

STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

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Commissioner

Wendy E. Saunders
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June 23, 2009 (UPDATE)

To: Virology Laboratory Directors

**Re: Expedited approval of molecular assays for detection of novel influenza A (H1N1) (swine-like) -
AND Amended Results and Reporting Criteria**

Applies to: non-Public Health Laboratories (PHL) holding New York CLEP Virology – General permit category

Purpose: Provides guidance for the expedited validation, submission, and review of applications for the use of novel influenza A (H1N1) molecular detection procedures originally developed, validated, and released for use by CDC or Wadsworth Center (originating agencies) under an FDA Emergency Use Authorization (EUA) for critical patient testing during public health emergencies.

Expedited approval for use of molecular assays for the detection of infectious agents will only be granted to laboratories that have previously been approved by the Clinical Laboratory Evaluation Program (CLEP) to perform molecular testing for infectious agents using similar testing platforms. For clarification on whether an assay and your laboratory qualifies for expedited approval, please contact CLEP at clep@health.state.ny.us.

To qualify for expedited approval, the laboratory MUST:

1. use the EXACT same amplification and detection oligonucleotide sequences as those developed and validated by the originating agency;
2. use the same reagents as those validated by the originating agency;
3. use the exact same temperature cycling conditions as those specified by the originating agency;
4. request approval only for the same specimen type(s) as those validated by the originating agency;
5. specify instructions in the SOPM for interpretive statements provided in patient reports that follow guidance specified by the originating agency; and,
6. specify instructions in the SOPM for reporting of results to NYS authorities as required under NYS disease reporting guidelines.

If this assay is changed or modified from the assay validated from the originating agency or EUA, the laboratory may need to submit a full validation package. Contact CLEP for further guidance if modifications are made to the assay.

Requirements for Standard Operating Protocols (SOP) for novel Influenza A (H1N1) molecular detection assays.

Laboratories seeking expedited approval will be required to include the following information in the SOPM:

- A detailed list of oligonucleotide sequences, reagents, assay conditions, and instrumentation;
- A complete description of controls that are used in the assay;
- A detailed algorithm describing how the results will be interpreted and reported;
- An explanation of how, if applicable, the assay will be utilized in conjunction with other assays;
- Oligonucleotide specification sheet from the manufacturer(s) for all primers and probes utilized in this assay; and,
- Sample reports for all potential test results.

The following information must also be submitted:

- Documentation of training and competency assessment of molecular diagnostic testing staff.

Requirement for validation of novel influenza A (H1N1) molecular detection assays.

- Performance data from the testing of seasonal and novel influenza must be submitted from at least 20 representative specimens tested in a blinded, randomized fashion, including at least five positive seasonal influenza samples and ten positive novel influenza specimens. Data obtained from testing of specimens with the new assay should be submitted together with original test data that previously determined the content of the samples, or an explanation of how the representative specimens were prepared (spiked samples are acceptable).
- Limit of detection studies are not required for submission of infectious agent assays of urgent public health importance.
- NOTE: If assistance is needed with the acquisition of virus-positive material for this portion of the work, submit to CLEP the documentation listed above under *Requirements for Standard Operating Protocols (SOP)* with a request for validation materials. The information will be reviewed, and if acceptable, materials will be sent with which to complete the validation studies.

Example Protocol:

Current CDC EUA protocol for the detection of novel H1N1, available here:

<http://www.who.int/csr/resources/publications/swineflu/realtimeptpcr/en/index.html>

Amended Results and Reporting Criteria – 06/23/09:

Refer to the posted companion documents: '***Amended Results and Reporting for Expedited H1N1 062309.pdf***' and '***Novel H1N1 Resulting Algorithm.pdf***' for criteria required for expedited approval of this molecular assay for the detection of novel influenza A (H1N1) (swine-like) for non-Public Health Laboratories (PHL) holding New York CLEP Virology – General permit category.

Proficiency Testing:

When the Wadsworth Center finds the SOP and validation data to be acceptable, the laboratory may be required to participate in a specialized assessment administered by the Center that will test laboratory proficiency and the limit of detection of the assay. Full approval will be granted after successful completion of the assessment. If performance on the specialized assessment is unsatisfactory, CLEP will contact the laboratory to provide guidance, and to discuss the action needed for the laboratory to obtain approval to perform the assay. Until the specialized proficiency assessment is available, laboratories must comply with requirements in CLEP's **Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy**