# Questionnaire for collecting information on the capacity and equipment of HIV sequencing laboratories

|  |  |
| --- | --- |
| **Laboratory name** |  |
| **Street address** |  |
| **City, state** |  |
| **Country** |  |
| **Director of department or institution** |  |
| **Email** |  |
| **Laboratory director** |  |
| **Email** |  |
| **Contact person for assessment visit** |  |
| **Position of contact person** |  |
| **Phone** |  |
| **Email** |  |
| **Date questionnaire completed** |  |

**Checklist**

**Mandatory criteria (laboratory self-assessment)**

|  |  |
| --- | --- |
| National plan for implementing surveillance of HIV drug resistance (national drug resistance laboratories and regional drug resistance laboratories only) |  |
| Designation letter from the health ministry (national drug resistance laboratories and regional drug resistance laboratories only) |  |
| At least one year of experience in genotyping HIV, and ≥100 specimens tested annually with satisfactory results (≥3 years and ≥200 specimens for regional drug resistance laboratories and specialized drug resistance laboratories) |  |
| Minimum infrastructure for HIV drug resistance genotyping in place |  |
| Capacity for dried blood spot (DBS) genotyping (regional drug resistance laboratories and specialized drug resistance laboratories only) |  |
| Capacity for genotyping integrase  |  |

**Mandatory criteria (to be assessed by WHO)**

|  |  |
| --- | --- |
| Need for laboratory support established |  |
| Demonstrated proficiency with quality assurance, management and reporting of sequencing data |  |
| Successful participation in the WHO HIV drug resistance proficiency testing programme |  |
| **Additional criteria for regional drug resistance laboratories and specialized drug resistance laboratories only** |  |
| Regionally recognized experience and leadership in HIV laboratory science |  |
| Adequate experience in providing training and establishing collaborations in laboratory sciences in the past five years |  |
| Good general knowledge of sequencing, including techniques other than commercially available kits |  |

**Documentation to be submitted to WHO**

The laboratory should submit the following documentation in electronic format (Adobe PDF preferred)

|  |  |
| --- | --- |
| Letter of support from the health ministry indicating that the laboratory has been identified to test specimens collected during WHO-recommended HIV drug resistance surveys (national drug resistance laboratories); for regional drug resistance laboratories, the letter should indicate that that the candidate laboratory has been identified to test specimens collected from other countries during WHO-recommended HIV drug resistance surveys and will provide training and capacity building to other laboratories in the Region |  |
| Maintenance records and service contract for major equipment. |  |
| Map of the genotyping facility |  |
| CVs of genotyping laboratory personnel (including supervisor) documenting their qualifications and experience in molecular biology |  |
| Description of the management structure of the genotyping laboratory personnel |  |
| Information on the financial sustainability of HIV drug resistance genotyping activities in the past five years |  |
| Records and documentation of the sequencing tests performed in the past two years, including both in-house methods and commercial kits |  |
| Proficiency panel testing reports from providers other than WHO in the past year |  |
| Standard operating procedures. including: (1) receipt, assessment and storage of specimens; (2) internal quality control; (3) all steps of genotyping tests, including sequencing; (4) handling and manipulating infectious human material, including handling infectious waste; (5) data management; and (6) post-testing sequence quality assurance. |  |
| Validation reports on DBS and integrase assays (regional drug resistance laboratories and specialized drug resistance laboratories only) |  |

**Questionnaire**

As part of the efforts to organize the WHO HIVResNet Laboratory Network, the existing capacity of your laboratory for HIV drug resistance sequencing will be evaluated. Please answer the following questions by checking the appropriate boxes or filling in the appropriate number or text.

**A. General information**

**1**. Is the laboratory performing drug resistance sequencing for HIV? Yes No

**2.** For what purpose is HIV drug resistance sequencing performed? (Check all that apply)

 Clinical care

 Research

 Public health or epidemiological purposes

**3**. How many years of experience does the laboratory have in performing HIV drug resistance sequencing? \_\_\_\_\_\_ years

**4**. How many HIV-1 drug resistance sequencing tests did the laboratory perform in each of the past two years?

 Number performed last year: \_\_\_\_\_\_\_\_\_\_\_ year: \_\_\_\_\_\_\_\_

 Number performed year before last: \_\_\_\_\_\_ year: \_\_\_\_\_\_\_\_

**5**. Is the laboratory integrated into the health ministry? Yes No

**6**. If not, is it a private laboratory? Yes No

Specify type:

**B. Personnel**

**7**. Indicate the personnel (scientific and technical personnel) available to perform HIV drug resistance sequencing and specify the ability to perform in-house home-brew assays. Please include the qualifications and training undertaken (add additional rows as needed). Indicate the time dedicated to sequencing per month by each individual. Attach the CVs of the personnel working in the genotyping laboratory.

| **Name** | **Qualification and traininga** | **Time dedicated**  | **Years experience with HIVDR genotyping** |
| --- | --- | --- | --- |
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|  |  |  |  |
|  |  |  |  |

aFor example, general technician, technician molecular diagnostics, biomedical scientist or physician.

**8**. Is a safety officer in place? Yes No

If **yes**, name of safety officer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**9**. Please provide an organizational chart showing the management structure of the laboratory or institution (attach a separate file). The chart should include all personnel listed in question 7.

**C. Quality management system**

**10**. Does the laboratory have standard operating procedures in place for HIV drug resistance sequencing? Yes No

If **Yes**, please provide the title and number of standard operating procedures for all steps of the HIV drug resistance sequencing procedure. (Add additional rows as needed.) Please submit copies of the standard operating procedures for HIV drug resistance for review along with this questionnaire.

| **Standard operating procedure number** | **Standard operating procedure title** |
| --- | --- |
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**11.** Are standard operating procedures managed using a quality assurance or document control system or under regulatory oversight (such as ISO or CAP/CLIA)? Yes No

If **Yes**, provide details:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**12**. Does the laboratory participate in an external quality assurance programme for HIV drug resistance sequencing? Yes No

If **Yes**, please specify:

 Name of the programme: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Name of the provider: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of participation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please submit a summary of the proficiency panel results from the past two years along with this questionnaire.

**13**. Indicate the frequency of power failure in number of times per year: \_\_\_\_\_\_\_\_\_ per year

Is backup available in case of power failure? Yes No

**D. Biosafety**

**14**. Does the laboratory have well-documented procedures for handling and manipulating infectious human material, including handling infectious waste? Yes No

If **Yes**, please provide the name and number of the standard operating procedure or laboratory protocol and submit a copy for review:

Name and number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**15**. Are laboratory disinfection procedures in place? Yes No

**16**. If **Yes**, please list the workspace or equipment disinfected, procedures and disinfecting agents used and frequency of disinfection in the following table (add additional rows as needed).

|  |  |  |
| --- | --- | --- |
| **Workspace or equipment** | **Procedure and disinfecting agent** | **Frequency** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
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**E. Dedicated molecular diagnostic workspace and workflow**

**17**. Are there separate laboratories, rooms or work areas for molecular diagnostic activities?

 Yes No

*If* ***Yes****, please answer questions 17a and 17b.*

17a. Is there a separate, dedicated room for specimen extraction and master mix preparation that remains free of contaminating DNA (pre-amplification)?

 Yes No

17b. Is there a separate, dedicated room for polymerase chain reaction (PCR) amplification and for handling amplification products and high-copy number DNA (post-amplification)?

 Yes No

**18**. Do all laboratory personnel respect a strict unidirectional workflow? Yes No

Please submit copies of standard operating procedures or laboratory procedures for workflow and provide a map of the genotyping facilities.

**19**. Are procedures in place for cleaning and molecular decontamination of the laboratory?

 Yes No

If **Yes**, please submit copies of standard operating procedures or laboratory procedures for cleaning and molecular decontamination. If a written document is not available, please use the table below to report the type and frequency of cleaning and molecular decontamination procedures or strategy the laboratory uses. (Add additional rows as needed.)

|  |  |  |
| --- | --- | --- |
| **Workspace or equipment** | **Procedure and decontaminating agent** | **Frequency** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**F. Equipment**

**20**. Indicate the type, year of purchase and the frequency of maintenance and calibration of the equipment present in the pre-amplification area.

|  |  |  |  |
| --- | --- | --- | --- |
| **Pre-amplification area equipment** | **Type** | **Year of purchase** | **Maintenance type and frequency** |
| Bench with sink and tap water |  |  |  |
| Biohazard flow, class IIb |  |  |  |
| Dead air cabinet (preparation mixes) |  |  |  |
| Dead air cabinet(nucleic acid extraction) |  |  |  |
| Freezer –20°C |  |  |  |
| Microcentrifuge 12 500–15 000  *g* |  |  |  |
| Vortex |  |  |  |
| Dedicated set of micropipettes |  |  |  |
| Ultracentrifugea 21 000–25 000  *g* |  |  |  |

aIn case the extraction procedure requires pelleting of virus.

