Supplement F: Laboratory Guidance

Appendix F3

Guidelines for Clinicians: The Consent Process for SARS-CoV RT-PCR and EIA Testing at CDC and Public Health Laboratories

Key Messages

- A consent form is recommended when submitting specimens for SARS-CoV reverse-transcription polymerase chain reaction (RT-PCR) or enzyme immunoassay (EIA) testing.
- Due to important public health concerns, if SARS-CoV testing is indicated, specimens will be tested even if a consent form is NOT received.
- A patient information sheet, informing patients about the tests and requesting permission for long-term storage of their specimen remainders, will be sent to the physician with the patient's test results. The physician should provide this document to the patient and return a signed copy to the local or state health department if consent for long-term specimen storage is obtained.

CDC has distributed a SARS-CoV RT-PCR assay (www.cdc.gov/ncidod/sars/lab/rtpcr/) under an FDA investigational device exemption (IDE) and an EIA assay (www.cdc.gov/ncidod/sars/lab/eia/) to state and local public health laboratories to test specimens for SARS-CoV. These tests are used to evaluate persons suspected of having SARS-CoV disease. The RT-PCR assay is used to test for SARS-CoV viral RNA in respiratory samples, stool, plasma, or serum. The EIA test is used to detect SARS-CoV antibodies in blood or serum specimens. A signed consent form for performance of each test is recommended because neither test has been licensed by the FDA and the RT-PCR test is being used under an FDA-approved IDE. A signed consent form is also required for storage of specimen remainders for future investigations.

To submit specimens for SARS-CoV RT-PCR or EIA testing, healthcare providers should follow these steps:

1. **Consult the state or local health department** to determine if SARS-CoV testing is indicated.
2. **Seek informed consent** from the patient for testing.
   The RT-PCR consent form can be found at:
   http://www.cdc.gov/ncidod/sars/lab/rtpcr/consent.htm.
   The EIA consent form can be found at:
   http://www.cdc.gov/ncidod/sars/lab/eia/consent.htm.
3. **Collect specimens** for testing. Guidelines for specimen collection are provided in Appendix F4.
4. **Submit specimens**, with a signed consent form and completed specimen submission form, to the state or local public health laboratory.

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Specimens will be tested at the reference public health laboratory. Final results will be reported to you through the state or local health department. Information on interpreting these test results is provided in Appendix F7.

5. **Deliver test results** to the patient. Provide a patient information sheet/consent for long-term specimen storage to the patient along with the test results. Specimen remainders stored long term may be used for future investigations.

   The RT-PCR patient information sheet/consent for long-term specimen storage can be found at: http://www.cdc.gov/ncidod/sars/lab/rtpcr/participant.htm.
   The EIA patient information sheet/consent for long-term specimen storage can be found at: http://www.cdc.gov/ncidod/sars/lab/eia/participant.htm.

6. **If a signed patient information sheet/consent for long-term storage is obtained, fax it** to the state or local public health department. Contact information is provided at http://www.cdc.gov/other.htm#states.

Frequently Asked Questions

Where can I find information on how to report a possible SARS case and submit specimens for SARS-CoV testing?
This information is available through the state or local health department. Contact information is provided at: http://www.cdc.gov/other.htm#states.

Why is a signed informed consent form recommended for SARS-CoV testing?
A signed consent form is recommended because neither the RT-PCR test nor the EIA test has been licensed by FDA and the RT-PCR test is being used under an FDA-approved investigational device exemption (IDE). In addition, consent is required to store specimen remainders for future investigations.

Why are there two different consent forms, one for RT-PCR and one for EIA?
Two forms are required because of differing IRB review requirements; CDC's IRB reviewed and approved two separate protocols.

What happens if I submit specimens for testing without a signed consent form?
Because of the potentially serious public health impact of SARS-CoV transmission, specimens that are received by a state or local public health laboratory without a signed consent form will still be tested.

What is the patient information sheet, and when do I use it?
The patient information sheet/consent for long-term specimen storage will be sent to the physician along with the patient's test results. The physician should provide this document to the patient. It explains to the patient why SARS-CoV testing was performed on their specimens, explains what the results mean, and asks the patient for permission to store specimen remainders for future investigations.

Why should a signed patient information sheet be returned?
The patient information sheet asks the patient for permission to store specimen remainders for future investigations. If a signed consent form is not received before testing, it is necessary to receive the signed patient information sheet to store any specimen remainders. Specimens without a signed informed consent or signed patient information sheet allowing long-term specimen storage must be destroyed.