Abbott Panbio Antigen Rapid Test
User Manual

Prepared by the B.C. Centre for Disease Control (BCCDC)

In Conjunction with

Provincial Laboratory Medicine Services (PLMS)

Version 1.4

April 23, 2021
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A.1 Provincial COVID-19 Rapid Point of Care Testing Program

Purpose
To establish a universal, provincial, validated, and accredited point of care program for COVID-19 rapid tests.

Policy
British Columbia Centre for Disease Control (BCCDC) in cooperation with Provincial Laboratory Medicine Services (PLMS) and under their authority is responsible for the creation of a provincial COVID-19 rapid test point of care program.

Responsibilities
BCCDC and PLMS are responsible for creation and validation of the program as well as technical and logistical support.

Geographic Health Authorities with existing Diagnostic Accreditation Program (DAP) accreditation for Point of Care Testing (POCT) are responsible for service delivery including oversight and quality assurance.

Scope
The policy and procedures apply to all personnel with assigned authority and responsibility to perform rapid COVID-19 patient testing. Personnel must also have successfully completed a training program and completed competency assessment.

Practice Standards
All rapid COVID-19 POCT will be performed in accordance with DAP Standards and conform to relevant Health Authority oversight, quality and health and safety procedures and protocols.

Compliance
Systemic failure to comply with defined policies, processes and procedures will result in removal of the rapid COVID-19 POCT at the direction of the Health Authority Laboratory Medical Director.

Issuing Authority – Provincial Health Services Authority

Effective Date: December 10, 2020

British Columbia Centre for Disease Control
Dr. Mel Krajden, Medical Director
Signature on file

Provincial Laboratory Medicine Services
Dr. Blake Gilks, Chief Medical Officer
Signature on file

Program & Document Maintenance

Note: The program and related documents may not be revised in any way without authorization.

Address queries to:
Kim Nicholson
Strategic Lead, Medical Biochemistry
Provincial Laboratory Medicine Services
kimball.nicholson@phsa.ca
A.2 Setting up Google Chrome for eFORM Site

Purpose
This document outlines the steps involved in setting up Google Chrome to use the eFORM Site.

Scope
The procedure applies to all personnel with assigned authority and responsibility to perform the Abbott ID NOW and Panbio COVID-19 rapid test and have been trained and passed a competency assessment.

Materials Required
Personal Computer (PC)
Internet Access
Google Chrome
Personal protective equipment
- Masks
- Gloves
- Fluid resistant gowns
Biohazard waste container

Procedure
1. Put on required personal protective equipment which must include, at a minimum, a mask, gloves and a fluid resistant gown.

   Note: Individual testing sites may have greater personal protective equipment requirements which must be adhered to.

2. Open Google Chrome.
   1. Click on the icon.
   2. Click on settings.
3. Click on **Privacy and security**.

4. Click on **site setting**.

5. Click on **Pop-ups and redirects**.
6. Click on Add in the “Allow” section.

![Add button]

7. Type in the eFORM PROD site link: https://www.eforms.phsahealth.ca

![Adding a site]

8. Click on Add.

9. Click on the icon to return to the Home screen.

10. Click on the icon.

11. Click on settings.

![Settings icon]
12. Click on **Autofill**.

13. Click on **Addresses and more**.

14. Turn off **Save and fill addresses**.

15. Click on the **Home** icon to return to the Home screen.

16. Remove gloves and discard in a biohazard waste container.

17. Perform hand hygiene and put a fresh pair of gloves before continuing to the next procedure.
A.3 Registering a Patient in eFORM

Purpose
This document outlines the steps involved in registering a patient in eFORM for COVID-19 rapid tests.

Scope
The procedure applies to all personnel with assigned authority and responsibility to perform the Abbott ID NOW and Panbio COVID-19 rapid tests, and have been trained and passed a competency assessment.

Materials Required
Personal Computer (PC)
Internet Access
eFORM Access (application submitted by the assigned manager or supervisor to eFORM IT Team)
Printer
Full Name/Last Name of Health Care Provider
Patient’s Personal Health Number (PHN)
Personal protective equipment
  • Masks
  • Gloves
  • Fluid resistant gowns
Biohazard waste container

Procedure

<table>
<thead>
<tr>
<th>Note:</th>
<th>Use Google Chrome for best performance.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Warning:</th>
<th>If Google Chrome is used, allow Pop-ups from the eFORM site and disable autofill. Refer to the procedure Setting up Google Chrome for eFORM site.</th>
</tr>
</thead>
</table>

1. Put on required personal protective equipment which must include, at a minimum, a mask, gloves and a fluid resistant gown.
   
