| Department of Health<br>Government of Nunavut | NURSING POLICY, PROCEDURE AND PROTOCOLS<br>Community Health Nursing | | |
|---|---|---|---|
| **TITLE:** | | **SECTION:** | **POLICY NUMBER:** |
| **Nirmatrelvir/Ritonavir (Paxlovid™) Treatment: Screening and Confirmatory Testing** | | **Pharmacy** | **09-022-00** |
| **EFFECTIVE DATE:** | **REVIEW DUE:** | **REPLACES NUMBER:** | **NUMBER OF PAGES:** |
| April 29, 2022 | April 29, 2023 | NEW | 9 |
| **APPLIES TO:** | | | |
| Health Care Providers; Virtual Public Health Nurses; Nurse Practitioners; Physicians | | | |

**1. BACKGROUND:**

The Department of Health (Health) is committed to improving access to quality health care and ensuring best practice guidelines are followed. Nirmatrelvir/Ritonavir (Paxlovid™) treatment is an available option in the Community Health Centres (CHC) for eligible clients who are considered high risk for poor outcomes presenting with mild severity of illness.

This policy outlines the required procedural steps for Health Care Providers (HCP) and Virtual Public Health Nurses (vPHN) to screen for potential eligible Nirmatrelvir/Ritonavir (Paxlovid™) clients and review the acceptable methods of confirmatory testing. This information will be used by the Physician or Nurse Practitioner (NP) to determine whether Nirmatrelvir/Ritonavir (Paxlovid™) can be prescribed.

**2. POLICY:**

2.1. All clients presenting to the CHC with "typical" signs and symptoms of COVID-19 unexplained by an alternative diagnosis and falling within the designated treatment window will be screened for Nirmatrelvir/Ritonavir (Paxlovid™) treatment eligibility.

2.2. All clients calling the COVID-19 hotline with "typical" signs and symptoms of COVID-19 falling within the designated treatment window will be screened for Nirmatrelvir/Ritonavir (Paxlovid™) treatment eligibility.

2.3. Clients who screen positive for Nirmatrelvir/Ritonavir (Paxlovid™) treatment eligibility will require either a confirmatory Polymerase Chain Reaction (PCR); Abbott ID NOW Point of Care Testing (POCT); HCP administered Rapid Antigen Test (RAT); or client self-administered RAT when considering treatment.

2.3.1. If there is no confirmatory testing readily available, and the physician or NP is highly suspicious of COVID-19 (based on symptoms and close contacts), they may decide to empirically treat the client with Nirmatrelvir/Ritonavir (Paxlovid™) at their discretion.

**3. PRINCIPLES:**

3.1. Nirmatrelvir/Ritonavir (Paxlovid™) significantly reduces the risk of hospitalization and mortality, consequently, it is important to ensure that Nunavummiut have timely access to treatment.

**4. DEFINITIONS:**

**Health Care Professional**: Community Health Nurse; Public Health Nurse; Advanced Care Paramedic.

**Typical signs and symptoms of COVID-19: fever/chills**; fatigue and myalgia; new or

worsening cough; new or worsening shortness of breath; loss of smell/taste; headache; Sore throat; GI symptoms (nausea, vomiting, diarrhea).

## 5. GUIDELINES FOR COVID-19 TREATMENT SCREENING IN THE CHC

5.1. Refer to **Appendix A: COVID-19 Treatment Decision Making Guide for the CHC** which provides an overview of the workflow.

5.2. All clients presenting to the CHC with "typical" signs and symptoms of COVID-19 not contributed to an alternative diagnosis will first have an assessment to determine if the client is within or outside the five day Nirmatrelvir/Ritonavir (Paxlovid™) treatment window.

5.2.1. Clients determined to be outside the five day treatment window will not require any confirmatory testing completed for the purposes of treatment.

5.3. Clients determined to be within the designated five-day Nirmatrelvir/Ritonavir (Paxlovid™) treatment window will be screened for eligibility criteria using **Appendix B: Determining the Risk of Disease Progression**.

5.3.1. Clients determined to be ineligible will not require any confirmatory testing completed for the purposes of treatment.

5.4. Clients who are eligible for Nirmatrelvir/Ritonavir (Paxlovid™) treatment will then require confirmatory testing with either a PCR; Abbott ID NOW; HCP administered RAT; or client self-administered RAT.

