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Texas Department of State Health Services

LRN Breakout Session

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2024 Influenza and Respiratory Disease Conference

Agenda

1. Overview of Influenza Season 2023-2024 (Austin Lab)
2. Submission Guidance
3. General Updates

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Overview of 2023-2024 Influenza Season

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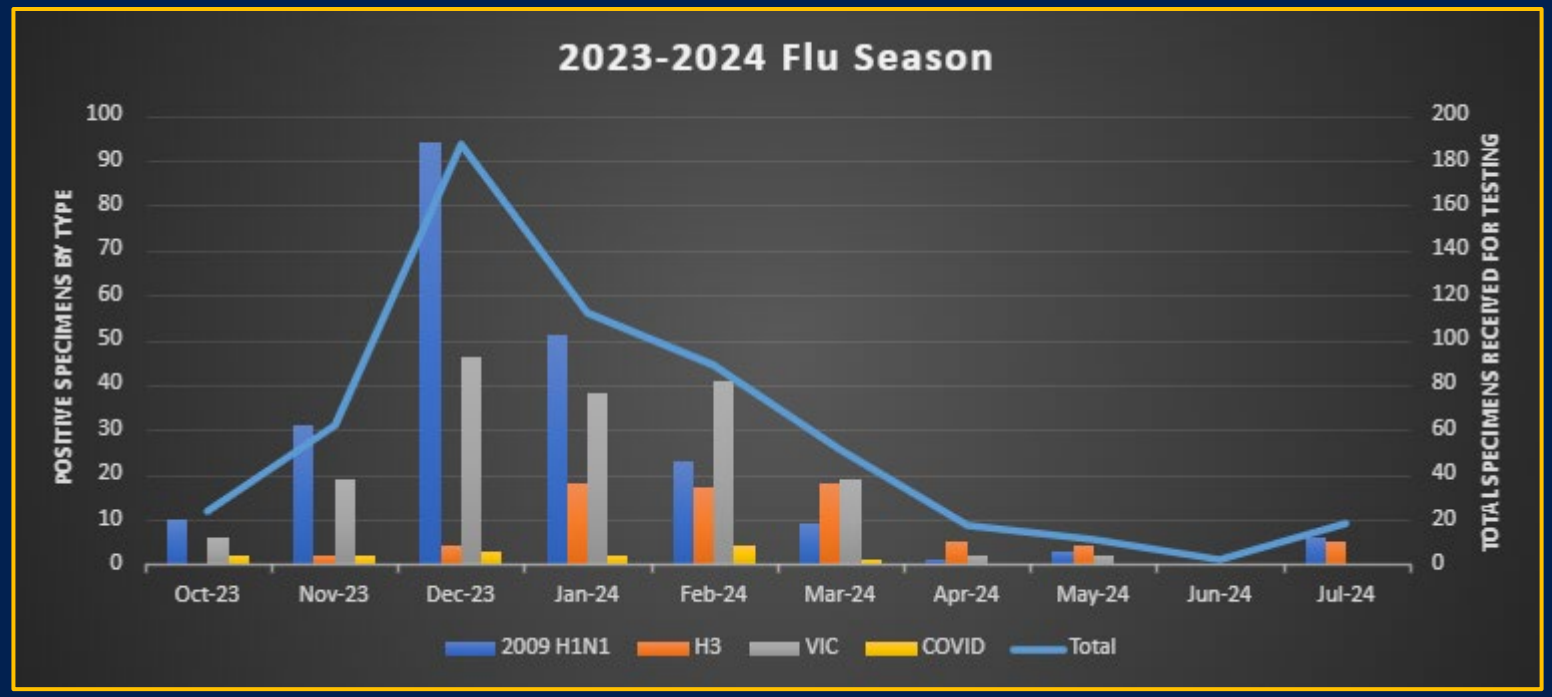
- Testing algorithm
  - Multiplex Assay used for all incoming influenza and/or COVID-19 specimens received
  - Performed typing on all flu positives using subtyping and lineage kits
- Specimen volume