<table>
<thead>
<tr>
<th>Note:</th>
<th>Individual testing sites may have greater personal protective equipment requirements which must be adhered to.</th>
</tr>
</thead>
</table>

2. Open the internet browser.
3. Type in or click on the following link: https://www.eforms.phsahealth.ca/appdash/
4. Click on Sign in with BC Health Authority Account.
5. Enter your **e-mail account** to sign-in to eFORM.

![HealthBC Sign in](Image)

6. **Click Next.** The next window will show at least one tile. Choose the PHSA eForms tile.

![PHSA eForms](Image)

**Note:** Each health authority may have a unique tile in eFORM. **Always** choose the PHSA eForms tile for access to the eFORM application.

7. **Click Launch Application** on the appropriate tile.

8. **Check the box** and **click I Agree** to accept the user agreement if displayed.
9. **Click** POC Rapid Test

10. Perform registration in the presence of the patient and using their BC Services Card. If the patient is not insured in British Columbia, use an alternate form of identification.

11. Enter the patient’s **Personal Health Number (PHN)** in the field **BC Personal Health Number**. Alternatively, a search may be performed using the Last Name, First Name and Birth Date.

12. **Click on Search.** If the patient is in the database, their information will be displayed.

13. **Click Cancel and proceed to Step XX** if the patient is not insured and does not have a PHN.

14. Click on the matching displayed patient and then **Click Select** in the Client Details dialogue box.

15. Enter the Practitioner’s last name in the **Name Search** field or their MSP ID in the **MSP ID Search** field and **Click Search**.

16. **Click on the appropriate Practitioner.**
17. The COVID-19 PoC Rapid Test screen will now be displayed with the patient and practitioners information prepopulated.

18. Click on **Health Authority** under COVID-19 screening by:

```
COVID-19 PoC Rapid Test

COVID-19 screening by:
- Industry
- Health Authority
```

**Note:** Do not choose Industry as this is reserved for a different testing group and contains fields not covered by this procedure.

19. Select the **Health Authority**.

```
Health Authority *
- FHA
- PHSA
- FNHA
- IHA
- VIHA
- VCH/PHC
- NHA
```

20. Select the **Testing Health Region** if either PHSA or FNHA is selected in Step 19.

```
Testing Health Region *
- Fraser
- Vancouver
- Island
- Interior
- North
```

21. Enter the name of the collection site in the **Collection Site Name** field.

```
Collection Site Name
Little Bo Peep Care Home
```

22. Click the down arrow and choose the type of site from the list displayed in the **Type of Site** field.

```
Type of Site *
- LTC - resident
```

**Note:** The **Patient ID** will be generated automatically and is used to identify the request for instrumentation. No input is required here.
23. Click the down arrow and choose the appropriate community from the drop down list.

![City selection](Port Alice)

**Note:** The first few letters of the community name may be entered to limit the search. Province/Territory is prepopulated and requires no action.

24. Check **Ordering Test Provider Information** section for correctness by confirming with the patient.

25. Ask the patient to verbally state the following to confirm the accuracy of **Section 2 – Patient Information** and to provide for positive patient identification:
   - Patient’s **First** and **Last Name**
   - Patient’s **Date of Birth (DoB)**

26. Select the **Test Kit Name** from the drop down list in **Point-of-care Test Information**.

![Test Kit Name](Panbio COVID-19 Ag)

27. Select the **Specimen Description** by clicking the appropriate choice.

![Specimen Description](Nasal)

28. Enter the Collection Date by clicking the Calendar Icon and choosing the date from the drop down calendar.

![Collection Date](yyyy-MM-dd)

29. Leave COVID-19 Test Result unselected for now. It will be filled out when the results are reported.

**Warning:** Do not click **Submit**.

30. Click **Save Draft**.
31. Click **Download PDF**

32. Print out the PDF.

33. Log out of eFORM if proceeding to the next procedure.

34. Remove gloves and discard in a biohazard waste container.

35. Perform hand hygiene and put a fresh pair of gloves before registering the next patient, continuing to the next procedure or collecting the patient’s sample.

36. **Proceed to Collecting a Patient Sample** or return to Step 9 if registering the next patient.
A.4 Collecting a Specimen for the Abbott Panbio COVID-19 Rapid Test

Purpose
This document provides the procedure for collecting a specimen for the Abbott Panbio COVID-19 Rapid Test. A quick reference guide can be found in the appendix.

Scope
The procedure applies to all personnel with assigned authority and responsibility to perform the Abbott Panbio COVID-19 rapid test, have been trained and passed a competency assessment.

