

## SEVERE ACUTE RESPIRATORY SYNDROME

### Supplement F: Laboratory Guidance

#### Appendix F1

# Proficiency Testing for Public Health Laboratories Providing SARS-CoV EIA and RT-PCR Diagnostics

CDC has developed and validated diagnostic assays for SARS-CoV, including an enzyme immunoassay (EIA) (<a href="www.cdc.gov/ncidod/sars/lab/eia/">www.cdc.gov/ncidod/sars/lab/eia/</a>) for detection of serum antibodies to SARS-CoV and a reverse transcription-polymerase chain reaction (RT-PCR) assay (<a href="www.cdc.gov/ncidod/sars/lab/rtpcr/">www.cdc.gov/ncidod/sars/lab/rtpcr/</a>) for detection of SARS-CoV RNA. Both the EIA and the RT-PCR tests are sensitive and highly specific for diagnosis of SARS-CoV infection. Testing with these assays is now available through state public health laboratories and CDC's Laboratory Response Network (LRN).

CDC is in the process of developing and implementing a quality assurance program to evaluate each laboratory's testing proficiency. To demonstrate competence in performing these tests, public health and LRN laboratories will be required to successfully identify positive and negative specimens provided in the proficiency panels.

#### **Process for Proficiency Panel Testing**

- 1. EIA proficiency panels will be shipped to designated public health laboratories, and RT-PCR proficiency panels will be distributed through the LRN.
- 2. Each laboratory should complete testing promptly and return results by the designated date.
- 3. Proficiency panel test results must be returned by electronic mail using a designated format.
- 4. Each laboratory will receive a complete summary of its own results as well as an aggregate summary of performance from all laboratories completing the proficiency testing.
- 5. CDC will provide a certificate of participation to the participating laboratory to help fulfill quality assurance requirements.

Results obtained from a laboratory's proficiency testing will initially be considered "educational," and laboratories will not be required to undergo additional training as remediation. However, successful completion of the proficiency test will be required for approval of a public health or LRN laboratory as a confirmatory testing site.

For more information, visit <a href="www.cdc.gov/sars">www.cdc.gov/sars</a> or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

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