5.4.1. Refer to **Appendix C: Client Self Administered RAT – Accuracy Verification Checklist** for considerations to determine the accuracy of the client self-administered RAT.

5.4.1.1. Whenever the HCP is in doubt about the accuracy of a client self-administered RAT, then a confirmation test should be obtained on the Abbott ID NOW or HCP administered RAT.

5.4.2. Due to the high degree of false negatives with RATs, clients who are eligible for Nirmatrelvir/Ritonavir (Paxlovid™) treatment, but had a negative RAT, should have a PCR or Abbott ID NOW POCT to confirm. This will prevent missed opportunities for treatment.

5.5. A Physician or NP is consulted on all eligible Nirmatrelvir/Ritonavir (Paxlovid™) clients with a confirmed diagnosis on one of the acceptable testing methods. The Physician or NP will then review eligibility, potential drug interactions and contraindications to determine whether to prescribe Nirmatrelvir/Ritonavir (Paxlovid™) treatment or not.

5.5.1. If there is no confirmatory testing readily available, and the physician or NP is highly suspicious of COVID-19 (based on symptoms and close contacts), they may decide to empirically treat the client with Nirmatrelvir/Ritonavir (Paxlovid™) at their discretion.

## 6. GUIDELINES FOR COVID-19 TREATMENT SCREENING FOR THE COVID-19 HOTLINE

6.1. Refer to **Appendix D: COVID-19 Treatment Decision Making Guide for the vPHN Hotline** which provides an overview of the workflow.

6.2. All clients calling the COVID-19 hotline with "typical" signs and symptoms of COVID-19 will first have a virtual assessment to determine if the client is within or outside the five day Nirmatrelvir/Ritonavir (Paxlovid™) treatment window.

6.2.1. Clients determined to be outside the five day treatment window will not require any confirmatory testing completed for the purposes of treatment.

6.3. Clients determined to be within the designated five day Nirmatrelvir/Ritonavir (Paxlovid™) treatment window will be screened for eligibility criteria by the vPHN using **Appendix E: vPHN Nirmatrelvir/Ritonavir (Paxlovid™) Screening Form.**

6.3.1. Clients determined to be ineligible will not require confirmatory testing for the purposes of

treatment and are not referred to the CHC or IHS to be assessed for treatment.

6.4. The vPHN will inquire about a client self-administered RAT and document the findings on the vPHN Nirmatrelvir/Ritonavir (Paxlovid™) Screening Form.

6.5. All eligible clients for Nirmatrelvir/Ritonavir (Paxlovid™) treatment are referred to either the CHC or IHS depending on the client's location.

## 7. Documentation

7.1. The HCP will follow the SOAP Documentation Guidelines (#06-009-01) and the Documentation Standard policy (06-008-00).

7.2. vPHNs will document the client telephone call encounter on the vPHN Nirmatrelvir/Ritonavir (Paxlovid™) Screening Form for all eligible and ineligible clients. Once completed, this form is to be emailed to the CHC or IHS and filed in the client's chart.

## 8. Related Policies, Protocols and Legislation

COVID-19 Public Health Protocol: Version 9.0

| | |
|---|---|
| Policy 07-042-00 | Establishing a Plan of Care for High Risk COVID-19 Clients |
| Policy 06-008-00 | Documentation Standards |
| Policy 06-008-01 | Documentation Standard Guidelines |
| Policy 06-009-00 | Documentation Format |
| Policy 06-009-01 | SOAP Documentation Guidelines |
| Order Set | Nirmatrelvir/Ritonavir (Paxlovid™) for Mild, Confirmed COVID-19 in Adults 18 years of age and older |

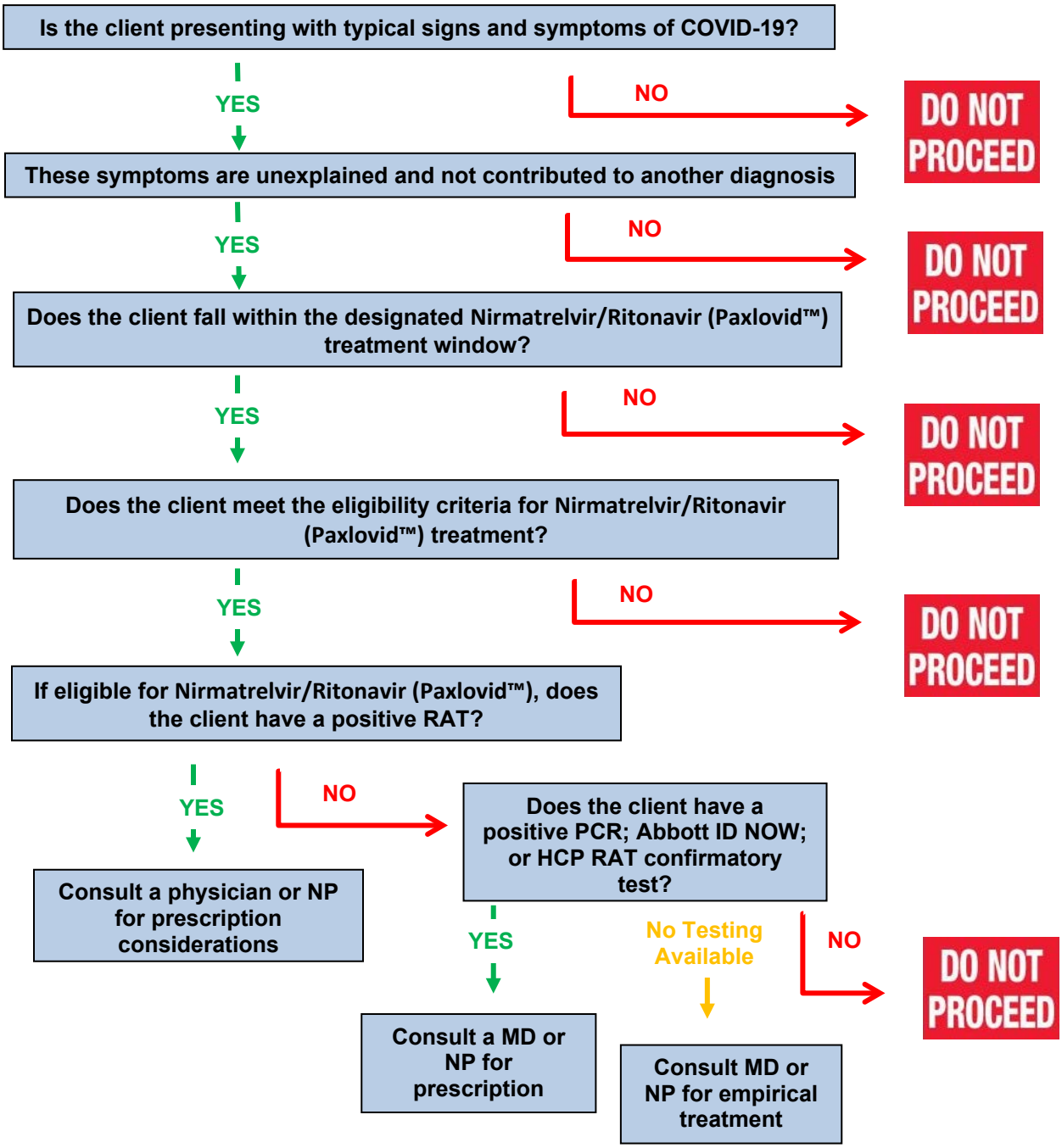
## 9. Appendix

Appendix A: COVID-19 Treatment Decision Making Guide for the CHC
Appendix B: Determining the Risk of Disease Progression
Appendix C: Client Self Administered RAT – Accuracy Verification Checklist
Appendix D: COVID-19 Treatment Decision Making Guide for the vPHN Hotline
Appendix E: vPHN Nirmatrelvir/Ritonavir (Paxlovid™) Screening Form

| | |
|---|---|
| Approved By: Jennifer Berry | Date: April 29, 2022 |
| Gogi Greely, a/Assistant Deputy Minister – Department of Health | |
| Approved By: Jenn Bujold | Date: April 29, 2022 |
| Jenifer Bujold, a/Chief Nursing Officer | |
| Approved By: | Date: |
| Dr Francois de Wet, Territorial Chief of Staff | |