Materials Required
Personal protective equipment
- Masks
- Gloves
- Fluid resistant gowns
Biohazard waste container
Abbott Panbio sterilized swab
Abbott Panbio extraction tube
Abbott Panbio extraction tube cap
Abbott Panbio tube rack
Abbott Panbio buffer

Procedure
1. Allow all Panbio kit components to reach room temperature (15 – 30°C) prior to collection. Allow 30 minutes.
2. Put on required personal protective equipment which must include, at a minimum, a mask, gloves and a fluid resistant gown.

Note: Individual testing sites may have greater personal protective equipment requirements which must be adhered to.

3. Clean area with appropriate disinfectant.
4. Place an extraction tube in the tube rack.
5. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube.

Caution: It is important to not to under or over fill the extraction tube. Excessive or insufficient buffer will lead to a false test result.
6. Place the filled extraction tube back in the tube rack.

7. Place an extraction tube cap loosely on top of the extraction tube.

8. Remove the swab from its protective wrapper taking care not to touch the top half of the swab.

9. Tilt the patient’s head back slightly about 70 degrees to straighten the passage from the front of the nose.

10. Insert the swab less than one inch into the nostril.

11. Rotate the swab 5 times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril.

12. Slowly remove the swab while rotating it and insert it into the extraction tube.

13. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times.

14. Squeeze out the swab by squeezing the extraction tube with your fingers.
15. Break the swab at the breakpoint and close the cap of extraction tube.

16. Dispose of the remaining swab wand in a biohazard waste container.

17. Clean area with appropriate disinfectant.

18. Remove gloves and discard in a biohazard waste container.

19. Perform hand hygiene and put a fresh pair of gloves before continuing to the next procedure or collecting the next patient.
A.5 Performing the Abbott Panbio COVID-19 Rapid Test

Purpose
This document provides the procedure for performing the Abbott Panbio COVID-19 rapid test once the specimen has been collected. A quick reference guide can be found in the appendix.

Scope
The procedure applies to all personnel with assigned authority and responsibility to perform the Abbott Panbio COVID-19 rapid test and have been trained and passed a competency assessment.

Materials Required
Personal protective equipment
- Masks
- Gloves
- Fluid resistant gowns
Biohazard waste container
Abbott Panbio test device
Extracted patient sample
Timer
Completed eFORM

Quality Control
The test device has a built in control. Refer to procedural step 8 for interpretation.
Daily quality control is not required.
New lot numbers of the test device are validated by the BC Centre for Disease Control (BCCDC) prior to release for general testing. Validation records are retained by the BCCDC.

Procedure
1. Allow all Panbio kit components to reach room temperature (15 – 30°C) prior to collection. Allow 30 minutes.
2. Put on required personal protective equipment which must include, at a minimum, a mask, gloves and a fluid resistant gown.

   Note: Individual testing sites may have greater personal protective equipment requirements which must be adhered to.

3. Clean area with appropriate disinfectant.
4. Open the dropping nozzle cap at the bottom of the extraction tube.
5. Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.
Caution: Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.

6. Close the nozzle and dispose of the extraction tube containing the used swab in biohazard waste disposal.

7. Set a timer for 15 minutes and start it.

8. Read the result at 15 minutes.

Caution: Correct timing is important. Reading the test results earlier than 15 minutes or later than 20 minutes will give false results.

9. Observe the result window on the device.

<table>
<thead>
<tr>
<th>If:</th>
<th>Then:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only the control line (C) is present</td>
<td>The result is negative</td>
</tr>
<tr>
<td><img src="image" alt="Control line (C) present" /></td>
<td></td>
</tr>
<tr>
<td>The control line (C) and the test line (T) are present</td>
<td>The result is positive</td>
</tr>
<tr>
<td><img src="image" alt="Control and test lines present" /></td>
<td></td>
</tr>
<tr>
<td>The control line (C) but the test line (T) is faint</td>
<td>The result is positive</td>
</tr>
<tr>
<td><img src="image" alt="Control line present, test line faint" /></td>
<td></td>
</tr>
</tbody>
</table>
10. Repeat invalid results with a freshly collected patient sample.

Note: The Panbio test may only be repeated once. If the test is invalid a second time the patient must be referred for conventional COVID-19 testing.

11. Record the result on the eFORM.
12. Dispose of the used device in biohazard waste disposal.
13. Clean area with appropriate disinfectant.
14. Remove gloves and discard in a biohazard waste container.
15. Perform hand hygiene and put a fresh pair of gloves before continuing to the next procedure or collecting the next patient.
A.6 Reporting Results in eFORM

Purpose
This document outlines the steps involved in reporting patient results in eFORM for the COVID-19 rapid tests.

