

Guidance for Limited-Service Laboratories for Standards-Based Electronic Laboratory Reporting the Results of Influenza A and Influenza B Virus CLIA Waived Tests to the NYSDOH Electronic Clinical Laboratory Reporting System (ECLRS)

Dear Limited-Service Laboratory Director:

Per Section 2.1 of Title 10 of the New York Codes, Rules, and Regulations the results of laboratory testing for Influenza Virus are required to be reported. Registered limited-service laboratories¹ that perform influenza testing must **report all positive influenza test results** electronically to the NYSDOH Electronic Clinical Laboratory Reporting System (ECLRS) for testing performed on-site. This guidance can be shared with your electronic medical record (EMR) vendor if you use the EMR as an interface to report to ECLRS.

We request use of the most specific and appropriate Logical Observation Identifiers Names and Codes² (LOINC®) code to report influenza type (e.g., Influenza A, Influenza B) and specimen type. Please do not use LOINC codes that do not differentiate influenza virus types.

For laboratories using Systematized Nomenclature for Medicine³ (SNOMED-CT) to report results, we request use of the most specific and appropriate result code. Preferred SNOMED-CT codes include:

1. 407479009 = Influenza A virus (organism)
2. 699872005 = Influenza A virus untyped strain present (finding)
3. 407480007 = Influenza B virus (organism)
4. 260373001 = Detected
5. 10828004 = Positive
6. 260415000 = Not Detected
7. 260385009 = Negative
8. 419984006 = Inconclusive
9. 82334004 = Indeterminate
10. 125154007 = Specimen unsatisfactory for evaluation
11. 373121007 = Test not done
12. 455371000124106 = Invalid result

Please see [Attachment 1](#) for preferred LOINC and SNOMED-CT codes and result text for ECLRS reporting. [Attachment 2](#) lists currently approved CLIA-waived influenza diagnostic tests⁴.

Laboratories using multiplex testing platforms that include two or more of influenza A, Influenza B, SARS-CoV-2, and RSV should report to ECLRS positive results of these tests using LOINC/SNOMED-CT codes for the **individual virus results**. **Do not use the LOINC codes associated with the overall multi-pathogen test.**

The ECLRS Help Desk (866-325-7743 or eclrs@health.ny.gov) is available to assist with reporting procedures.

The Bureau of Communicable Disease Control's Respiratory Surveillance unit (518-473-4439 or RespVirusDOH@health.ny.gov) can assist with LOINC or SNOMED-CT selection for influenza test results.

Additional information regarding influenza and general communicable disease reporting can be found here: <https://www.health.ny.gov/professionals/diseases/reporting/communicable/>.

Detailed information regarding the reporting of influenza subtype (e.g., Influenza A/H3, Influenza A/H1N1, etc.) or lineage (Influenza B/Victoria, Influenza B/Yamagata) is available here: https://www.health.ny.gov/professionals/diseases/reporting/communicable/docs/influenza_guidance_clinical.pdf

¹ <https://www.wadsworth.org/regulatory/clep/limited-service-labs>

² <https://loinc.org/>

³ <https://www.snomed.org/use-snomed-ct>

⁴ <https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/categorization>

**Attachment 1: Guidance for Limited Service Laboratories¹ for Standards-Based Electronic Laboratory Reporting
of the Results of Influenza A and Influenza B Virus CLIA² Waived Tests to the
NYSDOH Electronic Clinical Laboratory Reporting System (ECLRS)**

