Attachment B - Instrument: Web Version

Form Approved
OMB No. 0920-0879
Expiration Date 01/31/2021

Next Generation Sequencing Quality Management Survey

Instructions

Next-generation sequencing (NGS) is being broadly implemented as a diagnostic tool in public health laboratories (PHLs) at federal, state, and local levels. While NGS is transforming how we investigate disease and disorders, there is a recognized need for quality management systems (QMS) that ensure the synthesis of high quality, reliable data that is useful for diagnostic/reference testing and relevant to nationwide disease surveillance systems. This survey will help the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) determine the current, NGS-specific QMS landscape at the state and local level, assess the use of- and barriers to implementing a QMS, identify resources allocated for NGS, and aid in the development of future tools and resources that support NGS-specific QMS.

Completing this survey is voluntary and takes approximately 40 minutes. Responses will need to be submitted by (Month Day, 2020). Completion of this survey may require input from multiple departments, and we recommend public health laboratory directors consult with a quality manager, or designee, who oversees quality-related aspects of your laboratories NGS testing. Laboratory directors are asked to collate all responses and answer the survey as one program. CDC will not publish or share any identifying information about individual respondents. There are no known risks or direct benefits to you from participating or choosing not to participate. Data collected from this survey will be stored on secure, password-protected servers maintained by and only accessible to APHL. We ask you to include your business email address in case follow-up is needed to clarify your responses. Upon closing of the survey period, aggregated results that have been stripped of personally identifying information will be transferred from APHL to CDC for analysis.

If you have any questions or concerns about this survey, please contact [NAME] at [EMAIL].

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Demographics

I. Please select your laboratory from the below drop-down list.

II. Please enter your information (representative completing the survey).

Business Email Address

III. Are you performing next-generation sequencing testing in your laboratory?

- ○ Yes
- ○ No

[If no, survey ends] Thank you for participating in this survey, but we are only assessing the impact of quality management systems in laboratories currently performing NGS based tests.

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Quality System Essential I: Organization (OR)

1. Does your laboratory have a process in place to perform NGS budget forecasting to accommodate the costs of sequencing, equipment purchases and upgrades, data storage, etc.? Check all that apply.

- ☐ No forecasting
- ☐ Forecasting of costs of sequencing
- ☐ Forecasting of equipment purchases and upgrades
- ☐ Forecasting of data storage
- ☐ Forecasting of any other costs

2. Describe your laboratory's level of development to evaluate your infrastructure needs (ex. servers, instrumentation, and power supply) to support NGS testing.

- ○ No process in place
- ○ Process in development
- ○ Process developed, not implemented
- ○ Process developed, implemented and monitored

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Quality System Essential II: Customer Focus (CF)

3. For what percentage of the NGS test procedures has your laboratory established a standard data report for end users (ex. epidemiologists, clinicians, partner labs, etc.) of NGS data?

- ○ 0-25% of NGS test procedures have an established data report
- ○ 26-50% of NGS test procedures have an established data report
- ○ 51-75% of NGS test procedures have an established data report
- ○ 76-100% of NGS test procedures have an established data report

3a. List your NGS tests that do not have a standard report.

4. Describe your laboratory's level of SOP development for gathering feedback (such as technical assistance needs, testing or reporting needs) on NGS services from end users, such as epidemiologists, clinicians, partner labs.

- ○ No SOP in place
- ○ SOP in development
- ○ SOP developed, not implemented
- ○ SOP developed, implemented and monitored

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Quality System Essential III: Facilities and Safety (FS)

5. Does your laboratory's chemical and biological safety manuals include documentation specific to NGS?

- ○ No documentation specific to NGS methods included in the manuals
- ○ Documentation specific to NGS methods included in either chemical or biological manual but not both manuals
- ○ Documentation specific to some but not all NGS methods are included in both chemical and biological manuals
- ○ Documentation specific to all NGS methods are included in both chemical and biological manuals

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Quality System Essential IV: Personnel (PE)

6. Describe your laboratory's training plan for each step in the NGS workflow.

	No documented training plan	Training plan in development	Training plan developed, not implemented	Training plan developed, implemented and monitored
Sample Preparation	○	○	○	○
Library preparation	○	○	○	○
Sequencing	○	○	○	○
Bioinformatics Analysis	○	○	○	○
Data Storage/Retention	○	○	○	○

7. Indicate which steps in your NGS workflow are included in your laboratory's competency assessment process.

	A competency assessment is performed	A competency assessment is not performed
Sample Preparation	○	○
Library preparation	○	○
Sequencing	○	○
Bioinformatics Analysis	○	○
Data Storage / Retention	○	○

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Quality Systems Essential V: Purchasing and Inventory (PI)

8. Describe your laboratory's level of inventory management for reagents and consumables used in the NGS workflow.

- ○ No SOP in place
- ○ SOP in development
- ○ SOP developed, not implemented
- ○ SOP developed, implemented and monitored

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Quality System Essential VI: Equipment (EQ)

9. Describe your laboratory's overall establishment of maintenance and calibration SOPs for equipment used in each step in the NGS workflow.

