Diagnostic Development at the CDC: Update 2006 – antibodies and protein based diagnostics

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In the past year, development and validation, as well as performance analysis of diagnostic real time PCR orthopoxvirus assays has continued at the CDC. As additional clinical samples have been tested using the orthopoxvirus assays, progress has been made to approach the Food and Drug Administration for “approval” of at least one real time PCR nucleic acid test assay; a “510K” application is nearing readiness for submission. A laboratory testing algorithm, designed for triaging and testing febrile vesiculo-pustular rash illness specimens was posted on the CDC and Association for Public Health Laboratories websites; proficiency testing of laboratories using these assays and the algorithm was completed in 2005.

Slower progress on protein-based assays has also been made. Two monoclonal antibodies, generated in 2000, have been incrementally characterized; one appears to be fairly specific for variola virus, and could be valuable as a diagnostic tool. Additional studies using microarray have presumptively identified the orthopoxvirus protein target of the other. A point-of-care orthopoxvirus detection system, using antibody bound to a solid-support membrane, has shown promise in the laboratory, and in limited use in the field, to identify orthopoxviruses in specimen derived material.