

HELPFUL HINTS WHEN APPLYING FOR SPECIAL APPROVAL FOR HIV ANTIBODY TESTING FROM CALIFORNIA DEPARTMENT OF HEALTH SERVICES LAB FIELD SERVICES

PLEASE NOTE: This handout is provided as INFORMATION ONLY. Use of these suggestions in no way guarantees approval.

Determine which test you are using and read the directions corresponding to the Clinical Laboratory Improvement Amendment (CLIA)-waived or CLIA moderately complex for that test. All submitted materials must indicate if you are planning to use a CLIA-waived or CLIA moderately complex version of the test selected. If you will be using both CLIA –waived and CLIA moderately complex types of the manufacturer’s test you must submit two separate applications.

United States Food and Drug Administration (U.S. FDA) Approved Rapid HIV Tests	CLIA-Waived	Moderately Complex
BioRad Multispot HIV-1/HIV-2 Rapid Test	Not available	Plasma or Serum
MedMira Reveal G2 HIV-Antibody Test	Not available	Plasma or Serum
Oraquick Advance Rapid HIV 1/2	Whole Blood or Oral Fluid	Plasma
Trinity Biotech Uni-Gold Recombigen	Whole Blood	Plasma or Serum

CLIA-waived Rapid HIV Tests

Your submitted application packet must include the following.

1. Complete the application that is available for download at <http://www.dhs.ca.gov/publications/forms/pdf/lab165.pdf>.

EXAMPLE			
IV. APPROVAL REQUESTED (Please Type or Print)			
U.S. FDA Screening Test	U.S. FDA Confirmation Test <i>(complete of confirm test done in your lab)</i>	Complete if Confirmation Test is Not Performed <i>(in your lab)</i>	HIV Monitoring Test
Manufacturer Orasure	Manufacturer	Testing laboratory Quest Labs	Manufacturer
Method Oraquick Advance Rapid HIV 1/2	Method	Method/manufacturer Western Blot	Method
<p>Remarks:</p> <hr/> <p>I declare that the foregoing statements are true and correct; that I have read and understand the provisions that apply.</p> <p style="color: red; margin-top: 20px;">The Lab Director's signature must be an original.</p>			
Signature of laboratory director		Date	

2. Proof of your lab's enrollment in a proficiency testing program for CLIA-waived rapid HIV tests.
3. Names of your testing personnel in your lab and their qualifications to perform CLIA-waived tests.
4. Your written testing procedures for the specific test you will perform in your lab.

PLEASE NOTE: If you copy the test package insert for your procedures be sure to add to your procedures that "All reactive tests will be immediately sent to **[YOUR CONFIRMATION TESTING LAB]** for confirmation with **[WESTERN BLOT or IFA]**."

Moderately Complex Rapid HIV Tests

1. Complete the application that is available for download at <http://www.dhs.ca.gov/publications/forms/pdf/lab165.pdf>.

EXAMPLE			
IV. APPROVAL REQUESTED (Please Type or Print)			
U.S. FDA Screening Test	U.S. FDA Confirmation Test	Complete if Confirmation Test is Not Performed	HIV Monitoring Test
Manufacturer Orasure	Manufacturer	Testing laboratory Quest Labs	Manufacturer
Method Advance Rapid HIV 1/2	Method	Method/manufacturer Western Blot	Method
Remarks:			
I declare that the foregoing statements are true and correct; that I have read and understand the provisions that apply.			
The Lab Director's signature must be an original.			
Signature of laboratory director		Date	

2. Proof of your lab's enrollment in a proficiency testing program for CLIA moderately complex rapid HIV tests.
3. Names of your testing personnel in your lab and their qualifications to perform CLIA moderately complex tests.
4. Your written testing procedures for the specific test you will perform in your lab.

PLEASE NOTE:

1. If you copy the test package insert for your procedures you must add to your procedures "All reactive tests will be immediately sent to **[YOUR CONFIRMATION TESTING LAB]** for confirmation with **[WESTERN BLOT or IFA]**."
2. If you copy the test package insert for your procedures you must add to your EXTERNAL CONTROL procedures "Run the kit controls on each day of testing." This a requirement CLIA Regulations, Title 42, Code of Federal Regulations, Section 493.1256.