Overview of 2023-2024 Influenza Season

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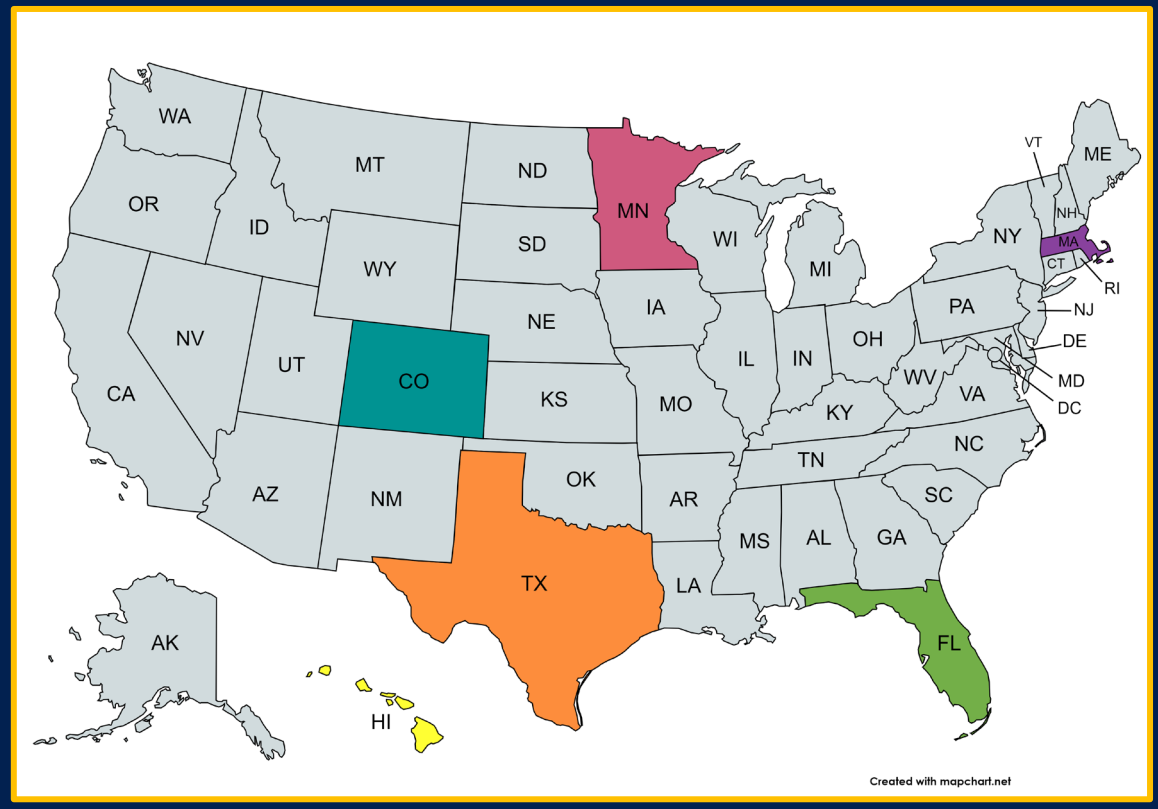
- Influenza Sequencing Center (ISC) efforts
  - ISC sites: CO, FL, HI, MA, MN, and TX!
  - TX ISC online January 2024
  - 53 samples sequenced in house by DSHS AMD team
  - Samples to National Influenza Surveillance Reference Center (NIRC) priority



LRN Specimen Submission to DSHS

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- 2023-2024 guidance document
- All LRNs except for HHD
- Up to 12 samples (3 of each type) every other week
  - One additional A/H3 specimen may be sent if all subtypes are not available
  - SC2/flu coinfections ok for ISC but not NIRC (note on G-2V)
  - Most recent dates of collection, ideally <14 days from DOC*
  - CT value <30
  - Ideal volume 0.8 – 1.0 mL (no less than 0.5 mL)
  - NP swabs - preferred specimen source
  - UTM and VTM acceptable
  - Additional specimen criteria to consider when selecting: Patients of varying ages, disease severity, and specimens for which level of care (inpatient/outpatient) is known

* Ship more frequently if DOC becomes an issue

What Austin DSHS Lab Sends to NIRC

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- Shipments every other week to California Department of Public Health (CDPH)
  - 6 H3, 4 pdmH1, 8 B (4 Vic, 4 Yam)
  - SC2 negative
  - DOC ≤14 days
  - Ct ≤28
  - 0.5 mL (0.3 mL minimum)
  - UTM and VTM acceptable
- Shipments every other week to New York State Department of Health (NYSDOH)
  - Antiviral resistance surveillance (suspended for the summer)
  - Up to 5 specimens every other week
  - Positive for influenza A(H1N1)pdm09, A(H3N2) and type B viruses
  - Ct <29

