

Date: May 6, 2009
To: Proficiency Testing (PT) Programs Offering Viral Antigen Modules
From: Val Coppola
Subject: Testing of Influenza A Direct Antigen

The Centers for Medicare & Medicaid Services is allowing certain Clinical Laboratory Improvement Amendment (CLIA) regulatory activities to be suspended due to the recent influenza A (H1N1) virus outbreak. These suspensions will apply to PT testing for viral antigen modules that require use of influenza A test kits that is conducted through May 15, 2009. The CLIA program's enforcement plans regarding proficiency testing requirements for modules that are scheduled to ship after May 15, 2009 will be addressed through subsequent communications prior to that date.

This means that, through May 15, 2009, your proficiency testing participants may decide whether to test any PT samples that require use of influenza A test kits or reserve their influenza A test kits for any unexpected increase in patient testing.

When you notify your participants, please advise them to continually visit the Centers for Disease Control and Prevention's (CDC) Web site:

<http://www.CDC.gov/swineflu/specimencollection>

This site gives CDC's "Interim Guidance on Specimen Collection, Processing, and Testing for Patients with Suspected Swine-origin Influenza A (H1N1) Virus Infection". Laboratories and clinicians should monitor this site for CDC's updates and any additional guidance.

You may notify your proficiency testing participants by whatever means you deem most appropriate. Such means might include fax, U.S. Postal Service, express carrier, etc. Regardless of the method used, we would request that you also post this information on your Web site.

If a participant decides not to test a PT sample in accordance with this communication (and in so doing leaves the results for that portion of the PT testing results blank, please use reason code #8, "Excused Participation") and assign a score of 100% when submitting PT test result data to the CMS PT monitoring system.

We wish to express our appreciation for your efforts during this public health emergency.