**21**. Are the centrifuges anti-aerosol? Yes No

**22**. Indicate the type, year of purchase and frequency of maintenance and calibration of the equipment present in the post-amplification area.

| **Post-amplification equipment** | **Type** | **Year of purchase** | **Maintenance type and frequency** |
| --- | --- | --- | --- |
| Bench with sink and tap water |  |  |  |
| Dead air cabinet (nested reaction) |  |  |  |
| Thermal cyclers |  |  |  |
| Agarose gel apparatus |  |  |  |
| Photo documentation of agarose gel |  |  |  |
| DNA sequencer |  |  |  |
| Computer  |  |  |  |
| Computer program (editing) | Version: |  |  |
| Microcentrifuge 450–550  *g* |  |  |  |
| Vortex  |  |  |  |
| Dedicated set of micropipettes  |  |  |  |
| Freezer –20°C |  |  |  |
| Refrigerator 4°C |  |  |  |

**23**. Indicate the type, year of purchase and frequency of maintenance and calibration of additional equipment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Equipment** | **Type** | **Year of purchase** | **Maintenance** |
| Freezer –20°C |  |  |  |
| Freezer –80°C |  |  |  |
| Autoclave |  |  |  |

**24**. Describe how the freezer temperature control is monitored: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**25**. Indicate the presence of the following materials for biosafety in the separate workspaces

|  |  |  |
| --- | --- | --- |
| **Workspace** | **Gloves** | **Paper lab coats** |
| Pre-amplification and extraction |  |  |
| Pre-amplification and mix preparation |  |  |
| Post-amplification |  |  |

**26**. If paper lab coats are used, how frequently are they changed? \_\_\_\_\_\_\_ times per month

26a. If paper lab coats are **NOT** used, are cloth lab coats used? Yes No

26b. If **Yes**, how frequently are the cloth lab coats cleaned? \_\_\_\_\_\_\_ times per month

**27**. Supplies:

27a. Are current inventories maintained? Yes No

27b. Is a system in place for replenishing supplies? Yes No

**28**. Computational capability

28a. Is a computer available in the laboratory? Yes No

28b. Is Internet access available? Yes No

**G. Specimens**

**29**. What types of specimens does the laboratory use for HIV drug resistance sequencing? (Check all that apply.)

 Ethylenediaminetetraacetic acid (EDTA) plasma

 Citrate plasma

 Serum

 Dried blood spot (DBS)

 Dried plasma spot (DPS)

 Dried serum spot (DSS)

**30**. If the laboratory uses dried blood, plasma or serum spots for HIV drug resistance sequencing, please indicate the type of membrane and manufacturer:

 Membrane 903 filter, manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Membrane FTA filter, manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Other membrane, manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**31**.If the laboratory uses dried blood, plasma or serum spots for HIV drug resistance sequencing, please indicate the storage conditions and detailed information on the processing of the specimen, including extraction, amplification and sequencing (quantities used, conditions, etc.). If a standard operating procedure or written laboratory protocol is available, you may submit a copy and indicate “see enclosed document” in the space below. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**32**. If the laboratory uses dried blood, plasma or serum spots for HIV drug resistance sequencing, please indicate the number of specimens tested annually in the last 2 years and years of experience in genotyping using DBS, DPS and DSS.

Number of specimens tested annually in past two years: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Years of experience genotyping using DBS, DPS and DSS: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**H. Specimen registration**

**33**. Indicate the information present on the stored specimens used for HIV drug resistance sequencing.

 Unique specimen identification code

 Patient identification code

 Identification code for the specimen collection centre

 Specimen collection date

 Specimen collection time

 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**34**. Indicate the number of aliquots stored for each patient: \_\_\_\_\_\_\_\_\_\_ Volume: \_\_\_\_\_\_

**35**. Indicate the system used for registering specimens. (Check all that apply.)

 Paper registry

 Computer registry

 Other (specify):

**36**. Indicate the information collected in the registry:

 Type of specimen

 Unique specimen identification code

 Patient identification code

 Patients’ date of birth

 Patients’ age group

 Patients’ antiretroviral therapy history

 Number of pregnancies (for women)

Other patient data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Identification code for the specimen collection facility

 Specimen collection date

 Specimen collection time

 Date specimen was sent to the sequencing lab

 Date specimen was received in the sequencing lab

 Specimen viral load

 Condition of the specimen

 Specimen volume and number of dried fluid spots

 Specimen storage location

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**I. Sequencing methods**

**37**. Please list the HIV-1 nucleic acid extraction method, manufacturer (if applicable), specimen type and starting volume for all specimen types used for HIV drug resistance sequencing.

|  |  |  |  |
| --- | --- | --- | --- |
| Extraction method | Manufacturer | Specimen type | Starting volume |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**38**. Method for your laboratory sequencing of HIV-1. (List all methods used.)