Submissions Directly to CDC Atlanta

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- Notify CDC of specimens with non-standard test results:
  - Influenza A unsubtypable with InfA Ct value <35*
  - Inconclusive influenza B viruses that are unable to be genotyped
  - All influenza B genotype results of B/Yamagata-lineage
  - Presumptive positive A/H3v
  - Inconclusive indicating possible variant influenza A virus similar to those circulating in swine
  - Specimens with results that suggest a mixture of influenza A viruses or mixture of influenza A and influenza B viruses
  - If specimen test results are presumptive positive for A/H5 or A/H7

*Note: Influenza A unsubtypable with InfA Ct value >35, the sample may be reported as inconclusive.

Submissions Directly to CDC Atlanta

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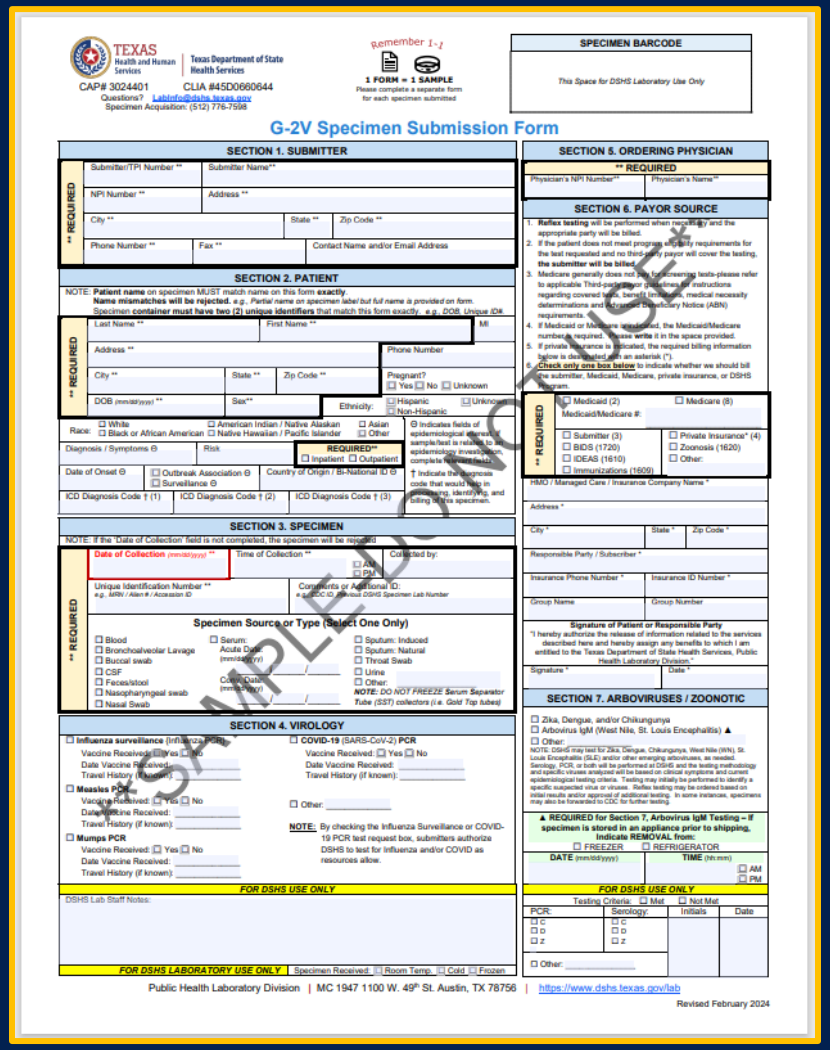
- Refer to the influenza PCR package insert for how/when to retest specimens with non-standard results

- For requests, please send an email to the following:
  - flusupport@cdc.gov and fzq9@cdc.gov
  - Cc Maria Nolen at maria.nolen@dshs.texas.gov and Jennifer Gonzales at jennifer.gonzales@dshs.texas.gov

  - To submit for diagnosis, fill out CDC Specimen Submission Form, CDC 50.34 or submit through CDC Specimen Test Order and Reporting (CSTOR) | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC

General Updates

- G-2V form – Last update 2024



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CAP# 3024401 CLIA #45D0660644
Questions? LabInfo@dshs.texas.gov
Specimen Acquisition: (512) 776-7598