	No SOP in place	SOP in development	SOP developed, not implemented	SOP developed, implemented and monitored
Sample Preparation	○	○	○	○
Library preparation	○	○	○	○
Sequencing	○	○	○	○
Bioinformatics Analysis	○	○	○	○
Data Storage / Retention	○	○	○	○

10. Describe your laboratory's level of development for the research, evaluation, and procurement of equipment for NGS testing.

- ○ No process in place
- ○ Process in development
- ○ Process developed, not implemented
- ○ Process developed, implemented and monitored

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Quality System Essential VII: Process Management (PM)

*For questions 11-13, the term validation means the provision of objective evidence through a defined process that NGS test(s) perform as intended.

11. What percentage of your laboratory's NGS tests are internally validated?

- O 0-25%
- O 26-50%
- O 51-75%
- O 76-100%

12. What percentsge of your laboratory's NGS tests are eternally reviewed, assessed, and/or validated (such as NY, WA, CAP, CLIA)?

- O 0-25%
- O 26-50%
- O 51-75%
- O 76-100%

13. Describe your laboratory's documented validation guidelines for NGS methods.

- O No validation guidance in place
- O Validation guidance in development
- O Validation guidance developed, not implemented
- O Validation guidance developed, implemented and monitored

14. For each types of bioinformatics analyses performed by your laboratory, indicate whether or not you have a data set for validation. (For example for the ANI/RefID

Bionumerics workflow, a data set from CDC EDLB_WGS Validation Toolkit is used for validation.)

	Data Set for Validation
Enter Analysis Type	
Enter Analysis Type	

15. What was your laboratory's total NGS test volume in 2019?

- ○ 1-100
- ○ 101-500
- ○ 501-1000
- ○ 1000+

16. Describe your laboratory's level of SOP development for each step in the NGS workflow.

	No SOP in place	SOP in development	SOP developed, not implemented	SOP developed, implemented and monitored
Sample Preparation	○	○	○	○
Library preparation	○	○	○	○
Sequencing	○	○	○	○
Bioinformatics Analysis	○	○	○	○
Data Storage / Retention	○	○	○	○

17. Describe your laboratory's level of development for QC controls/QC checkpoints for each step in the NGS workflow.

	No QC controls/ checkpoint established	No QC controls/ checkpoint in development	No QC controls/checkpoint developed, not implemented	No QC controls/checkpoint developed, implemented and monitored
Sample Preparation	○	○	○	○
Library preparation	○	○	○	○
Sequencing	○	○	○	○
	○	○	○	○

	No QC controls/ checkpoint established	No QC controls/ checkpoint in development	No QC controls/checkpoint developed, not implemented	No QC controls/checkpoint developed, implemented and monitored
Bioinformatics Analysis				
Data Storage / Retention	○	○	○	○

18. Describe your laboratory's established test requirements and performance expectations for its submitters. Requirements and expectations may include: collection and transport, sample acceptance, turnaround times, and reporting.

	No requirements /performance expectations defined	Requirements / performance expectations in development	Requirements / performance expectations developed, not implemented	Requirements/ performance expectations developed, implemented and monitored
Requirements for collection and transport of samples	○	○	○	○
Sample acceptance / rejection criteria	○	○	○	○
Turnaround times	○	○	○	○
Reporting results, including critical values for NGS	○	○	○	○

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Quality Systems Essential VIII: Document Records (DR)

19. Describe your laboratory's level of development for document control (the creation, review, and approval).

- ○ No process in place
- ○ Process in development
- ○ Process developed, not implemented
- ○ Process developed, implemented and monitored

20. Describe your laboratory's level of development for records management related to NGS workflow (to include creation, identification, collection and review of records) for each phase indicated below.

	No SOP in place	SOP in development	SOP developed, not implemented	SOP developed, implemented and monitored
Sample Submission Records	○	○	○	○
Equipment Records	○	○	○	○
Personnel Records	○	○	○	○
Purchasing Records	○	○	○	○
Validation Records	○	○	○	○
Sequencing Data	○	○	○	○
Data Analysis records	○	○	○	○

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Quality System Essential IX: Information Management

21. Describe your laboratory's level of development for tracking samples and associated data through the NGS workflow.

- ○ No system in place
- ○ System in development
- ○ System developed, not implemented
- ○ System developed, implemented and monitored

22. Does your laboratory have a process for responding to questions from epidemiologists and clinical partners regarding NGS test reports?

