IMM.41100 RPR Needles **Phase II**

If antigen is delivered by needles, the volume of delivery is checked under each of the following circumstances:

1. **Each time a new needle is used**
2. **When control patterns cannot be reproduced**
3. **When the antigen drop does not fall cleanly from the tip**

Evidence of Compliance:

✓ Records of needle verification

REFERENCES

1) Larsen SA, Pope V, Johnson RE, Kennedy EJ Jr, eds. *Manual of Tests for Syphilis.* Washington, DC. Amer Public Health Assn: 1998.

IMM.41400 New Reagent Lot/Shipment Confirmation of Acceptability - RPR, TPPA and VDRL **Phase II**

New reagent lots/shipments of antigen for RPR, TPPA, and VDRL tests are checked in parallel with the existing lot to confirm appropriate levels of reactivity.

NOTE: New reagent lots and shipments must be checked with samples (either patient specimens or controls) with known reactivity. For laboratories reporting only qualitative (positive/negative) results, a non-reactive sample along with a sample with low titer (for RPR and VDRL) or low reactivity (for TPPA) must be tested to verify detection of low-grade reactivity. Laboratories reporting RPR or VDRL titers or TPPA semi-quantitative reactivity must test at least one additional positive sample with known high titer or reactivity. Laboratories must have written criteria for acceptance of new lots (eg, acceptance of ±1 dilution of expected result).

Evidence of Compliance:

✓ Records of verification data of new lots/shipments

REFERENCES

1) Kennedy EJ, *et al*. Quality Control. In, SA Larsen *et al* (eds). A manual of tests for syphilis, 9th ed. Washington, DC: American Public Health Association, 1998; chap 4

*****REVISED** 12/26/2024***

IMM.41420 Syphilis Antibody Screening **Phase II**

If the laboratory offers screening for syphilis, a complete screening algorithm is followed including appropriate confirmatory/secondary tests.

NOTE: Screening for infection by Treponemal pallidum can be performed by initial testing with either a nontreponemal (lipoidal antigen) antibody test (ie, traditional syphilis screening) or a treponemal antibody test (ie, reverse sequence syphilis screening). The reverse screening algorithm (with anti-treponemal antibody testing performed initially) may be preferred in cases of recent infection or in cases of late latent or tertiary syphilis when nontreponemal antibodies may not be detectable (even in the absence of adequate treatment).

Regardless of the method used, a positive (reactive) result in the primary screening assay must be reflexively tested by at least one secondary test method. In the traditional syphilis screening algorithm, a nontreponemal (lipoidal antigen) antibody screening assay must be reflexively tested by an anti-treponemal assay (such as EIA or TPPA).

In the reverse sequence screening algorithm, a treponemal antibody screening assay must be tested by a nontreponemal (lipoidal antigen) assay (such as RPR or VDRL). When discordant results are obtained (screening anti-treponemal antibody positive, nontreponemal (lipoidal antigen) negative), an additional anti-treponemal test (eg, TPPA or EIA) must be performed given the possibility of false positive results in anti-treponemal antibody screening assays.

Reflex testing in either algorithm may be performed on site or by a referral laboratory.

If the nontreponemal (lipoidal antigen) antibody test is performed to monitor treatment of patients with known syphilis infection (not as a screening tool), anti-treponemal antibody testing is not required. Because anti-treponemal antibodies persist after successful treatment, testing patients with previously diagnosed syphilis using a reverse algorithm approach is discouraged; therefore, laboratories should provide a clear option for providers to order nontreponemal (lipoidal antigen) titers directly for following serologic response to treatment.

This checklist requirement only applies to testing serum/plasma specimens. For testing CSF specimens, stand-alone anti-treponemal (eg, FTA-ABS or TPPA) and/or nontreponemal (lipoidal antigen) (eg, VDRL) tests may be used at the discretion of the laboratory director.

Evidence of Compliance:

✓ Records of confirmatory testing of positive screening antibody results with appropriate secondary assays

REFERENCES

1) Papp JR, Park IU, Fakile Y, Pereira L, Pillay A, Bolan GA, CDC laboratory recommendations for syphilis testing, United States, 2024. *MMQR Recomm Rep.*2024;73 (No. RR-1): 1-32.
2) Rhoads DD, et al. Prevalence of traditional and reverse-algorithm syphilis screening in laboratory practice. A survey of participants in the College of American Pathologists syphilis serology proficiency testing program. *Arch Pathol Lab Med.* 2017;141(1):93-97.

HIV PRIMARY DIAGNOSTIC TESTING

Inspector Instructions:

READ

- Sampling of HIV diagnostic testing policies and procedures
- Sampling of HIV result reports

IMM.41450 HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing Phase I

The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

NOTE: If additional testing after a primary screening test is recommended by public health authorities, the laboratory:

- *Performs additional testing reflexively if the specimen is suitable and the test is performed in house, or*
- *Sends additional testing to a referral laboratory if the specimen is suitable, or*
- *Provides guidance to providers on submission of additional specimens, if needed for supplemental or confirmatory testing.*

The US Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) provide recommendations for HIV testing. Guidelines and recommended algorithms can be found on the CDC and APHL websites.

Evidence of Compliance:

✓ Patient reports with initial screening results and reflexive testing results and/or guidance

REFERENCES

1) Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014. Accessed 11/19/2019.
2) National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (US). Divisions of HIV/AIDS Prevention; Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens, Available at: https://stacks.cdc.gov/view/cdc/50872. Published January 2018. Accessed 4/2/2023.