Ontario Health

Guidance to reporting COVID-19 Lab Based PCR Test Results

Ontario Laboratories Information System (OLIS) Requirements Version 4.1

May, 2021

Ontario Health

Version History

Version No.	Date	Summary of Change
1.0	March 27, 2020	Initial Document created
1.1	April 3, 2020	Section 1.1: • MRN usage has been clarified for the PID Segment • New Test Request Code added Section 1.1.1, Section 1.1.2, Section 1.1.3: • Guidance added around requested interpretations. Section 1.1.4 • Guidance added for the RealStar testing kit
2.0	April 6, 2020	Section 1.1.1: • New Result codes added. All Section Edits: • Reorganization of resulting LOINC Codes • Clarification for Interpretation verbiage Section 1.1.3: • Guidance update for interpretation
2.1	April 23, 2020	Section 1.1.3 • Update to Interpretation code
3.0	June 10, 2020	Section 1.2 • Guidance added for reporting of Shared Living Facilities results Section 1.1.4 Testing Method Change • Moved to Section 1.3 Section 1.1.5 Contact • Moved to Section 2.0
3.1	June 25, 2020	Entire document re-formatted and Table of Contents added Section 1.0 • Added guidance to submit all information documented on requisition form and link to COVID-19 Requisition-Laboratory Reporting Mapping guidance document Section 1.2 • Guidance added for Preliminary Reports Section 1.3 • Guidance added for Amended Reports Section 1.4 • Entire section 'Additional Requirements for Shared Living Facilities' moved/re-named from Section 1.2 Link added for COVID-19 Requisition- Laboratory Reporting Mapping guidance document
4.0	May, 2021	• Changed Document Title to be specific to lab based PCR testing. • Re-numbering of Sections to accommodate inclusion of reporting guidance for Respiratory Virus Panel + SARS-CoV-2 (COVID-19) • New section 2.0 (originally section 1.4) changed to no longer be specific to Shared Living Facilities, as the OCMOH is expecting this data reported for all COVID results where possible. Expanded to include the additional data captured on the COVID-19 lab requisition form requested to be reported wherever possible. • Fixed broken hyperlinks • Fixed formatting
4.1	July, 2021	• Formatting corrections • Added hyperlink for PHO Requisition form • Updated SMTP addresses to Ontariohealth.ca addresses

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1.0 OLIS Guidance to reporting lab based COVID-19 PCR Test Results

Ontario Health (Digital Excellence in Health) has engaged with Public Health Ontario and the Office of the Chief Medical Officer of Public Health (OCMOH) to align OLIS nomenclature and result codes for consistency of COVID-19 result reporting.

All labs reporting COVID-19 tests must ensure:

- All results are reported to OLIS
- All information documented on the COVID-19 Test requisition form must be submitted to OLIS as per the COVID-19 Requisition-Laboratory Reporting Mapping
- Errors are corrected and resubmitted as soon as possible
- Adherence and alignment to reporting guidelines with one of the following approaches for nomenclature and reporting

1.1 COVID-19 Reporting for OLIS

- **PID segment**:
    - Patients having an Ontario Health Card (OHIP) must be identified with this information.
    - Medical Record Number (MRN) information may also be included in the PID segment, in addition to the OHIP number, or when the OHIP number is not available.
    - FULL Patient address information is required to support Case & Contact Management at the Public Health Units and therefore must be submitted as completely as possible, including postal code.
- **OBR.15: Specimen source** for COVID-19 testing **must be identified here**.
- **ZBR.6: Performing Lab** must be identified in ZBR.6.
    - When submitting any results to OLIS, where the tests were performed at another facility, contributing labs must ensure that they are properly identifying the **Performing Laboratory** in ZBR.6
    - In addition, any notes accompanying the results from the Performing lab must be identified as coming from the performing lab in the ZNT segment.
- One of the following **Test Request codes** must be used to order COVID-19 regardless of reporting approach:
    - TR12936-1 / 2019 Novel Coronavirus PCR
    - TR12937-9 / 2019 Novel coronavirus RNA panel

1.1.1 Preferred Approach: Discrete Data Reporting

The preferred approach to report COVID-19 results is in a **Discrete Data format**.
If this cannot be accomplished in the microbiology module of the LIS, labs should build the discrete reporting format in the Core Lab/ Chemistry module.