## APPENDIX A: NIRMATRELVIR/RITONAVIR (PAXLOVID™) TREATMENT DECISION MAKING GUIDE FOR THE CHC

*For adults 18 years of age and older



## APPENDIX B: DETERMINING THE RISK OF DISEASE PROGRESSION

**Identify Risk Factors (check all that apply):**

- ❑ Obesity (BMI 30 or greater)
- ❑ Diabetes Mellitus
- ❑ Heart disease, hypertension, congestive heart failure
- ❑ Chronic respiratory disease, including cystic fibrosis
- ❑ Cerebral Palsy
- ❑ Intellectual disability
- ❑ Sickle Cell Disease
- ❑ Moderate or severe kidney disease (eGFR less than 60 mL/min)
- ❑ Moderate or severe liver disease (e.g., Child Pugh Class B or C cirrhosis)

**Higher risk** individuals are those who have a 5% or greater risk of hospitalization if they develop COVID-19. **Standard risk** individuals are those who have a less than 5% risk of hospitalization.

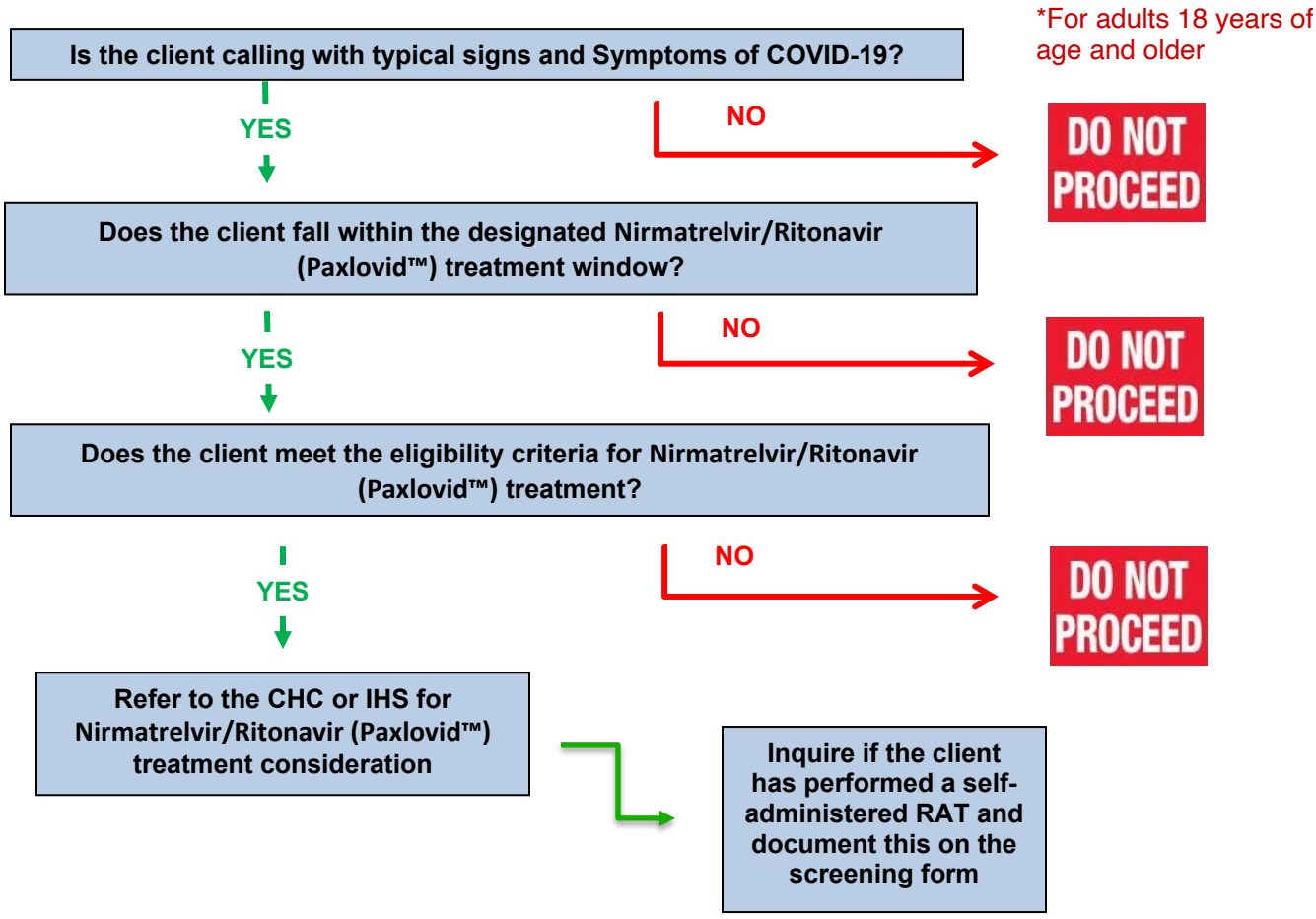
**Determine risk of disease progression below.** Individuals with a **Higher risk of disease progression** qualify for treatment.

