



****DO NOT DISCARD: Important product-specific information****

Data Interpretation Update to the CDC Flu rRT-PCR Dx Panel (Catalog # FluIVD03)

BACKGROUND:

From July 2011 to April 2012, the CDC in partnership with U.S. public health laboratories identified and confirmed 13 human cases with infection of influenza A(H3N2) variant (A(H3N2)v) virus. The influenza A(H3N2)v virus contains gene segments originating from viruses of both human and swine. From July until August 4, 2012, thirty additional cases have been confirmed by the CDC. Most cases have been associated with direct or indirect exposure to swine, with many cases being linked to visits to swine barns at county or state fairs. All cases have been initially identified by testing specimens with the CDC Flu rRT-PCR Dx Panel. Specimens from humans infected with A(H3N2)v will be positive for InfA, H3, and pdmInfA markers and negative for H1 and pdmH1 markers.

DATA INTERPRETATION UPDATE:

Because of the recent increased numbers of human cases of influenza A(H3N2)v and need for timely public health response, the results interpretation of the CDC Flu rRT-PCR Dx Panel have been updated to the following:

When all controls exhibit expected performance and growth curves for InfA, H3 AND pdmInfA markers cross the threshold line within 38.00 cycles (< 38.00 Ct) and H1 and pdmH1 markers are negative:

Report the specimen to be “Presumptive Positive for Influenza A(H3N2)v Virus” and contact the CDC Influenza Division immediately to coordinate transfer of the specimen to CDC for additional testing.

Non-Standard Results with the Influenza A Subtyping Assay

InfA	H1	H3	pdm InfA	pdm H1	RP	Result Interpretation	Report for CDC Surveillance	Notes and Special Guidance
+	-	+	+	-	±	Influenza A Detected; Presumptive positive for Influenza A(H3N2) variant virus	Presumptive positive for Influenza A(H3N2)v	Refer specimen to CDC immediately for confirmation

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