

Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Launches New VITROS® Anti-T. cruzi Assay

September 28, 2018

Assay is now available in Mexico and countries that accept CE mark

Ortho Clinical Diagnostics (Ortho), a global leader of in vitro diagnostics, today announced the introduction of its next-generation Anti-T. cruzi assay, with CE Mark approval and approval for use in Mexico. Ortho's VITROS® Anti-T. cruzi assay offers best-in-class sensitivity^{1,2} which is key to the early detection of Chagas disease, and best-in-class specificity,^{1,2} valued by blood banks.

"We're committed to expanding our menu with new and innovative offerings," said Jennifer Paine, Chief Product Portfolio and Quality, Regulatory and Compliance Officer at Ortho. "The launch of Ortho's VITROS® Anti-T. cruzi assay will strengthen our VITROS® donor screening solution, allowing us to serve more blood banks."

The World Health Organization (WHO) estimates that approximately 7-8 million people worldwide are infected with *Trypanosoma cruzi*, a blood-borne protozoan parasite that causes Chagas disease. With its incapacitating effects and mortality, this disease is one of the biggest public health problems in Latin America. Since human transmission occurs primarily through blood transfusions and organ transplants from infected donors, testing for *Trypanosoma cruzi* has become mandatory for blood screening in Latin America and parts of Europe.³

Ortho's VITROS® Anti-T. cruzi assay is approved for use on the VITROS® ECi/ECiQ Immunodiagnostic System, VITROS® 3600 Immunodiagnostic Systems, VITROS® 5600 Integrated System and the next-generation VITROS® XT 7600 Integrated System.

About Ortho's VITROS® Systems

The VITROS® Chemistry, Immunodiagnosics and Integrated Systems from Ortho Clinical Diagnostics are a portfolio of products and patented enabling technologies which help clinical laboratories diagnose, monitor and treat disease. VITROS® Products are engineered to help clinical laboratories with organizational, operational and economic challenges.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

1. Based on a comparison of sensitivity and specificity listed in other manufacturers' Instructions for Use

2. Serological Sensitivity: 100% (95% CI 99.1% - 100%), Parasite Positive Sensitivity: 100% (95% CI 94.3% - 100%), Specificity Donor Population: 100% (CI 99.93-100%), Specificity Clinical Population: 100% (CI 98.2-100%); VITROS® Anti-T. cruzi (Chagas) Instructions For Use

3. Screening Donated Blood for Transfusion- Transmissible Infections – Recommendations, World Health Organization, 2009

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