Rapid Influenza Diagnostic Tests (RIDT)³ - Antigen Detection Only				
	LOINC	LOINC LONG COMMON NAME	TEXT RESULT	SNOMED-CT RESULT
REPORT POSITIVE/DETECTABLE RESULT TO ECLRS AS:				
INFLUENZA A DETECTED	50697-2	Influenza virus A Ag [Identifier] in Isolate	Flu A (influenza A antigen present)	407479009 = Influenza A virus (organism)
	46082-4	Influenza virus A Ag [Presence] in Nasopharynx by Immunoassay	Flu A (influenza A antigen present)	407479009 = Influenza A virus (organism)
	44564-3	Influenza virus A Ag [Presence] in Nose by Immunoassay	Flu A (influenza A antigen present)	407479009 = Influenza A virus (organism)
	80382-5	Influenza virus A Ag [Presence] in Upper respiratory specimen by Rapid immunoassay	Flu A (influenza A antigen present)	407479009 = Influenza A virus (organism)
	44562-7	Influenza virus A Ag [Presence] in Bronchial specimen	Flu A (influenza A antigen present)	407479009 = Influenza A virus (organism)
	5862-8	Influenza virus A Ag [Presence] in Specimen by Immunoassay	Flu A (influenza A antigen present)	407479009 = Influenza A virus (organism)
INFLUENZA B DETECTED	46083-2	Influenza virus B Ag [Presence] in Nasopharynx by Immunoassay	Flu B (influenza B antigen present)	407480007 = Influenza B virus (organism)
	44575-9	Influenza virus B Ag [Presence] in Nose by Immunoassay	Flu B (influenza B antigen present)	407480007 = Influenza B virus (organism)
	80383-3	Influenza virus B Ag [Presence] in Upper respiratory specimen by Rapid immunoassay	Flu B (influenza B antigen present)	407480007 = Influenza B virus (organism)
	5866-9	Influenza virus B Ag [Presence] in Specimen by Immunoassay	Flu B (influenza B antigen present)	407480007 = Influenza B virus (organism)
Nucleic Acid Detection Based Tests⁴				
	LOINC	LOINC LONG COMMON NAME	TEXT RESULT	SNOMED-CT RESULT
REPORT POSITIVE/DETECTABLE RESULT TO ECLRS AS:				
INFLUENZA A DETECTED	76078-5	Influenza virus A RNA [Presence] in Nasopharynx by NAA with probe detection	Flu A (influenza A virus present)	407479009 = Influenza A virus (organism)
	100973-7	Influenza virus A RNA [Presence] in Nose by NAA with non-probe detection	Flu A (influenza A virus present)	407479009 = Influenza A virus (organism)
	85477-8	Influenza virus A RNA [Presence] in Upper respiratory specimen by NAA with probe detection	Flu A (influenza A virus present)	407479009 = Influenza A virus (organism)
	88599-6	Influenza virus A RNA [Presence] in Lower respiratory specimen by NAA with probe detection	Flu A (influenza A virus present)	407479009 = Influenza A virus (organism)
	34487-9	Influenza virus A RNA [Presence] in Specimen by NAA with probe detection	Flu A (influenza A virus present)	407479009 = Influenza A virus (organism)
INFLUENZA B DETECTED	49535-8	Influenza virus B RNA [Presence] in Isolate by NAA with probe detection	Flu B (influenza B virus present)	407480007 = Influenza B virus (organism)
	80591-1	Influenza virus B NS gene [Presence] in Nasopharynx by NAA with probe detection	Flu B (influenza B virus present)	407480007 = Influenza B virus (organism)
	100974-5	Influenza virus B RNA [Presence] in Nose by NAA with non-probe detection	Flu B (influenza B virus present)	407480007 = Influenza B virus (organism)
	85478-6	Influenza virus B RNA [Presence] in Upper respiratory specimen by NAA with probe detection	Flu B (influenza B virus present)	407480007 = Influenza B virus (organism)
	92141-1	Influenza virus B RNA [Presence] in Respiratory system specimen by NAA with probe detection	Flu B (influenza B virus present)	407480007 = Influenza B virus (organism)
40982-1	Influenza virus B RNA [Presence] in Specimen by NAA with probe detection	Flu B (influenza B virus present)	407480007 = Influenza B virus (organism)	

¹ www.wadsworth.org/regulatory/celep/limited-service-lab-certs

² www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/cartegorization

³ www.cdc.gov/flu/hcp/testing-methods/table-ridt.html

⁴ www.cdc.gov/flu/php/laboratories/nucleic-acid-detection.html

**Attachment 2: Guidance for Limited Service Laboratories for Standards-Based Electronic Laboratory Reporting
Clinical Laboratory Improvement Amendments (CLIA)¹ Waived Influenza Diagnostic Tests²**

