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

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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.