| AGE (years) | NUMBER OF VACCINE DOSES | | |
|---|---|---|---|
| | **0 or 1 doses** | **2 doses** | **3 doses** |
| **Less than 20** | ❑ **Higher risk** if 3 or more risk factors | Standard risk | Standard risk |
| **20 to 39** | ❑ **Higher risk** if 3 or more risk factors | ❑ **Higher risk** if 3 or more risk factors | Standard risk |
| **40 to 64** | ❑ **Higher risk** if 1 or more risk factors | ❑ **Higher risk** if 3 or more risk factors | Standard risk |
| **55 or greater and Indigenous** | ❑ **Higher risk** | ❑ **Higher risk** | ❑ **Higher risk** if 3 or more risk factors |
| **65 or greater** | ❑ **Higher risk** | ❑ **Higher risk** if 1 or more risk factors | ❑ **Higher risk** if 3 or more risk factors |
| **Immunocompromised[1] individuals of any age** | ❑ **Higher risk:** Therapeutics should always be recommended for immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying immune status, regardless of age or vaccine status. | | |
| **Pregnancy[2]** | ❑ **Higher risk** | Standard risk | Standard risk |

## APPENDIX C: CLIENT SELF ADMINISTRATION RAPID ANTIGEN TEST (RAT) – ACCURACY VERIFICATION CHECKLIST

| | | | |
|---|---|---|---|
| Was the expiration date of the RAT known? | Yes | No | **If RAT is expired, confirm with ID NOW** |
| Method of collection was reviewed and instructions followed | Yes | No | **If collection is questionable, confirm with ID NOW** |
| The liquid used for mixing the solution was the buffer supplied in the Kit | Yes | No | **If the buffer solution was not used, confirm with ID NOW** |
| A timer was used (not estimated) to determine when the result is due to be read | Yes | No | **If a timer was not used, confirm with ID NOW** |
| The result was read at 15 minutes (not before or after) | Yes | No | **If the timeframe for reading the result was not accurate, confirm with ID NOW** |
| The client described the result as a control line and test line both being visible | Yes | No | **If the interpretation is questionable, confirm with ID NOW** |
| Optional: The client provided a picture of the result | Yes | No | |

## APPENDIX D: PAXLOVID TREATMENT DECISION MAKING GUIDE FOR THE COVID-19 HOTLINE



Appendix E: vPHN Nirmatrelvir/Ritonavir (Paxlovid™) Screening Form

**Allergies:**
☐ NKA
☐ Unobtainable
☐ _____

Patient Name: _____
(Last Name) (First Name)
DOB: _____ (DD/MM/YY) Age: _____
Gender: M / F / U

## vPHN Nirmatrelvir-Ritonavir (Paxlovid) Screening Form

Patient's community: _____
Phone Caller's Name: _____
Contact Number: _____
Phone Caller's Relationship to the Patient
(If not the patient): _____

Date of Referral: _____
Reason for the Call: _____
_____
_____
_____

**In order to qualify for therapy, patients need to:**

- ❑ Be symptomatic;
- ❑ Be within 5 days of symptom onset;
- ❑ Be an outpatient or inpatient and meet the definition for Mildly Ill
  - **Mildly Ill:** Patients who do not require new or additional supplemental oxygen from their baseline status.
- ❑ Meet criteria below for being at higher risk of disease progression; and
- ❑ Have an expected survival of greater than 1 year from all causes.