Rapid Influenza Diagnostic Tests (RIDT) ³ - Antigen Detection Only					
Manufacturer	Product	Platform/Instrument	Influenza Virus Types Detected	Other Respiratory Viruses Differentiated	CLIA waived
Abbott	Binax Now Influenza A & B Card 2	DIGIVAL™	Influenza A and B (differentiated)	None	Yes
Becton Dickinson & Co.	BD Veritor™ Flu A + B	BD Veritor Reader	Influenza A and B (differentiated)	None	Yes
Becton Dickinson & Co.	BD Veritor™ Flu A + B	BD Veritor Plus Analyzer	Influenza A and B (differentiated)	None	Yes
Princeton BioMeditech Corp.	BioSign® Flu A & B	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Princeton BioMeditech Corp.	LABSCO Advantage Flu A & B	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Princeton BioMeditech Corp.	McKesson Consult Diagnostics Influenza A&B	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Princeton BioMeditech Corp.	Meridian BioScience ImmunoCard STAT Flu A&B	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Princeton BioMeditech Corp.	OraSure QuickFlu Rapid A + B	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Princeton BioMeditech Corp.	Polymedco Poly stat	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Princeton BioMeditech Corp.	Status Flu A & B	N/A	Influenza A and B (differentiated)	None	Yes, nasal and NP specimens only
Quidel Corp.	QuickVue® Influenza A + B	N/A	Influenza A and B (differentiated)	None	Yes
Quidel Corp.	Sofia® Influenza A + B FIA	Sofia FIA Analyzer	Influenza A and B (differentiated)	None	Yes
Quidel Corp.	Sofia® Influenza A + B FIA	Sofia 2 FIA Analyzer	Influenza A and B (differentiated)	None	Yes
Remel/Thermo Fisher	XPECT™ Flu A & B	N/A	Influenza A and B (differentiated)	None	No
Sekisui Diagnostics, LLC	Acucy Influenza A&B Test	The Acucy System	Influenza A and B (differentiated)	None	Yes
Sekisui Diagnostics, LLC	OSOM Ultra Plus Flu A&B Test	N/A	Influenza A and B (differentiated)	None	Yes

Nucleic Acid Detection Based Tests ⁴					
Manufacturer	Product	Platform/Instrument	Influenza Virus Types Detected	Other Respiratory Viruses Differentiated	CLIA waived
Abbott	ALINITY m RESP-4-PLEX ASSAY	ID NOW™	Influenza A and B (differentiated)	Respiratory Syncytial Virus and SARS-CoV-2	Yes
Abbott	ID NOW™ Influenza A & B 2	ID NOW™ Platform	Influenza A and B (differentiated)	None	Yes
Cepheid	Xpert Xpress Flu	GeneXpert Xpress	Influenza A and B (differentiated)	None	Yes
Cepheid	Xpert Xpress Flu/RSV	GeneXpert Xpress	Influenza A and B (differentiated)	Respiratory Syncytial Virus	Yes
Roche Molecular Diagnostics	Cobas® Influenza A/B & RSV Assay	Cobas® Liat® Analyzer	Influenza A and B (differentiated)	Respiratory Syncytial Virus	Yes
Roche Molecular Diagnostics	Cobas® Influenza A/B Assay	Cobas® Liat® Analyzer	Influenza A and B (differentiated)	None	Yes
Sekisui Diagnostics	Silaris Influenza A & B	Silaris Dock	Influenza A and B (differentiated)	None	Yes

¹ www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/cartegorization

² www.fda.gov/medical-devices/in-vitro-diagnostics/influenza-diagnostic-tests

³ www.cdc.gov/flu/hcp/testing-methods/table-ridt.html

⁴ www.cdc.gov/flu/php/laboratories/nucleic-acid-detection.html