

ACTG IMPAACT Laboratory Center

IMPAACT and ACTG Laboratory Center
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From: ACTG and IMPAACT Laboratory Center

Re: CD4 testing

Date: March 11, 2025

At the behest of NIAID leadership, the IQA explored options for non-US, ACTG and IMPAACT (NIAID & NICHD) laboratories experiencing reagent stock-outs or other interruptions in CD4 testing. They have determined that the CD4 molecules on cells are stable after storage for up to 4 days at 2-8°C provided the samples are handled as described below.

1. Blood should be collected in an EDTA tube (purple top).
2. Invert tubes per the manufacturer's instructions.
3. Place the tube in a box Pack following Class B shipping instructions. Samples must be maintained at 2°C to 8°C. Do not place blood in direct contact with ice packs if you are using them to maintain cold chain.
4. Specimens should be shipped immediately - do not hold onsite in the refrigerator for more than absolutely necessary.
5. Ship with cold packs to maintain cold chain or use temperature-controlled boxes as described below.
6. Must be received at testing lab and analyzed within the 4-day window. Confirm that timeline can be met with end testing lab and shipping company.

Sites are responsible for all required arrangements with the end-testing lab, e.g. MTAs, contracts etc. In addition, any testing labs must be in good standing with the IQA for CD4 testing and must be listed on an approved PAL. We recommend that you consider having all contractual and regulatory arrangements in place at time of lab activation in case you need to take advantage of this option for testing.

Shipping Instructions

Some companies (World Courier, Biocair) that routinely ship biological specimens offer 2-8°C temperature-controlled boxes for international transit. This is the preferred method of transport for international locations.



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