Scope
The procedure applies to all personnel with assigned authority and responsibility to perform the Abbott ID NOW and Panbio COVID-19 rapid tests, and have been trained and have passed a competency assessment.

Materials Required
Personal Computer (PC)
Internet Access
Printed out eFORM
Personal protective equipment
- Masks
- Gloves
- Fluid resistant gowns
Biohazard waste container

Procedure

1. Put on required personal protective equipment which must include, at a minimum, a mask, gloves and a fluid resistant gown.

   Note: Individual testing sites may have greater personal protective equipment requirements which must be adhered to.

2. Open the internet browser.
3. Type in or click on the following link: https://www.eforms.phsahealth.ca/appdash/
4. Click on Sign in with BC Health Authority Account.

   Warning: In Google Chrome, allow Pop-ups from the eFORM site and disable autofill. Refer to procedure Setting up Google Chrome for eFORM site.

   Note: Use Google Chrome for best performance.
5. Enter your **e-mail account** to sign-in to eFORM.

6. **Click Next.** The next window will show at least one tile. An example (i.e. PHSA) is shown below:

![PHSA eForms](image)

**Note:** Each health authority will have a unique tile in eFORM. Choose the appropriate tile, based on your jurisdiction.

7. **Click Launch Application** on the appropriate tile.
8. **Check the box** and click **I Agree** to accept the user agreement if displayed.
9. Click on Drafts.

10. Identify the patient’s name in the menu and click on it.

Note: Patient’s name will only appear if their eFORM was previously saved as a draft during registration. Refer to the procedure Registering Patients in eFORM for the Abbott ID NOW.

11. Scroll down to Section 3 – Point-of-care-Test Information.

12. Click the appropriate test result under COVID-19 Test Result.
13. Click **Submit**.

<table>
<thead>
<tr>
<th>If:</th>
<th>Then:</th>
</tr>
</thead>
</table>
| Submit X  
Please check the form and correct all errors before submitting. | Correct all errors in the eFORM and go to step 13. |
| COVID-19 PoC Rapid Test Form Submission Success Ref.No.: 5be30994-e31a-44b4-b58b-160158299d90 | Click **OK** and go to step 14. |

14. Log out of eFORM if there are no further entries.

15. Remove gloves and discard in a biohazard waste container.

16. Perform hand hygiene and put a fresh pair of gloves before continuing to the next procedure.
A.7 Performing COVID-19 Rapid Testing during eFORM Downtime

Purpose
This document outlines the steps involved to perform COVID-19 rapid testing during the unavailability of the eFORM application, i.e., downtime.

Scope
The procedure applies to all personnel with assigned authority and responsibility to perform COVID-19 rapid test, and have been trained and passed a competency assessment.

The downtime procedure is to be implemented as soon as the eFORM application is unavailable for any reason and ensure uninterrupted patient testing.

Materials Required
Abbott ID NOW & Panbio Downtime Form
Personal protective equipment
- Masks
- Gloves
- Fluid resistant gowns
Biohazard waste container

Procedure
1. Put on required personal protective equipment which must include, at a minimum, a mask, gloves and a fluid resistant gown.
2. Have the patient present their Care Card. If the patient is uninsured in British Columbia ask for an alternate form of identification.
3. Fill out all fields on the Downtime Form using the information on the Care Card as well as asking the patient for the information not included such as provider etc.
4. Proceed to sample collection and testing and follow the appropriate procedures.
5. Record results on the Downtime Form. Retain the form.
6. Use the registration and result entry procedures and the downtime form to register and enter results of all patients processed during the downtime.

Note: All fields on the Downtime Form are required in order to register and report results when the eFORM application is available.

Note: If another person will perform collection and testing ensure hand hygiene is performed and fresh gloves are put on before serving the next patient.
# Appendix A. Abbott ID NOW & Panbio Downtime Form

<table>
<thead>
<tr>
<th>COVID-19 Screening By:</th>
<th>Testing Health Region [PHSA / FNHA only]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>FHA</td>
</tr>
<tr>
<td>Health Authority</td>
<td>PHSA</td>
</tr>
<tr>
<td></td>
<td>Fraser</td>
</tr>
<tr>
<td></td>
<td>FNHA</td>
</tr>
<tr>
<td></td>
<td>Vancouver</td>
</tr>
<tr>
<td></td>
<td>IHA</td>
</tr>
<tr>
<td></td>
<td>Island</td>
</tr>
<tr>
<td></td>
<td>VIHA</td>
</tr>
<tr>
<td></td>
<td>Interior</td>
</tr>
<tr>
<td></td>
<td>VCH/PHC</td>
</tr>
<tr>
<td></td>
<td>North</td>
</tr>
<tr>
<td></td>
<td>NHA</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collection Site Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>City</td>
</tr>
<tr>
<td>Province/Territory</td>
</tr>
<tr>
<td>British Columbia</td>
</tr>
</tbody>
</table>