This means that the unique LOINC codes, representative of the individual COVID-19 genes tested, must be reported in individual OBX segments of the HL7 message to OLIS.

- One of the following Test Request codes MUST be used to order COVID-19:
    - TR12936-1 / 2019 Novel Coronavirus PCR
    - TR12937-9 / 2019 Novel coronavirus RNA panel

- The current codes available for COVID reporting are:
    - 94315-9 / 2019 Novel coronavirus E gene:PrThr:Pt:XXX:Ord:Probe.amp.tar
    - 94314-2 / 2019 Novel coronavirus RdRp gene:PrThr:Pt:XXX:Ord:Probe.amp.tar
    - 94316-7 / 2019 Novel coronavirus N gene:PrThr:Pt:XXX:Ord:Probe.amp.tar
    - XON13529-3 / SARS coronavirus 2 ORF1ab:PrThr:Pt:XXX:Ord:Probe.amp.tar
    - XON13528-5 / SARS coronavirus 1:PrThr:Pt:XXX:Ord:Probe.amp.tar
    - XON13531-9 / SARS coronavirus 2 S gene RNA:PrThr:Pt:XXX:Ord:Probe.amp.tar

- The above result codes must be resulted using one of the following options:
    - Detected
    - Not Detected
    - Indeterminate or
    - Invalid

- The overall interpretation of the COVID-19 virus reporting MUST be reported using the following narrative interpretation code:
    - XON13527-7 / COVID-19 virus PCR Interpretation:Imp:PT:XXX:Nar

Requested Interpretations:

- The appropriate interpretation, from the list below, MUST be the first line of the interpretation and **must match exactly as shown** below, in order to ensure that the exact data supports other downstream system integrations supporting the Ontario pandemic response .
    - COVID-19 virus NOT detected by real-time PCR.
    - COVID-19 virus DETECTED by real-time PCR.
    - Indeterminate for COVID-19 virus.
    - COVID-19 virus PCR test unable to be completed.

- Additional discretionary interpretation verbiage can be added in subsequent lines, which may include but is not limited to, the identification of the specific COVID-19 genes tested.

  E.g. COVID-19 virus RdRp gene: Detected
  COVID-19 virus E gene: Detected
- If you are capturing COVID results in your LIS that were referred to another laboratory for testing, (e.g. Public Health Ontario (PHO)) also include the Interpretation that was included on the performing laboratory's report.

1.1.2 Alternative Approach 1: Use if the Preferred Approach is not available

This approach can be used if the LIS does not support the reporting of discrete data in the Microbiology module, and the lab is constrained or unable to build the report in the Core Lab/ Chemistry module.

- One of the following Test Request codes MUST be used to order COVID-19:
  - TR12936-1 / 2019 Novel Coronavirus PCR
  - TR12937-9 / 2019 Novel coronavirus RNA panel
- The following approach should be used for reporting COVID-19 results.
  - POSITIVE results are to be reported by identifying the organism using the SNOMED Code 840533007 / SARS-CoV-2
  - NEGATIVE results are to be reported by identifying that no virus was identified using the SNOMED Code 168209000 / No Virus Identified
- Both SNOMED Code (microorganism) reports MUST be reported using the LOINC:
  - 41461-5 / Virus identified:Prid:Pt:XXX:Nom
- If an overall interpretation is added it MUST be done so using the following narrative interpretation code:
  - XON13527-7 / COVID-19 virus PCR Interpretation:Imp:PT:XXX:Nar

<u>Requested Interpretations:</u>

- The appropriate interpretation, from the list below, MUST be the first line of the interpretation and must match exactly as shown below.
  - COVID-19 virus NOT detected by real-time PCR.
  - COVID-19 virus DETECTED by real-time PCR.
  - Indeterminate for COVID-19 virus.
  - COVID-19 virus PCR test unable to be completed.
- Additional discretionary interpretation verbiage can be added in subsequent lines, which may include but is not limited to, the identification of the specific COVID-19 genes tested.