 Kit-based assay: name/version: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 name/version: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Home-brew (developed in-house) assay

**39**. If the laboratory uses a kit-based HIV genotyping assay, describe the deviations from the standard procedure, if any:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**40**. If the laboratory uses a home-brew (developed in-house) assay, provide information on the primers and method:

1. RT and PCR primers: from a published reference designed by laboratory
2. Sequencing primers: from a published reference designed by laboratory
3. RT assay conditions: from a published reference designed by laboratory
4. First PCR assay conditions: from a published reference designed by laboratory
5. Second PCR assay conditions: from a published reference designed by laboratory

*If applicable, the laboratory must provide documentation of the references used.*

**41**. Has the method been validated in the laboratory? Yes No

If **Yes**, please attach a summary of how the method was validated, including information on the specimen types validated, the number of specimens tested and the method of evaluation or reference assay used for comparison.

**42**. Minimal region sequenced on both strands (both directions):

 For protease: codons \_\_\_\_ to \_\_\_\_

 For reverse transcriptase: codons \_\_\_\_ to \_\_\_\_

 For integrase: codons \_\_\_\_ to \_\_\_\_

**43**. Is the viral load of specimens submitted for genotyping known? Yes No

**44**. Assay sensitivity: what is the minimal viral load required for sequencing?

Plasma: \_\_\_\_\_\_\_\_\_\_ copies/ml DBS: \_\_\_\_\_\_\_\_\_\_ copies/ml

Proportion of samples with viral load between 1000 and 5000 copies/ml that can be amplified

Plasma: \_\_\_\_\_\_\_\_\_\_ DBS: \_\_\_\_\_\_\_\_\_\_\_\_\_

How was the assay sensitivity (minimal required viral load for sequencing) determined? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**45**. Is the preservation time for reagents controlled? Yes No

**46**. How are specimens or derivatives kept cold during sequencing? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**47**. What is the mean turn-around time and throughput for sequencing?

Turn-around time: \_\_\_\_\_ days Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Throughput: \_\_\_\_\_ samples/week Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**48**. Is a positive run control included in every run? Yes No

If yes, indicate the step(s) in which positive controls are included, the specimen type of the control and the viral load, if known:

Step: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Type of specimen: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ viral load: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Step: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Type of specimen: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ viral load: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**49.** If a positive run control is included in every run, please complete the following:

One positive control is used per \_\_\_\_ specimens.

What measures are in place in case of a negative result in the positive control?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**50**. Is a negative run control included in every run? Yes No

If the answer is yes, please complete the following:

One negative control is used per \_\_\_\_ specimens.

What measures are in place in case of a positive result in the negative control?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**51**. Are filter tips used for reaction set-up? Yes No

If yes, indicate the steps in which they are used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**J. Sequence editing**

**52**. Indicate the software used for sequence editing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**53**. Which of the following are taken into account when evaluating the raw sequence data? Check all that apply.

 Signal intensity; limit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signal-to-noise ratio

 Reading forward and reverse strand

 Amount of editing needed; limit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Other; specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**54**. How is sequence editing performed? Check all that apply.

 Manual reading

 Software-associated editing; specify software: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Other; specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**55**. Are the edited sequence results confirmed by a second or independent person? Yes No

If yes, please provide documentation for this procedure.

**56**. Does a supervisor critically review results? Yes No

**K. Data management**

**57**. Indicate the information registered during the processing and sequencing of the specimen.

 Dates of the various steps in specimen processing (extraction, amplification and sequencing)

 Detailed information on the specimen processing (quantities used and conditions)

 The results of each step

 Other attempts in case of failure

 The personnel performing each step of specimen processing

 Storage of interim material (extracted nucleic acids and PCR product)

 Lot numbers of kits and materials

**58**. What type of registry are these data records kept in?

 Paper registry

 Computer or electronic registry

**59**. Are the data and results archived? Yes No

If yes, how long are the data and results kept?

 Specimen registries Length of time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Laboratory processing registry Length of time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Raw sequence data Length of time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Final sequence result Length of time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Format: \_\_\_\_\_\_\_\_\_\_

**60**. Are backup procedures for sequences data in place? Yes No

Describe the backup method and the frequency of backup: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**L. Financial sustainability**

**61.** Describe the mechanism(s) for funding operations in the laboratory, including the annual budget.

**62.** What is the cost of genotyping? Provide the cost per test, assuming a volume of about 500 specimens per year.

 Cost for general testing:

 Cost expected to be reimbursed by an external funder for WHO surveillance work:

Comments about costs (such as including or excluding labour costs, volume dependent, etc.):

**Additional remarks, if any:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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