Ontario Health
Digital Services

Guidance to reporting COVID-19 results

Ontario Laboratories Information System (OLIS) Requirements Version 3.1

July 16, 2020

Version History

Version No.	Date	Summary of Change
1.0	March 27, 2020	Initial Document created
1.1	April 3, 2020	Section 1.1: 1. MRN usage has been clarified for the PID Segment 2. New Test Request Code added Section 1.1.1, Section 1.1.2, Section 1.1.3: 1. Guidance added around requested interpretations. Section 1.1.4 1. Guidance added for the RealStar testing kit
2.0	April 6, 2020	Section 1.1.1: 1. New Result codes added. All Section Edits: 1. Reorganization of resulting LOINC Codes 2. Clarification for Interpretation verbiage Section 1.1.3: 1. Guidance update for interpretation
2.1	April 23, 2020	Section 1.1.3 1. Update to Interpretation code
3.0	June 10, 2020	Section 1.2 1. Guidance added for reporting of Shared Living Facilities results Section 1.1.4 Testing Method Changes 1. Moved to Section 1.3 Section 1.1.5 Contact 1. Moved to Section 2.0
3.1	June 25, 2020	Entire document re-formatted and Table of Contents added Section 1.0 1. Added guidance to submit all information documented on requisition form and link to COVID-19 Requisition-Laboratory Reporting Mapping guidance document Section 1.2 1. Guidance added for Preliminary Reports

Version No.	Date	Summary of Change
		Section 1.3 1. Guidance added for Amended Reports Section 1.4 1. Entire section 'Additional Requirements for Shared Living Facilities' moved/re-named from Section 1.2 2. Link added for COVID-19 Requisition-Laboratory Reporting Mapping guidance document

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1.0 OLIS Guidance to reporting COVID-19 results

Ontario Health (Digital Services) has engaged with Public Health Ontario and the Office of the Chief Medical Officer of Public Health to align OLIS nomenclature and result codes.

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.
- **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.
    - 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

1.3.1 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|
```

1.3.2 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 Additional Requirements for Shared Living Facilities (Long-Term Care, Retirement Homes and Shelters)

Additional reporting requirements for residents of shared facilities are outlined in this section. This includes reference data and guidance to capture additional discrete data elements required for this population (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.

1.4.1 Preferred Approach: Discrete Data Reporting

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

- **Investigation/Outbreak No.** (COVID-19 Virus Test Requisition -Section 1-Patient Information)
    - **XON13544-2 / Outbreak Number:ID:Pt:^Event:Nom**

  Note:

    - An outbreak at a LTCH will have one reference number for all patients related to the outbreak. Enter the event specific outbreak number (OB#) provided by the local public health unit since the same facility home can have more than one outbreak event/number.
    - Investigation numbers (INV#) must be entered and are generated by PHO to support targeted testing campaigns, e.g., testing of long-term care home staff, or testing of other congregate living settings.

- **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.

- **Clinical Information – (COVID-19 Virus Test Requisition- Section 8)**
    - **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.

1.4.2 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/Outbreak Number:**

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

- **Patient Setting:**
    - Select the COVID-19 Mobile Testing Unique ID 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\

Data should be separated with a line break.

e.g.: *Outbreak Number: ####-####-###\.br\ Patient Setting: LTC-####\.br\Clinical Information: Health Care Worker, Asymptomatic\.br*

Where your LIS may not accommodate Line Breaks in the NTE segments, contact Ontario Health (Digital Services) at Clinical Data Management team to validate alternatives.

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

1.4.3 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. Inquire directly with Ontario Health (Digital Services) Clinical Data Management for further details at ClinicData.ManagSupp@ehealthontario.on.ca

2.0 Testing Method Changes

Ontario Health (Digital Services) 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.

3.0 Contact:

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