Certified Service Provider Program Overview

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## Revision History

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<td>A</td>
<td>Initial Release</td>
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<td>Clarified kits and chips for practical evaluation are to be provided by service provider. Clarified renewal year section</td>
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CSP Program Overview

Introduction to the Bionano Genomics Certified Service Provider Program

The goal of the Bionano Genomics Certified Service Provider Program (CSPP) is to give customers interested in Bionano Genomics whole genome imaging, the option to contract with a service provider that has undergone rigorous validation to ensure the highest quality level of service and support for any Bionano project. By committing to work with a Certified provider, customers can be assured they are contracting with an organization that is using up-to-date equipment, current DNA extraction and labeling protocols, updated bioinformatics software and assembly pipelines and are experienced in delivering high quality results. By choosing a Certified provider, customers can also expect to be properly supported downstream as they incorporate Bionano data into their projects.

The Bionano Genomics Certified Service Provider Program assures researchers they are working with a partner they can trust to support their research efforts, while also offering participating providers many competitive advantages.

Why Become Certified?

Beyond recognition as a trusted Bionano partner, completing the CSPP certification process provides several material benefits to drive business and differentiate your institution. These include:

- Increased visibility: social media promotion via Bionano outlets and exclusive inclusion on the Certified Service Provider page on the Bionano website: https://bionanogenomics.com/company/certified-service-providers/

- Sales Referrals: preferential referrals when customers seek a Bionano service provider

- Co-branding: produce marketing materials that include the Bionano Certified Service Provider Program badge

- Marketing activities: co-branded marketing materials are made available at events that Bionano attends, as well as inclusion in periodic co-marketing activities such as seminars, local events, contests, grant programs, etc.

What Does Being Certified Mean?

The CSPP certification process covers three specific categories: personnel, equipment and data quality.

Service providers' personnel that complete the certification process will be able to advise customers on experimental design, be proficient in relevant current Bionano sample prep protocols, DNA labeling methods, operation of the Saphyr instrument, data collection, delivering data to the customer and discussing any significant findings.
Certification also means:

- All primary and necessary ancillary equipment is updated and functioning properly,
- Best practice for sample and reagent usage and storage is being followed,
- All Bionano equipment is kept under an active service contract and,
- Latest versions of any Bionano software are used as soon as possible after official release, current ongoing projects permitting.

Certified service providers are the first line for supporting their customers including data analysis and Bionano Access software installation.

Program Overview and Getting Started

Bionano service providers interested in becoming part of the Certified Service Provider Program can contact either their local Bionano sales person or Field Application Scientists (FAS) to get started. The certification program is directly administered by the local FAS as a part of the Bionano Genomics Customer Solutions department. As previously mentioned, personnel, equipment and data quality are the three certification targets. The CSPP is completed in five stages as shown in the following overview diagram.

Bionano offers three types of certifications: full certification (all samples); partial certification for Human samples or partial certification for Plant and Animal tissues.

Overview of Bionano Genomics’ Certified Service Provider Program

Stage 1: Pre-Qualification

Pre-qualification starts when a Bionano Service Provider decides they want to become a Bionano Certified Service Provider and contacts either their local sales person or FAS. After reviewing the various benefits of the program, costs, and other commitments and the decision is made to proceed, the CSPP Certification process can start. Please review the CSPP - Service Provider Guidelines as it is the key document that serves as an index with links to current versions of all necessary support material, required forms, protocols and other useful guides.
The majority of the certification process is focused on providing the local personnel running the Bionano service platform with all the reference material, training, and access to support documentation they need. Completing each project requires three basic roles (project manager, lab scientist and data scientist) which, depending on local skill sets, may be filled by varying combinations of individuals. Elements of our certification process are specific to each role, so as part of the Pre-Qualification role assignments are made for the individuals being certified to determine who will need to complete certain tasks (e.g. the individual assigned the ‘data scientist’ role would need to take the Bioinformatics Practical Exam).

The next step of Pre-Qualification is confirming that all equipment on the CSPP - Pre-Qualification Form has been purchased and is fully operational. Sign, date and return this form to FAS as it will be used as the basis for the on-site audit.

The CSPP process is managed by the local FAS at Bionano Genomics. All questions, email and test results associated with CSPP need to be sent to your local FAS.

**Stage 2: Training (on-site)**

The training stage of the CSPP workflow is provided as a mean of making sure all staff are up-to-date with the techniques and best practices involved in Bionano workflow for which the service provider is certifying. As part of the visit an audit will be performed to ensure compliance with Bionano user-supplied equipment requirement list and to record software versions.

**A. Technique**

Certified service providers should be familiar with each of Bionano’s sample prep they are certifying for in addition to labeling methods. The on-site certification training will be hands-on for unfamiliar techniques and provide a review of other techniques. The on-site training and site audit are organized and led by the local FAS and will cover:

- gDNA isolation
- Labeling methods
- Sample Run – Chip loading and instrument operation (review)
- Troubleshooting (sample prep and instrument operation)
- Data Analysis and Delivery

Particular focus will be paid on unfamiliar or troublesome protocols or techniques. Any kits, reagents, and samples necessary for this training need to be ordered, or provided, and ready to use before FAS arrives on-site for training.
B. Best Practices

A section of the training will focus on best practices for:

- Use of the tracking document (CSPP - Recording Form)
- Sample intake (one of the most important ways to assure success is starting with the best version of each sample)
- Chip handling / loading
- Sample and reagent storage

C. Site Audit

The FAS will verify that all required equipment is present and fully operational. The FAS may also make suggestions for the workspace to improve overall workflow and identify any elements that might negatively impact sample prep or instrument operation.