Remember 1-1
1 FORM = 1 SAMPLE
Please complete a separate form for each specimen submitted

SPECIMEN BARCODE
This Space for DSHS Laboratory Use Only

G-2V Specimen Submission Form

SECTION 1. SUBMITTER
** REQUIRED
Submitter/TPI Number **
Submitter Name**
NPI Number **
Address **
City **
State **
Zip Code **
Phone Number **
Fax **
Contact Name and/or Email Address

SECTION 2. PATIENT
NOTE: Patient name on specimen MUST match name on this form exactly.
Name mismatches will be rejected. e.g., Partial name on specimen label but full name is provided on form.
Specimen container must have two (2) unique identifiers that match this form exactly. e.g., DOB, Unique ID#
** REQUIRED
Last Name **
First Name **
MI
Address **
Phone Number
City **
State **
Zip Code **
Pregnant? ☐ Yes ☐ No ☐ Unknown
DOB (mm/dd/yyyy) **
Sex**
Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown
Race: ☐ White ☐ Black or African American ☐ American Indian / Native Alaskan ☐ Native Hawaiian / Pacific Islander ☐ Asian ☐ Other
Diagnosis / Symptoms Θ
Risk
REQUIRED** ☐ Inpatient ☐ Outpatient
Date of Onset Θ
☐ Outbreak Association Θ ☐ Surveillance Θ
Country of Origin / Bi-National ID Θ
ICD Diagnosis Code † (1)
ICD Diagnosis Code † (2)
ICD Diagnosis Code † (3)
Θ Indicates fields of epidemiological interest. If sample/test is related to epidemiology investigation, complete highlighted fields.
† Indicate the diagnosis code that would help in processing, identifying, and billing of this specimen.

SECTION 3. SPECIMEN
NOTE: If the 'Date of Collection' field is not completed, the specimen will be rejected.
** REQUIRED
Date of Collection (mm/dd/yyyy) **
Time of Collection **
☐ AM ☐ PM
Collected by:
Unique Identification Number **
e.g., MRN / Alien # / Accession ID
Comments or Additional ID:
e.g., CDC ID, Previous DSHS Specimen Lab Number
Specimen Source or Type (Select One Only)
☐ Blood
☐ Bronchoalveolar Lavage
☐ Buccal swab
☐ CSF
☐ Feces/stool
☐ Nasopharyngeal swab
☐ Nasal Swab
☐ Serum: Acute Date (mm/dd/yyyy) ___/___/___ Convl Date(s) (mm/dd/yyyy) ___/___/___
☐ Sputum: Induced
☐ Sputum: Natural
☐ Throat Swab
☐ Urine
☐ Other:
NOTE: DO NOT FREEZE Serum Separator Tube (SST) collectors (i.e. Gold Top tubes)

SECTION 4. VIROLOGY
☐ Influenza surveillance (Influenza PCR) *
Vaccine Received: ☐ Yes ☐ No
Date Vaccine Received:
Travel History (if known):
☐ Measles PCR
Vaccine Received: ☐ Yes ☐ No
Date Vaccine Received:
Travel History (if known):
☐ Mumps PCR
Vaccine Received: ☐ Yes ☐ No
Date Vaccine Received:
Travel History (if known):
☐ COVID-19 (SARS-CoV-2) PCR
Vaccine Received: ☐ Yes ☐ No
Date Vaccine Received:
Travel History (if known):
☐ Other:
NOTE: By checking the Influenza Surveillance or COVID-19 PCR test request box, submitters authorize DSHS to test for Influenza and/or COVID as resources allow.
FOR DSHS USE ONLY
DSHS Lab Staff Notes:
FOR DSHS LABORATORY USE ONLY Specimen Received ☐ Room Temp. ☐ Cold ☐ Frozen

SECTION 5. ORDERING PHYSICIAN
** REQUIRED
Physician's NPI Number**
Physician's Name **

