News Release
Arlington Scientific, Inc. (ASI)
Springville, Utah
Date: 19 February 2015
Release: Immediate

Topic: Arlington Scientific, Inc. (ASI) Receives FDA CBER Clearance for Cadaveric Specimens to be processed with the ASiManager-AT™ with their RPR Syphilis Kit for use in vitro diagnostics, blood donor and cadaveric (non-heart beating) donor screening. FDA 510(k) BK140192

Arlington Scientific, Inc. (ASI), a leader in the field of syphilis testing, announces the United States Food and Drug Administration (FDA) CBER clearance for the ASiManager-AT™ in RPR interpretation and screening of cadaveric (non-heart beating) donors.

Last Year the ASiManager was cleared with two important firsts: the first clearance of an RPR Nontreponemal Syphilis Analyzer by the Center for Biologics Evaluation and Research (CBER), and the first non-treponemal (RPR) system cleared for blood donor screening. Today's notice is another first making it the only method cleared for syphilis testing for use in vitro diagnostics, blood donor and cadaveric donor screening. The FDA CDRH cleared the ASiManager for diagnostic testing in November 2012.

The ASiManager is intended to be used as an integrated digital particle analyzer to objectively interpret the ASI RPR Card Test for Syphilis. The ASiManager is designed to provide standardized test interpretation, and to provide the benefits of storage, retrieval, and transmittal of RPR test results.

"Automated treponemal enzyme and chemiluminescence immunoassays (EIA/CIA), can yield false-positive results" says Mike Hyde Vice President of Sales and Marketing at ASI. "Our RPR nontreponemal analyzer allows blood banks and blood and tissue donor facilities to use CDC recommended traditional algorithm that leaves blood donations safe, available for donation and not wasted needlessly. This new claim has very significant impact on the tissue market by providing the best screening method to maximize donations since RPR nontreponemal testing identifies active infection, not old treated infections and should meet the 2013 HCT/P Draft Guidance for Industry issued by FDA."

The ASiManager brings state-of-the-art digital technology to laboratory analysis, interpretation and data management of ASI serology agglutination tests.

ASI is a privately held corporation with expertise in developing and manufacturing in vitro diagnostic test kits, serology analyzers, and blood donor lounges.

For additional information please contact:
Mike LaDow, Director of Sales and Marketing
801-489-8911
mladow@arlingtonscientific.com
www.arlingtonscientific.com