Stage 3: Theoretical Evaluations

The Theoretical Evaluations stage is comprised of three written tests aimed at each of the three defined roles, including project manager, lab scientist and data scientist. These tests evaluate both general and specific knowledge of the platform within the confines of each role and are drawn from Bionano protocols and user guides.

Project Manager Role - A series of typical “project scenarios” questions that asks the individual assigned to the project manager role to respond as appropriate to a few theoretical customer inquiries to determine the correct series of actions needed to initiate their project. This test also asks the project manager to assess a few in progress projects to determine best next steps.

Lab Scientist Role – A series of multiple-choice questions covering DNA extraction, labeling, reagent handling and storage, equipment run, equipment maintenance, troubleshooting and platform User Interface necessary for data generation and delivery to customer.

Data Scientist Role - A series of multiple-choice questions covering usage of Bionano Solve to assemble maps, construct hybrid assemblies, and perform SV callings. Also covers using Access to manipulate data and filter SV call using the Variant Annotation pipeline.
Stage 4: Practical Evaluations

The Practical Evaluations are divided in two parts:

- Wet Lab Practical (DNA Prep, Labeling, and Instrument operation)
  - Evaluated based on molecule metrics, MQR, DNA and labeling QCs and photo report when required.

- Bioinformatics (Assembly and Analysis)
  - Evaluated based on assembly and relevant application metrics

These practical exams test lab technique and understanding of all the various elements necessary to run a project from sample to data deliverables.

A. Samples

For a full Certification Bionano Genomics will send you 2 samples to process:

- Frozen Human whole blood
- Frozen young leaves from lettuce

For a partial Certification (“Plant and Animal tissues” or “Human samples”) you will receive one or the other sample.

In addition to these physical samples you will have also received the CSPP - Recording Form to record test progress (delivered during the on-site training).

B. Wet lab and Instrument operation practical test

The Bionano kits and chips necessary to complete the practical exams are provided by the service provider.

Once the samples have been received please start the practical test and complete the CSPP - Recording Form as you progress through the test for each sample type.

Wet Lab & Instrument Operation Practical Examination form has 5 sections:

1. Project Proposal (Note: This tab has been filled-in already by Bionano Genomics with background information to complete the test – please READ before starting)
2. Sample Receiving
3. Isolated raw DNA QC
4. Labeled DNA QC
5. Run QC
Additionally, for the plant DNA extraction, you are requested to complete a photo report of the DNA isolation procedure, please fill in the [CSPP - Report Template – Plant Prep Photos](#) form as you progress through the protocol.

When complete, please send the completed [CSPP - Recording Form](#), the MQR(s) and [CSPP - Report Template – Plant Prep Photos](#) form to your local FAS.

### C. Bioinformatics practical test

Once the run check has been completed, please begin the Bioinformatics Practical Exam by performing the following Bioinformatics tasks within Bionano Access (use the documentation and guidelines provided to you):

- **Lettuce leaves sample:**
  - Run HS using the reference (fasta) above as NGS input data. Assess the HS report and comment; explain choice of analysis parameters.
    
    *Note: the reference and the sample you processed are not of the same origin. This is not normally recommended to do and is only done here as an exercise, results will be affected by this difference.*

- **Human whole blood sample:**
  - Perform *de novo* assembly for SV analysis. Assess the assembly report and comment; explain choice of analysis parameters.
  - Run VAP (single sample)
  - Complete the [CSPP - Report Template – Final Project](#) (Structural Variation section from slide 25 of the template) with screenshots of the Bionano Access viewer for 2 examples of your choice of SVs overlapping genes (use the VAP results and appropriate filtering options). Select these SVs to be included in a pdf report, generate the report and export filtered SVs list (SMAP) in .csv format.

Provide the following to your local FAS:

- [CSPP - Recording Form](#) with completed Bioinformatics tab
- All corresponding reports specified in the Bioinformatics tab of the [CSPP - Recording Form](#) for both samples with your assessment and comments.
- The SV report and exported filtered SV list for the human sample.
D. Final Report

Using the CSPP - Report Template – Final Project provided, please prepare a report for both practical samples and downstream applications and forward to your local FAS. Optionally, applicants are welcome to present the results to the Bionano team as a practice and to receive feedback on presentation best practices.

Advantages

- Chance to practice presentation on the technology, services provided and results
- Safe space to develop a customer pleasing presentation
- Live feedback from Bionano team members for real time improvements of delivery

Stage 5: Certification

After the theoretical and practical exams have been completed, returned, graded and assessed, the FAS will arrange a conference call to discuss the results. Corrective actions and any necessary re-tests will be assigned at that time. If no additional testing or training is necessary, awarding the final Certification can proceed. Congratulations!

The CSPP is an annual certification process. The CSPP certification process covers three specific categories: personnel, equipment and data quality. Changes to service providers’ personnel that were certified need to be reported and new certification training arranged for their replacements to maintain certified status. All instruments must maintain active Service Contracts and any persistent data quality issues need to be quickly resolved.

In a renewal year any new techniques or protocols that have been introduced will be trained or reviewed. The FAS will also conduct a brief site audit to ensure equipment and environment remain in good and working order.

Conclusion

Certification through the Bionano Certified Service Provider program provides many benefits that differentiate your business and improve your overall visibility among other non-certified Bionano service centers. Customers can appreciate they are receiving the highest quality work and can be confident in the data they are provided. As a trusted partner we look forward to seeing your business grow.
Technical Assistance

For technical assistance, contact Bionano Genomics Technical Support.

You can retrieve documentation on Bionano products, SDS's, certificates of analysis, frequently asked questions, and other related documents from the Support website or by request through e-mail and telephone.

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