JAN 23, 2019

OPEN ACCESS

DOI:
dx.doi.org/10.17504/protocols.io.xdwfi7e

Protocol Citation: Qiang Wang, Yan Lei, Xiaolan Lu, Guangrong Wang, Qin Du, Xiaolan Guo, Quming Fan, Guoyuan Zhang, Dongsheng Wang 2019. Urea-mediated dissociation alleviate the false-positive *Treponema pallidum*-specific antibodies detected by ELISA. **protocols.io** <https://dx.doi.org/10.17504/protocols.io.xdwfi7e>

MANUSCRIPT CITATION:

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Protocol status: Working
 We use this protocol and it's working

Created: Jan 23, 2019

Last Modified: Jan 23, 2019

Urea-mediated dissociation alleviate the false-positive *Treponema pallidum*-specific antibodies detected by ELISA

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ABSTRACT

The serological detection of antibodies to *Treponema pallidum* is essential to the diagnosis of syphilis. However, for the presence of cross-reaction, the specific antibody tests [e.g., enzyme-linked immunosorbent assay (ELISA)] always have false-positive results. In this study, we derived and validated the dissociation of urea in an attempt to alleviate the situation of false-positive antibodies to *T. pallidum* detected by ELISA. Six serum samples that were false-positive antibodies to *T. pallidum* detected by ELISA, and 16 control serum samples (8 sera positive for both specific IgG and IgM, and 8 IgG-positive and IgM-negative sera) were collected to select the appropriate dissociated concentration and time of urea. Our goal was to establish improved an ELISA method based on the original detection system of ELISA. The sensitivity of the improved ELISA was evaluated by 275 serum samples with class IgM-positive antibodies to *T. pallidum*. At 6 mol/L with 10 minutes dissociation of urea, 6 samples with false-positive antibodies to *T. pallidum* were converted to negative, and compared with true-positive antibodies to *T. pallidum*. The sensitivity of the improved ELISA was 100% by detecting the class IgM-positive antibodies to *T. pallidum* in sera of patients with syphilis. Considering the importance at the diagnosis of syphilis, antibodies to *T. pallidum* in serum samples should be retested by the improved ELISA method to avoid false-positive results.

MATERIALS

6 sera that were false-positive antibodies to *T. pallidum* detected by ELISA, 16 control sera (8 sera positive for both specific IgG and IgM, 8 IgG-positive and IgM-negative sera) and 275 sera (IgM positive), obtained from patients with *T. pallidum* primary infection.

PROTOCOL integer ID:
19606

Keywords: Urea; Treponema pallidum; enzyme-linked immunosorbent assay; false-positive

- 1 Design the experimental steps.
- 2 Collect clinical samples to meet the needs of the experiment, especially false positive samples detected by ELISA.
- 3 Using different methods to detect TP antibodies, and to understand the characteristics of different samples, so as to facilitate grouping.
- 4 Pre-experiment to explore the basic conditions of urea dissociation.
- 5 Formal experiment to select the best condition of urea dissociation.
- 6 Sensitivity evaluation of the improved TP-ELISA.