SECTION 6. PAYOR SOURCE
1. Reflex testing will be performed when necessary and the appropriate party will be billed.
2. If the patient does not meet program eligibility requirements for the test requested and no third-party payor will cover the testing, the submitter will be billed.
3. Medicare generally does not pay for screening tests-please refer to applicable Third-party payor guidelines for instructions regarding covered tests, benefit limitations, medical necessity determinations and Advanced Beneficiary Notice (ABN) requirements.
4. If Medicaid or Medicare is indicated, the Medicaid/Medicare number is required. Please write it in the space provided.
5. If private insurance is indicated, the required billing information below is designated with an asterisk (*).
6. Check only one box below to indicate whether we should bill the submitter, Medicaid, Medicare, private insurance, or DSHS program.
** REQUIRED
☐ Medicaid (2) ☐ Medicare (8)
Medicaid/Medicare #:
☐ Submitter (3) ☐ Private Insurance* (4)
☐ BIDS (1720) ☐ Zoonosis (1620)
☐ IDEAS (1610) ☐ Other:
☐ Immunizations (1609)
HMO / Managed Care / Insurance Company Name *
Address *
City *
State *
Zip Code *
Responsible Party / Subscriber *
Insurance Phone Number *
Insurance ID Number *
Group Name
Group Number
Signature of Patient or Responsible Party
"I hereby authorize the release of information related to the services described here and hereby assign any benefits to which I am entitled to the Texas Department of State Health Services, Public Health Laboratory Division."
Signature *
Date *

SECTION 7. ARBOVIRUSES / ZOONOTIC
☐ Zika, Dengue, and/or Chikungunya
☐ Arbovirus IgM (West Nile, St. Louis Encephalitis) ▲
☐ Other:
NOTE: DSHS may test for Zika, Dengue, Chikungunya, West Nile (WN), St. Louis Encephalitis (SLE) and/or other emerging arboviruses, as needed. Serology, PCR, or both will be performed at DSHS and the testing methodology and specific viruses analyzed will be based on clinical symptoms and current epidemiological testing criteria. Testing may initially be performed to identify a specific suspected virus or viruses. Reflex testing may be ordered based on initial results and/or approval of additional testing. In some instances, specimens may also be forwarded to CDC for further testing.
▲ REQUIRED for Section 7, Arbovirus IgM Testing – If specimen is stored in an appliance prior to shipping, indicate REMOVAL from:
☐ FREEZER ☐ REFRIGERATOR
DATE (mm/dd/yyyy)
TIME (hh:mm) ☐ AM ☐ PM
FOR DSHS USE ONLY
Testing Criteria: ☐ Met ☐ Not Met
PCR: ☐ C ☐ D ☐ Z
Serology: ☐ C ☐ D ☐ Z
Initials
Date
☐ Other:

SAMPLE - DO NOT USE

Public Health Laboratory Division | MC 1947 1100 W. 49th St. Austin, TX 78756 | https://www.dshs.texas.gov/lab
Revised February 2024

General Updates

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- CDC Influenza and SARS-Co-V-2 Molecular Performance Evaluation Panels – Due to the ongoing H5 emergency, CDC has not yet determined if they can provide a PEP panel for Winter 2024-2025.

- APHL recent Influenza A(H5N1) Update #14, 7/17/24 –
  - Instructions for use (IFU) updated for the kits below to allow for testing of specimens transported in universal transport media (UTM) in addition to viral transport media (VTM)
    - Influenza A Subtyping Kit
    - B Lineage Genotyping Kit
    - A/H5 Subtyping Kit
    - A/B Typing Kit
  - Conjunctival Swab Specimen Collection – Desk Reference Graphic

- IRR Flu SC2 Multiplex Assays reserves and ancillary (FR-102, FR-1251, RR-2, RR-3) support for 2024-2025 season is unknown at this time

General Updates

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- Equipment Platform Status Update 2024.pdf (aphl.org)

Automated Extraction and PCR Platform Marketing & Support Status

For use in 2024 funding proposals by PHLs

Please note instrument marketing and support is dynamic situation. Information presented here reflects APHL's best understanding as of March 1, 2024, but laboratories are encouraged to communicate directly with manufacturers for the most up to date information.

The platforms in Table 1 are FDA authorized as in vitro diagnostic (IVD) devices and are most likely to be considered by CDC in future assay development including new emergency use authorization (EUA) assays.

Table 1. Automated platforms with IVD claims.

