State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

GAVIN NEWSOM
Governor

Ebola Real-Time RT-PCR Assay

Category	Information
Description	Ebola real-time RT-PCR assay was developed by the Centers for Disease Control and Prevention (CDC) and approved by the U.S. Food and Drug Administration under emergency use authorization.
Prior Approval Required	No samples may be submitted for testing unless prior approval has been obtained. Health Care Providers must contact their local public health department. The California Department of Public Health will coordinate with the local health department and other partners to prepare and respond in evaluating a suspect patient.
Laboratory Submittal Forms (One State and two CDC forms required)	• VRDL General Purpose Specimen Submittal Form at https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/VRDL_Specimen_Submittal_Forms.aspx • CDC Infectious Disease (CDC Form 50-34, VRDL version) provided by the local health department • CDC Viral Special Pathogens Branch (VSPB) Specimen Submission Form at https://www.cdc.gov/hantavirus/pdf/specimen-submission-508.pdf
Specimen types and minimum volume	Two (2) tubes whole blood, each containing a minimum of 4 mL preserved with EDTA, clot activator, sodium polyanethol sulfonate (SPS) or citrate in plastic collection tubes. DO NOT SUBMIT SPECIMENS IN GLASS CONTAINERS. Purple, yellow or blue top tubes are preferred. Do not submit specimens preserved in heparin (green top) tubes.
Specimen Labeling	Minimum information is patient name, date collected and DOB
Storage and Shipment Conditions	Specimens should be stored and shipped refrigerated.
Shipping Instructions	PRIOR APPROVAL IS REQUIRED TO SHIP THESE SAMPLES FOR TESTING. Work with your local public health department to ensure samples are packaged according to instructions for Biological Substance – Category A (UN 2814) shipment. Please provide the tracking number and estimated time of delivery (ETA) to the VRDL so staff can be available to receive the samples.
Test Method and TAT	Real-time RT-PCR with a TAT of 24 hours
Test Interpretation and limitation	This assay is specific for Ebola Zaire virus and does not detect other Ebola species or other hemorrhagic fever viruses. Specimens from patients who have received therapeutics or vaccines based on nucleic acid sequences derived from Ebola Zaire virus may exhibit false positive or other confounding test results. If fever or symptoms have been present for less than 72 hours, a repeat test may be required to rule out Ebola virus infection.
Normal Reference Range	Not Detected