  E.g. COVID-19 virus RdRp gene: Detected
  COVID-19 virus E gene: Detected
- If you are capturing COVID results in your LIS that were referred to another laboratory for

testing, (e.g. Public Health Ontario (PHO)) also include the Interpretation that was included on the performing laboratory's report.

1.1.3 Alternative Approach 2: Use only if either of the above approaches are not available

One of the following Test Request codes MUST be used to order COVID-19:

- TR12936-1 / 2019 Novel Coronavirus PCR
- TR12937-9 / 2019 Novel coronavirus RNA panel

Report all results in a narrative interpretation using LOINC:

- XON12338-0 / Microbiology Report:Find:Pt:XXX:Nar

The appropriate interpretation, from the list below, MUST be the first line of the interpretation and must match exactly as shown below.

- COVID-19 virus NOT detected by real-time PCR.
- COVID-19 virus DETECTED by real-time PCR.
- Indeterminate for COVID-19 virus.
- COVID-19 virus PCR test unable to be completed.

Additional discretionary interpretation verbiage can be added in subsequent lines, which may include but is not limited to, the identification of the specific COVID-19 genes tested.

E.g. COVID-19 virus RdRp gene: Detected
COVID-19 virus E gene: Detected

If you are capturing COVID results in your LIS that were referred to another laboratory for testing, (e.g. Public Health Ontario (PHO)) also include the Interpretation that was included on the performing laboratory's report.

1.2 Preliminary Reports

Do not submit Preliminary COVID-19 results to OLIS. Suppressing the submission of these results will prevent data inaccuracies and complications where result data is used by downstream systems and various analytics.

1.3 Amended Reports

2.1.1 Preferred Approach

When amending a textual result previously reported with XON13527-7 / COVID-19 VIRUS PCR INTERPRETATION:IMP:PT:XXX:NAR

1. Record the previously reported result and the reason for amendment in a **Result Level Note**
2. Update the textual result with the corrected test result. This will generate an Observation Result Status (OBX-11) of 'C' in the HL7 message.

As an example, the resulting HL7 message will appear as:

```
OBX|1|TX|XON13527-7^COVID-19 virus PCR
Interpretation:IMP:Pt:XXX:NAR^HL79902|412288637|COVID-19 virus NOT
DETECTED by real-time PCR||||||C||||||^
ZBX|20200604173845-0400|0004|
NTE|1|L|Corrected Report. Please disregard previous Report\.br\Previously
reported as COVID-19 virus DETECTED by real-time PCR on 2020-06-
03|RE^Remark^HL70364|
ZNT|^2.16.840.1.113883.3.59.1:4009^ISO|
```

2.1.1 Alternative Approach if Site unable to submit Result Level Note

This approach can be used for sites unable to submit a Result Level Note.

When amending the textual result previously reported with XON13527-7 / COVID-19 VIRUS PCR INTERPRETATION:IMP:PT:XXX:NAR

1. Submit the previously reported result and the reason for amendment using the LOINC:
    - XON10441-4 \ Specimen Result Comment.Micro:IMP:Pt:XXX:NAR
2. Update the textual result with the corrected test result. This will generate an Observation Result Status (OBX-11) of 'C' in the HL7 message.

1.4 Respiratory Virus Panel + SARS-CoV-2 Reporting

To support the ability for a single specimen collected to be tested for both the seasonal respiratory virus panel (which includes Influenza A Virus, Influenza B Virus and Respiratory Syncytial Virus), as well as SARS-CoV-2 (COVID-19); the following guidance is being provided.