- ○ Yes
- ○ No

23. Describe your laboratory's level of development for verifying or validating the integrity of NGS data after data transfer or transmission.

- ○ No process in place
- ○ Process in development
- ○ Process developed, not implemented
- ○ Process developed, implemented and monitored

24. Describe your laboratory's level of development for managing software updates on each equipment used for NGS testing.

	No process in place	Process in development	Process developed, not implemented	Process developed, implemented and monitored
Commercial pipelines/software	○	○	○	○
	○	○	○	○

	No process in place	Process in development	Process developed, not implemented	Process developed, implemented and monitored
Open-source pipelines/software				
In-house pipelines/software	○	○	○	○

Date Storage and Retention

25. Does your laboratory have a data retention policy?

○ Yes

○ No

26. How long is the data kept in your laboratory for the following files?

	No Retention	1-3 years	4-7 years	7+ years	N/A
FastQ	○	○	○	○	○
Fast5	○	○	○	○	○
Raw Reads	○	○	○	○	○
All files associated with the run	○	○	○	○	○

Bioinformatics Analysis

27. What informatics tool(s) does your laboratory use for bioinformatics analysis? Please enter the relevant details to each analysis in the box in front of it.

	Please describe here. If NA, please skip.
CDC developed pipelines/software	
In-house pipelines/software	
Commercial pipelines/software	
Open-source pipelines/software	

28. What data set(s) does your laboratory use to validate bioinformatics pipelines?

	Please enter the text here.
Commercial pipelines/software	
Open-source pipelines/software	

	Please enter the text here.
In-house pipelines/software	

29. Describe your laboratory's level of development for documenting version control of the bioinformatics pipeline(s).

	No SOP in place	SOP in development	SOP developed, not implemented	SOP developed, implemented and monitored
Commercial pipelines/software	○	○	○	○
Open-source pipelines/software	○	○	○	○
In-house pipelines/software	○	○	○	○

30. Describe your laboratory's level of development for managing software updates on equipment used for NGS testing.

	No process in place	Process in development	Process developed, not implemented	Process developed, implemented and monitored
Commercial pipelines/software	○	○	○	○
Open-source pipelines/software	○	○	○	○
In-house pipelines/software	○	○	○	○

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Quality Systems Essential X: Nonconforming Events Management (NC)

31. Describe your laboratory's level of SOP development for capturing nonconforming events (e.g. exceptions, deviations, and complaints) related to NGS.

- ○ No SOP in place
- ○ SOP in development
- ○ SOP developed, not implemented
- ○ SOP developed, implemented and monitored

32. Describe your laboratory's level of development for the corrective action life-cycle (includes performing root cause analysis, developing action plans, and tracking follow-up actions) for NGS.

- ○ No process in place
- ○ Process in development
- ○ Process developed, not implemented
- ○ Process developed, implemented and monitored

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Quality System Essential XI: Assessments (AS)

33. How often does your laboratory perform or participate in any internal assessments/audits for NGS tests (inclusive of wet and dry lab) on a routine basis?

	Never	Every 6 months	Annually	Other
Wet Lab	○	○	○	○
Dry Lab	○	○	○	○

34. Does your laboratory participate in any external proficiency testing (PT) programs?

- ○ Yes
- ○ No

35. Does your laboratory participate in external performance assessment examinations for NGS tests (CAP, CLEP)?

- ○ Yes
- ○ No

36. Describe your laboratory's level of development for handling unfavorable audit results for sequencing.

- ○ No process in place
- ○ Process in development
- ○ Process developed but not implemented
- ○ Process developed, implemented, and monitored

37. How often does your laboratory report audit results to laboratory management for review?

- ○ Never
- ○ Every 6 months
- ○ Annually
- ○ Other (Please specify)

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Quality Systems Essential XII: Continual Improvement

38. How often does your laboratory conduct a management review of quality data (ex. internal audit reports, trends in data, non-conforming events, customer feedback, competencies and training) related to NGS testing?

- ○ Never
- ○ Monthly
- ○ Quarterly
- ○ Every 6 months
- ○ Annually
- ○ Other

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Survey Quality

Select the statement that best describes your agreement with the following:

	Strongly Agree	Agree	Disagree	Strongly Disagree
39. The survey questions were clear and understandable	○	○	○	○
40. The length of time to complete the survey was reasonable.	○	○	○	○

41. How can this survey be improved?

42. If you are a member of APHL, would you be interested in participating in a focus group to discuss more specific needs and challenges your laboratory faces around quality management for NGS testing?

- Yes
- No

42a. [If yes] Please contact Christin Hanigan Sr. Specialist, Advanced Molecular Detection APHL at Christin.Hanigan@aphl.org.

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