for Genotyping Laboratories* — laboratories will be assigned conditional certification status. CDCB staff will determine any deficiencies requiring correction and will define the timeframe for the necessary remedial actions to achieve full certification.

Genotyping Laboratories that receive conditional certification status will be authorized to begin submitting data to the CDCB Collaborator Database.

Genotyping Laboratories will remain certified unless CDCB staff designate them as conditional, provisional or decertified due to systematic failure to meet core requirements.

Certification Status

Certified

A certified Genotyping Laboratory meets the Quality Certification Requirements for Genotyping Laboratories.

Conditional

Conditional certification status may be assigned to both new and existing Genotyping Laboratories. A new Genotyping Laboratory may receive conditional certification if CDCB staff determine that the laboratory has demonstrated the competence to perform the necessary procedures that meet the *Quality Certification Requirements for Genotyping Laboratories* but has not yet undergone a comprehensive review.

An existing provisional Genotyping Laboratory may be assigned conditional certification status if CDCB staff determine that the laboratory has met all required conditions and corrected previously identified deficiencies but has not yet undergone a follow-up review. Alternatively, a fully certified Genotyping Laboratory that fails to meet the requirements stated above may be downgraded to conditional certification status.

Conditional certification status may be granted a maximum of two times within a **five-year** period. If a Genotyping Laboratory receives this status for a **third time** within **10 years** (following the first review), or exceeds the **two-time** limit within **five years**, CDCB reserves the right to decertify the Genotyping Laboratory.

Provisional

A conditionally certified Genotyping Laboratory that fails to meet the core requirements for Genotyping Laboratories will be assigned provisional certification status on a temporary basis.

Following further evaluation and review by CDCB staff, a Genotyping Laboratory with temporary provisional status may remain in that status until an Annual Review Call is conducted. After the call, the Genotyping Laboratory will either:

i) Be upgraded to conditional certification status if it meets the core requirements for certified Genotyping Laboratories.

ii) Be decertified if non-compliances persist.

To regain conditional certification status, a provisionally certified Genotyping Laboratory must comply with the following requirements:

i) A **three-month** Corrective and Preventive Action (CAPA) plan with measurable outcomes and due dates must be submitted to the CDCB team within **10 business days** of receiving provisional certification status.

   a. The CAPA plan should include actions to increase the number of submissions (where applicable), implement preventative measures, and outline a comprehensive strategy for improving current services.

   b. Additional corrective actions may include, but are not limited to: providing complete responses to monthly Report Cards within **one week**; maintaining proactive communication with CDCB; and implementing business or marketing changes, if necessary.

ii) A **monthly** meeting between CDCB and the Genotyping Laboratory will be held to assess progress against the CAPA plan.

Upon successful completion of the CAPA plan milestones, demonstration of consistent and proactive communication, and fulfillment of the core requirements for Genotyping Laboratories, the Genotyping Laboratory will be reinstated to conditional certification status. If progress is limited, communication remains poor, or the Annual Review Call is unsuccessful, CDCB reserves the right to decertify the Genotyping Laboratory.

Provisional certification is a temporary status that may be granted **only once** within a **five-year** period. If a Genotyping Laboratory receives provisional certification a **second time** within **10 years**, or exceeds this **one-time limit** within **five years**, CDCB reserves the right to immediately decertify the laboratory.

Suspended

CDCB reserves the right to temporarily suspend services at its discretion when immediate action is required and deferral to the Annual Review Call is not feasible. This status is applied only in urgent or emergency circumstances. Upon notification of the suspension, the Genotyping Laboratory must promptly contact CDCB to address and resolve the issue that led to suspension. Failure to do so within one week of the suspension may result in decertification. A reinstatement fee of **$500** must be paid to resume services.

Decertified

A Genotyping Laboratory that fails to meet the *Quality Certification Requirements for Genotyping Laboratories,* even after a period of provisional certification and review, will be decertified by CDCB. A decertified Genotyping Laboratory will not be permitted to submit data to the CDCB collaborator database. Notification of decertification will be sent by CDCB via email and/or postal mail.

Decertification will be considered only when:

i) The performance of the Genotyping Laboratory has fallen below the minimum standards established by CDCB;

ii) The Genotyping Laboratory fails to take prompt action to return to compliance within the time period specified by CDCB; or

iii) The Genotyping Laboratory fails to pay fees due to CDCB.