Platform	Marketing Status	Service/Reagent Support	CDC Assays
MagNA Pure 96	Available	Indefinite; public health pricing available	• Influenza SARS-CoV-2 Multiplex (EUA) • 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA) • Influenza (characterization panel) • Trioplex (EUA) • Non-variola Orthopoxvirus Real-time PCR Assay
MagNA Pure 24	Available	Indefinite; public health pricing available	• 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA) • Non-variola Orthopoxvirus Real-time PCR Assay • LRN-B
EZ1 Advanced XL	Available	Indefinite; public health pricing available	• Influenza SARS-CoV-2 Multiplex (EUA) • 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA) • Influenza (characterization panel) • Non-variola Orthopoxvirus Real-time PCR Assay • LRN-B
NucliSENS® easyMag®	Discontinued; limited availability of refurbished	At least through end of 2023	• Influenza SARS-CoV-2 Multiplex (EUA) • Influenza (characterization panel and H7 EUA)

Automated Extraction and PCR Platform Marketing & Support Status

For use in 2024 funding proposals by PHLs

The platforms in Table 2 are not FDA authorized IVD devices and less likely to be considered by CDC in future assay development including new EUA assays. These platforms were primarily authorized to address significant reagent supply chain issues during the COVID-19 response.

Table 2. Automated platforms without IVD claims authorized for use with EUA assays.

	Platform	Marketing Status	Service/Reagent Support	CDC Assays
QIAGEN	QIAcube[1]	Discontinued, Jan 1, 2019	Ends Jan 15, 2026	• Influenza SARS-CoV-2 Multiplex (EUA) • 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA)
	QIAcube HT	Available	Indefinite; public health pricing available	• Influenza SARS-CoV-2 Multiplex (EUA)
	QIAcube Connect	Available	Indefinite; public health pricing available	Chemistries authorized for use with follo platform to be used during COVID-19 re • Influenza SARS-CoV-2 Multiplex (EU • 2019-nCoV Real-Time RT-PCR Diagn
Thermo Fisher Scientific	KingFisher™ Flex Purification System	Available	Indefinite	• Influenza SARS-CoV-2 Multiplex (EU • Non-variola Orthopoxvirus Real-tim
	MagMAX Express-96 Deep Well Magnetic Particle Processor	Unavailable	Support is ending; will support if parts are available	• Ebola Virus NP Real-Time RT-PCR as
Promega	Maxwell® RSC 48	Available	Indefinite; public health pricing available	• Influenza SARS-CoV-2 Multiplex (EU • 2019-nCoV Real-Time RT-PCR Diagn

Automated Extraction and PCR Platform Marketing & Support Status

For use in 2024 funding proposals by PHLs

Thermo Fisher Scientific discontinued selling the Applied Biosystems™ 7500 Fast Dx (ABI 7500 Fast Dx) at the end of 2022. They will continue to support the instrument through 2029. CDC completed an analysis of available thermocyclers in 2023 as described in this summary report. CDC programs are currently evaluating the performance of CDC assays on several of the platforms outlined in the memo.

Table 3. PCR Platforms with IVD claims authorized for use with EUA assays.

	Platform	Marketing Status	Service/Reagent Support	CDC Assays
Thermo Fisher Scientific	ABI 7500 Fast Dx [2]	Discontinued December 2022	December 2029	• Influenza SARS-CoV-2 Multiplex (EUA) • 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA) • Influenza (characterization panel) • Non-variola Orthopoxvirus Real-time PCR Assay • LRN-B • Trioplex (EUA) • MERS Coronavirus (EUA)
	QuantStudio Dx (QSDX)[3]	Discontinued December 2023	December 2028	• Influenza SARS-CoV-2 Multiplex (EUA) • 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA) • Trioplex (EUA) • Non-variola Orthopoxvirus Real-time PCR Assay • LRN-B

General Updates

- ABI 7500 Dx discontinuation – 2024 Respiratory Virus Surveillance Workshop update
  - CDC Genomics and Diagnostics Team (GDT) is currently evaluating:

Real-Time PCR Instruments

BioRad CFX OPUS 96 Dx

Thermo QuantStudio 5 Dx

Thermo QuantStudio 7 Pro Dx

Extraction Instruments

Roche MagNA Pure 24

Qiagen EZ2 Connect MDx

- LRNs - New instruments/validations?

Open Discussion & Questions

1. Changes in testing algorithms? Any LRNs using a different assay other than the CDC Flu SC2 Multiplex assay? RVP panel?
2. Accomplishments or challenges with current testing?
3. Summer influenza or COVID-19 activity increase?
4. Any ongoing issues when sending samples to DSHS?
5. Any challenges with meeting submission criteria?
6. Influenza A/H5 conjunctival swab verifications?
7. Any other questions or information to share?

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Thank You

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