Proficiency Testing Assay Instructions for anti-*Toxoplasma* Antibodies (TOXOPT)

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/.

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.
3. Handle these specimens as routine specimens. 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. Instructions for direct data entry are located in the NSQAP Participant Portal at: https://nbs.dynamics365portals.us/
6. Complete each presumptive interpretation based on assay results, and enter the clinical assessment derived from your routine IgM analysis. Every enclosed specimen represents a full-term (>2500g) baby.

Late data will not be accepted for any reason. If data are not reported once within four 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.