Date of symptom onset: _____
(Treatment must be started within 5 days of symptom onset)

Date of positive self-administered RAT (If Applicable): _____
*If Patient self administered RAT is positive: Refer to **Appendix A** Accuracy Verification Checklist

Symptoms: ❑ Fever ❑ Cough ❑ SOB ❑ Fatigue ❑ Loss of taste ❑ Loss of smell
❑ Other: _____

**Identify Risk Factors (check all that apply):**

- ❑ Obesity (BMI 30 or greater)
- ❑ Diabetes Mellitus
- ❑ Heart disease, hypertension, congestive heart failure
- ❑ Chronic respiratory disease, including cystic fibrosis
- ❑ Cerebral Palsy
- ❑ Intellectual disability
- ❑ Sickle Cell Disease
- ❑ Moderate or severe kidney disease (eGFR less than 60 mL/min)
- ❑ Moderate or severe liver disease (e.g., Child Pugh Class B or C cirrhosis)

**Higher risk** individuals are those who have a 5% or greater risk of hospitalization if they develop COVID-19. **Standard risk** individuals are those who have a less than 5% risk of hospitalization.

**Contradictory Medications:**
❑ Antiarrhythmics ❑ Oral anticoagulants ❑ Immunosuppressants ❑ Anticonvulsants ❑ Antineoplastics
❑ Neuropsychiatric drugs
*This is not an all-inclusive list and specialized resources (listed on the order set) need to be consulted by the MD/NP for all drug interactions.

**Eligibility:**
Using **Appendix B** Determine if the individual is "high risk"
❑ Patient meets "high risk" criteria and is eligible for Nirmatrelvir-Ritonavir (Paxlovid) ❑ Patient is not eligible
❑ Patient consents to have an assessment completed regarding treatment considerations
❑ Patient does not consent to have an assessment completed regarding treatment considerations

vPHN Name: _____ Date: _____

**Allergies:**
☐ NKA
☐ Unobtainable
☐ _____

Patient Name: _____
(Last Name) (First Name)
DOB: _____ (DD/MM/YY) Age: _____
Gender: M / F / U

## Appendix A: Client Self Administration Rapid Antigen Test (RAT) – Accuracy Verification Checklist

| | | | |
|---|---|---|---|
| Was the expiration date of the RAT known? | Yes ❑ | No ❑ | **If RAT is expired, confirm with ID NOW** |
| Method of collection was reviewed and instructions followed | Yes ❑ | No ❑ | **If collection is questionable, confirm with ID NOW** |
| The liquid used for mixing the solution was the buffer supplied in the Kit | Yes ❑ | No ❑ | **If the buffer solution was not used, confirm with ID NOW** |
| A timer was used (not estimated) to determine when the result is due to be read | Yes ❑ | No ❑ | **If a timer was not used, confirm with ID NOW** |
| The result was read at 15 minutes (not before or after) | Yes ❑ | No ❑ | **If the timeframe for reading the result was not accurate, confirm with ID NOW** |
| The client described the result as a control line and test line both being visible | Yes ❑ | No ❑ | **If the interpretation is questionable, confirm with ID NOW** |
| Optional: The client can provided a picture of the result | Yes ❑ | No ❑ | |

## Appendix B: Determine Risk of Disease Progression

**Individuals with a Higher risk of disease progression qualify for treatment.**

| Age (Years) | NUMBER OF VACCINE DOSES | | |
|---|---|---|---|
| | **0 OR 1 Dose** | **2 Doses** | **3 Doses** |
| **Less than 20** | ❑**Higher Risk**: if 3 or more risk factors | Standard Risk | Standard Risk |
| **20 to 39** | ❑**Higher Risk**: if 3 or more risk factors | ❑**Higher Risk**: if 3 or more risk factors | Standard Risk |
| **40 to 64** | ❑**Higher Risk**: if 1 or more | ❑**Higher Risk**: if 3 or more risk factors | Standard Risk |
| **55 or greater and Indigenous** | ❑**Higher Risk**: | ❑**Higher Risk**: | ❑**Higher Risk**: if 3 or more risk factors |
| **65 or greater** | ❑**Higher Risk**: | ❑**Higher Risk**: if 1 or more risk factors | ❑**Higher Risk**: if 3 or more risk factors |
| **Immunocompromised individuals of any age** | ❑**Higher Risk:** Therapeutics should always be recommended for immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying immune status, regardless of age or vaccine status. | | |
| **Pregnancy** | ❑**Higher Risk**: | Standard Risk | Standard Risk |