Course of Action upon Decertification:

i) If no appeal is initiated, the **"in"** and **"check"** directory in SFTP will be disabled **10 business days** after the Notice of Decertification is issued.

ii) The Genotyping Laboratory must cease genotype submissions no later than **10 business days** after the Notice of Decertification is issued. Failure to comply will result in immediate full decertification by CDCB.

iii) The **"out"** directory in SFTP will be disabled **90 calendar days** after the Letter of Decertification is sent.

iv) The Genotyping Laboratory will be prohibited from reapplying for certification for **two years** from the date of the Final Decertification Letter.

Decertification Appeals

Any Genotyping Laboratory decertified by CDCB has the right to appeal the decision within **10 business days** from the date the Notice of Decertification is issued. However, decertification may only be appealed if the Genotyping Laboratory was decertified after receiving its first provisional certification status.

The appeal must consist of a written report submitted to the CDCB certification team. The report must explain why the reviewer's decision should be reconsidered and include a Corrective and Preventive Action (CAPA) plan addressing the identified issues over the next **three months**.

The appeal will be reviewed by CDCB within **30 calendar days** of receipt, and CDCB's decision will be final. If CDCB upholds the findings of the CDCB staff, no additional data will be accepted from the Genotyping Laboratory after **30 calendar days** from the time CDCB notifies the appealing entity of its decision.

If no appeal is submitted, no further data will be accepted after the appeal deadline. Genotyping Laboratories that are no longer certified but wish to reapply after the **two-year suspension period** must meet the same requirements and conditions as a new entity seeking certification.

Review of Genotyping Laboratories

The performance of Genotyping Laboratories will be monitored continuously to ensure that service delivery, data processing, and data quality continue to meet the standards outlined in the *Quality Certification Requirements for Genotyping Laboratories.*

CDCB staff may request submission of electronic or hard-copy data or documents at any time it is deemed necessary to determine whether the Genotyping Laboratory is fulfilling the requirements. The submitted material will be used solely for evaluation purposes and will be assessed on a pass/fail criteria.

Review Types

Reviews of Genotyping Laboratories are classified as either mandatory or discretionary:

1. Mandatory Review

   A mandatory review is defined as the Annual Review of the Genotyping Laboratory. CDCB staff schedule these reviews toward the end of the year and into the beginning of the following year to determine whether the Genotyping Laboratory is eligible to continue submitting data to the CDCB collaborator database and to assign the appropriate certification status.

   During the review, CDCB requires:

   i) Submission of an updated Standard Operating Procedures (SOP) document from the previous year.

   ii) Participation in the Annual Review Call.

2. Discretionary Review

   A discretionary review is defined as a review deemed necessary by either CDCB staff or the Genotyping Laboratory and is scheduled on an **as-needed** basis when:

   i) Changes in facilities, procedures, or staffing have occurred.

   ii) Certain aspects of the Genotyping Laboratory's performance are out of compliance with *Quality Certification Requirements for Genotyping Laboratories*.

   iii) The Genotyping Laboratory seeks to attain full certification from a conditional certification status.

   iv) The Genotyping Laboratory aims to move out of provisional certification status; or

   v) The Genotyping Laboratory intends to regain provisional certification following decertification (typically during the appeal process).

CDCB Staff Responsibilities

The CDCB staff are responsible for ensuring that all certified Genotyping Laboratories meet the *Quality Certification Requirements for Genotyping Laboratories.*

CDCB staff responsibilities include, but are not limited to, the following:

1. Ensuring that trained staff are available to perform the Annual Review.
2. Reviewing the Genotyping Laboratory's monthly Report Cards, assessing responses to non-compliances, and communicating with Genotyping Laboratories to ensure that data are submitted according to the specifications outlined in the *Quality Certification Requirements for* Genotyping *Laboratories.*
3. Assigning a certification status to each Genotyping Laboratory reviewed.
4. Including certified Genotyping Laboratories on the official list of Approved CDCB Genotyping Laboratories.
5. Submitting the Final Report within **30 calendar days** of the Annual Review Call to the Genotyping Laboratory, identifying any missing or deficient data, along with guidance for addressing deficiencies prior to the expiration of the laboratory's certification status.