### Ordering Test Provider Information

<table>
<thead>
<tr>
<th>Provider First Name</th>
<th>Provider Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone Number:</th>
<th>Extension:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MSP ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

### Patient Information

<table>
<thead>
<tr>
<th>PHN</th>
</tr>
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<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>Primary Contact Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>YYYY MM DD</td>
<td></td>
</tr>
</tbody>
</table>

### Section 3 – Point of Care Test Information

<table>
<thead>
<tr>
<th>Test Kit Name</th>
<th>Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YYYY MM DD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen Description</th>
<th>COVID-19 Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngeal</td>
<td>Positive</td>
</tr>
<tr>
<td>Nasal</td>
<td>Negative</td>
</tr>
<tr>
<td>Throat</td>
<td>Invalid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test performed by:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Registration and result back-entry performed by:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
Appendix B. COVID-19 Rapid Test Validation Report (Executive Summary)

The Abbott ID NOW™ and Panbio™ COVID-19 tests are Health Canada approved point-of-care (POC) tests for individuals experiencing symptoms consistent with COVID-19. The federal government of Canada purchased the tests for distribution to the provinces and territories.

These two tests have reduced sensitivity compared to gold-standard nucleic acid tests (NAT). The National Microbiology Laboratory and the Canadian Public Health Laboratory Network have drafted guidance documents for the potential use of these tests. Local (i.e. provincial) analytical and clinical validations are required to provide insight into their performance within the local environment.

A series of analytical and clinical validation studies were performed across multiple laboratory and patient care sites using both the Panbio™ and ID NOW™ test devices. The results of these studies will provide guidance for public health and clinical leaders to define the use cases for these POC tests.

Approved sample types vary between the two rapid tests: nasopharyngeal (NP) and bilateral nares swabs for the ID NOW™, and NP swab only for the Panbio™. Saline gargle (SG) samples were tested on both POC devices as part of this evaluation. Panbio™ showed a significant decrease in test performance and therefore, SG samples are not suitable. SG data were variable with the ID NOW™ so further work is required before making a recommendation on its use.

The analytical, or laboratory-based, studies found that the ID NOW™ test requires approximately 20 times more virus to be present before it can be detected than NAT. Panbio™ requires 1000 times more virus to be present. In the laboratory, the ID NOW™ correctly identified a positive COVID-19 case 85.5% of the time while the Panbio™ ranged from 35.0 – 61.5% depending on sample type.

Clinical trials focused on three scenarios: symptomatic individuals in a community with high numbers of COVID-19 cases, symptomatic individuals in the vulnerable homeless population and outbreak response in health care settings.

In the clinical studies, the overall agreement between ID NOW™ and NAT results varied from 80 – 100%. The COVID-19 Collection Centre site had the largest sample size with an overall agreement of 96.2% and in this population, the ID NOW™ correctly identified positives cases 82.5% of the time while the Panbio™ ranged from 35.0 – 61.5% depending on sample type.

Clinical trials focused on three scenarios: symptomatic individuals in a community with high numbers of COVID-19 cases, symptomatic individuals in the vulnerable homeless population and outbreak response in health care settings.

Operationally, the ID NOW™ requires an analyzer and test cartridges while the Panbio™ resembles a pregnancy test. Panbio™ is easier to use, requires less training and has all necessary components for testing supplied in the kit. However, unlike the ID NOW™, the test reagents and procedure do not inactivate the virus; therefore, special care must be taken when testing. Samples and test cassettes must be disposed of in biohazard waste after testing.
The primary use for both tests is likely in scenarios where there is a need to rapidly rule-in COVID-19. The analytical and clinical performance for the tests mean that they cannot be used to rule-out COVID-19. Detailed recommendations for both tests are provided within.

The validation report is limited by the sample sizes included in the analysis and the patient populations evaluated. However, these results are consistent with published literature. Both tests are Health Canada approved for symptomatic testing only; use for primarily asymptomatic testing was not considered in this report.

Further investigations are needed to understand the feasibility of whole genome sequencing (WGS) from residual rapid test swabs. Until those evaluations are complete, it is recommended that an NP or SG sample be collected if WGS is desired.