# 510(k) Summary

**Submitter Name:** Arlington Scientific, Inc

**Contact:** David Binks

**Device Name:** **ASI TPHA Test**
**Common Name:** Microhemagglutination test for *Treponema pallidum*
**Classification Name:** Antigens, HA, Treponema pallidum

**Predicate Device:** Olympus PK™ TP System

**Description:** The **ASI TPHA Test** is a qualitative microhemagglutination test for the presence of antibodies to *Treponema pallidum*, the causative agent for syphilis, in serum and EDTA plasma. It is formulated for use on the Olympus PK7200™ Automated Microplate System.

**Reagents:**

**TPHA Test Cells** -- Preserved chicken erythrocytes, tanned and coated with antigens of *T. pallidum*, suspended in sorbent with rabbit serum and bovine serum albumin (US source), 0.002% gentamycin and 0.1% sodium azide as preservatives.

**TPHA Diluent** -- Phosphate buffered saline solution containing absorbers, ox erythrocyte stroma, rabbit serum, bovine serum albumin (US source), Tween 80 surfactant, preserved with 0.1% sodium azide.

**TPHA Controls (Reactive and Nonreactive)** -- Human plasma, preserved with 0.1% sodium azide.

**Intended Use:** The **ASI TPHA TEST** is a qualitative microhemagglutination test for the presence of IgG and IgM antibodies to *Treponema pallidum*, the causative agent for syphilis, in serum and EDTA plasma. It is formulated for use on the Olympus PK7200™ Automated Microplate System. Serum is the sample of choice and any repeat or confirmatory testing must be done on serum. This test is for blood screening only.

**Technological Characteristics:**
The **ASI TPHA Test**, like the predicate device, uses preserved avian erythrocytes coated with antigens of *T. pallidum* (Nichols strain) to bind with specific antibodies present in the donor's sample. The cells are suspended in diluent containing components to eliminate nonspecific reactions. Positive reactions are characterized by hemagglutination of the cells. The PK-7200™ reads the wells and differentiates agglutinated from non-agglutinated cell patterns.

**Non-clinical test results:**

A. **ASI TPHA test** detected 38 of 38 known reactive samples and 17 of 17 nonreactive samples for 100% accuracy and identified one reactive unknown among 835 random samples which was also detected by the predicate device.
B. In 835 tests, overall correlation with the Olympus predicate device is 99.87%
C. Run-to-run precision is >99%
D. Within run precision is >99%

**Conclusions: ASI TPHA test** is a safe and effective test for detection of antibodies to *Treponema pallidum*, the causative agent of Syphilis, during automated screening of blood donor samples. It is substantially equivalent to the currently marketed predicate device, the Olympus PK™ TP System