Labs are requested to follow this recommended reporting, to allow the SARS-CoV-2 (COVID-19) results reporting to be captured in the data extracts required by the Ministry of Health, and be displayed to patients in the COVID-19 Patient Results Viewer.

As well, it will support consistent reporting for the Public Health Units, to easily navigate the data for COVID based test result interpretations.

The Respiratory Virus Panel and SARS-CoV-2(COVID-19) test must be ordered using the Test Request Code:

- **TR12945-2 \ Respiratory Virus Panel + SARS-CoV-2 (COVID-19)**

The results for the Respiratory Virus Panel + SARS-CoV-2 (COVID-19) must be reported discretely using the following results codes:

- **34487-9^ Influenza virus A RNA:ACnc:Pt:XXX:Ord:Probe.amp.tar**
- **40982-1^ Influenza virus B RNA:ACnc:Pt:XXX:Ord:Probe.amp.tar**
- **40988-8^ RESPIRATORY SYNCYTIAL VIRUS RNA:ACNC:PT:XXX:ORD:PROBE.AMP.TAR**
- **XON13527-7^COVID-19 virus PCR interpretation:Imp:Pt:XXX:Nar**

Specifically for the COVID-19 virus PCR interpretation, the appropriate interpretation, from the list below, MUST be the first line of the interpretation and must match exactly as shown below.

- **COVID-19 virus NOT detected by real-time PCR.**
- **COVID-19 virus DETECTED by real-time PCR.**
- **Indeterminate for COVID-19 virus.**
- **COVID-19 virus PCR test unable to be completed**.

2.0 Reporting of Additional Requisition Data – All COVID Test Results

2.1 COVID-19 Requisition Form – Additional Data Reporting to OLIS

Additional COVID-19 data reporting requirements, as captured on the Public Health Ontario (PHO) COVID-19 Virus Test Requisition form, are outlined in this section. (PHO Requisition form)

This includes reference data and guidance to capture additional discrete data elements required to support the provincial reporting request (quick guide: COVID-19 Requisition-Laboratory Reporting Mapping).

For each of these additional reporting requirements, three (3) options will be accommodated: as a discrete data element; prescribed syntax in Order Level Notes/NTE segment or; via an additional test request/code.

NOTE: the **same Filler Order Number (OBR.3 segment) MUST be used throughout all sections of the same order**. This is especially important when utilizing the Preferred Approach (Discrete Data) to enter order/results data.

2.1.1 Preferred Approach: Discrete Data Reporting

The REQUIRED test codes for each data element are outlined below.

- **Investigation or Outbreak Number -** (COVID-19 Virus Test Requisition -Section 1-Patient Information)
    - **XON13544-2 / Outbreak Number:ID:Pt:^Event:Nom**

  Note:

    - An outbreak number is assigned for specific facilities and / or situations where monitoring is required (e.g. LTC homes or Shared Living facilities, School based testing, etc.).
    - Investigation numbers (INV#) must be entered and are generated by PHO to support targeted testing campaigns and surveillance screenings, e.g., testing of long-term care home staff, Airport screenings, or testing of other congregate living settings.

- **Travel History –** (COVID-19 Virus Test Requisition – Section 3)
    - **10182-4 / Travel:HX:Pt:^Patient:Nar**

- **Exposure History –** (COVID-19 Virus Test Requisition - Section 4)
    - **XON13545-9/ Exposure history:Imp:Pt:^Patient:Nar**

- **Patient Setting /Type - (COVID-19 Virus Test Requisition - Section 7)**

- **56816-2 / Patient location:Loc:Pt:^Patient:Nom** or within the PV1.3 PATIENT SETTING Field within the HL7 Message to OLIS

- This data **must be captured discretely and selected** from the Shared Living Facility and Assessment Centre reference table. A minimum of the eight character "**COVID-19 Mobile Testing Unique ID**" from this table must be reported (e.g. LTC-1001). This ID may be documented in the "Other" box of section 7 of the requisition form.

