

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Proficiency Testing Assay Instructions for Anti-HIV-1 Antibodies in Dried Blood Spots (HIVPT)

CAUTION

The human blood products used for preparing dried blood spots at the Centers for Disease Control and Prevention (CDC) were tested by FDA approved methods and found to be non-reactive for the following: hepatitis B surface antigen (HBsAg), HIV1/2 antibodies, hepatitis C viral antibodies, Chagas Disease (*T. cruzi*), Syphilis, and Zika Virus. The blood products were non-reactive for HIV-1, HCV, and West Nile when tested by FDA approved RNA nucleic acid testing (NAT). Hepatitis B virus was non-reactive when tested by FDA licensed DNA NAT. Because no test method offers complete assurance that these or other infectious agents are absent, treat all specimens as potentially infectious and follow universal precautions. For more information on bloodborne pathogens, visit <https://www.cdc.gov/niosh/topics/bbp/>. HIVPT positive DBS specimens have been prepared using heat inactivated HIV-positive donor serum.

You can find information about preventing the transmission of HIV virus and hepatitis B virus in the workplace in the CDC publication, *Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers*, MMWR 1989;38(25);446 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001414.htm>.

SPECIMEN QUALITY STATEMENT

NSQAP strives to create specimens that mimic newborn dried blood spots. Prepared specimens have been certified and may depart from established visual criteria for assessing specimen quality. These specimens are fit for the purposes of proficiency testing.

CONFIDENTIALITY STATEMENT

NSQAP participant information and evaluations are confidential and shared only with individual participants, unless written authorization for release is received.

ASSAYING AND REPORTING INSTRUCTIONS

1. Inspect all proficiency testing (PT) specimens upon receipt. If a panel is incomplete or contains unlabeled specimens, request a new panel within 48 hours. Send the following information to NSQAPDMT@cdc.gov: laboratory code number, PT Panel Type, Specimen Number(s), and reason for requesting new panel.
2. Refrigerate the enclosed specimens at 4°C upon receipt if storage is necessary. If you are unable to analyze the specimens within three weeks of the shipment date, store them at -20°C until use, and notify the project administrator as soon as possible.
3. Handle these specimens as routine specimens. Assay them by enzyme immunoassay (EIA) and Western blot or other confirmatory method (if EIA positive) according to your laboratory's testing algorithm. Assay them as part of your normal daily workload.

Participating laboratories must generate and submit their own results and must not share NSQAP PT test results or specimens with any other laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. Participants found to have falsified or shared results will be barred from participation in the NSQAP PT program.

4. Punch all dried blood disks for analysis from within the blood spots on the specimen cards.
5. Download the HIVPT Data Reporting form from the Participant Portal at: <https://nbs.dynamics365portals.us/>
6. Fill out all information on the Data Reporting Form, save the file for your records.
7. Upload the form to the Participant Portal as instructed.

Late data will not be accepted for any reason. If data are not reported once within three events, your laboratory will be inactivated for this analyte program. To view dates for future shipments, see the NSQAP Shipping Schedule at: <https://nbs.dynamics365portals.us/> For questions, send an email to NSQAPDMT@cdc.gov and include your **laboratory code** in the email subject line.