- **COVID-19 Vaccination Status** - (COVID-19 Virus Test Requisition – Section 8)
  - **97155-6 / SARS coronavirus 2 immunization status:Hx:Pt:^Patient:Nom**

- **Clinical Information – (COVID-19 Virus Test Requisition - Section 9**
  - **XON13543-4 / Patient symptoms:Imp:Pt:^Patient:Nar**
  - **76425-8 / Date of onset:Date:Pt:^Patient:Qn:Reported (if provided)**

  - Symptom status (asymptomatic/symptomatic) MUST BE entered.
  - Date of onset should be entered in the format: YYYY-MM-DD
  - Enter all patient symptoms and other/additional symptom details (e.g. temperature) as one response.

2.1.3 Alternate Approach 1: Order Level Notes

If the data fields cannot be reported using the preferred approach, use the below syntax for reporting these values in the **Order Level notes.**

- **Investigation or Outbreak Number:**

  ####-####-### OR AAA-####-###\.br\

- **Patient Setting:**

  - Select the COVID-19 Unique ID's representative of the Local Assessment Centre, Long Term Care or Retirement Home, selected from the Shared Living Facility and Assessment Centre reference table

    e.g., Patient Setting: LTC-####\.br

- **Clinical Information:**

  Clinical Information: [group type], [symptom status]

  e.g., Clinical Information: Health Care Worker, Asymptomatic\.br\

- **Exposure History:**

  Indicate probably of exposure to a confirmed case [Yes/ No] and provide exposure details, if provided

- **COVID-19 Vaccination Status:**

  Indicate the COVID-19 Vaccination Status as capture on the requisition:

  Received all required doses >14 days ago

  Unimmunized/ partial series/ ≤14 days after final dose

  Unknown

IMPORTANT: Data should be separated with a line break (see example).

e.g.: *Investigation or Outbreak Number: ABCD-EF-001\.br\Recent Travel: FLORIDA 2020/09/03-2020/09/21\.br\Patient Setting: LTC-1234\.br\Clinical Information: Symptomatic, Sore Throat, Headache (Only)\.br\Exposure History: Yes, received COVID Alert\.br\COVID-19 Vaccination Status: Unimmunized/partial series/≤14 days after final dose\.br*

Information will appear as the following on the OLIS Lab Result report:

Investigation or Outbreak Number: ABCD-EF-001
Recent Travel: FLORIDA 2020/09/03-2020/09/21
Patient Setting: LTC-1234
Clinical Information: Symptomatic, Sore Throat, Headache (Only)
Exposure History: Yes, received COVID alert
COVID-19 Vaccination Status: Unimmunized/ partial series/ ≤14 days after final dose

Where your LIS may not accommodate Line Breaks in the NTE segments, contact Ontario Health (Digital Excellence in Health) at oh-ds_clinicdata.managsupport@ontario.ca to validate alternatives.

All **other NOTES or details** should **follow** the above data elements.

2.1.3 Alternate Approach 2: Test Requisition

An additional alternative of leveraging a separate Test Request/code was proposed and would be considered on a case-by-case basis if technical or workflow constraints exist.
Please inquire directly with Ontario Health (Digital Excellence in Health) Clinical Data Management for further details at: oh-ds_clinicdata.managsupport@ontario.ca, before proceeding with this alternate approach.

3.0 Testing Method Changes

Ontario Health (Digital Excellence in Health) is actively working with Public Health Ontario to ensure any new nomenclature related to new COVID-19 testing methods are being added to the OLIS nomenclature as soon as they are identified.

Check the Ontario Health website frequently for updates.

4.0 Contact:

To engage directly with the OLIS COVID-19 nomenclature subject matter experts, email the Clinical Data Management team at Ontario Health (Digital Excellence in Health).