

Working with the university of yaounde' as the site for our clinical trial

Opinion

The Muse Auto CD4/CD4% system is designed and manufactured by EMD Millipore, a division of Merck, KGaA, of Darmstadt, Germany. The Muse Auto CD4/CD4% system is designed to measure and count T cells in the blood samples of adult and pediatric viral patients. The Muse Auto CD4/CD4% system is intended for IVD clinical use for patients living in developing countries that accept the CE-IVD mark. EMD Millipore chose to work with the University of Yaounde' in Cameroon to conduct the clinical trials. This article describes the selection process for our choice of the University of Yaounde', how cooperation with the university led to product improvements, and why customers should evaluate the Muse Auto Cd4/CD4% system for their laboratories.

The selection process

The Muse Auto CD4/CD4% system was deemed ready for clinical testing in September 2013. The development team compiled a list of requirements for an acceptable clinical site: Here are the requirements:

- a. The Muse Auto CD4/CD4% system was intended for IVD clinical use for both adult and pediatric patients. EMD Millipore would require a clinical site with both adult and pediatric viral positive patients
- b. The Muse Auto CD4/CD4% system was to be compared to its predicate device, the Guava Auto CD4/CD4% system for filing of self declared CE-IVD mark. EMD Millipore would provide the instruments and reagents for testing. It was a requirement that trained field service representation be close by should problems develop.
- c. Sales asked that the site be located in sub Saharan Africa, the intended target market for sales.
- d. Marketing requested the site be located in a city with an easily accessible airport.
- e. The site had to follow WHO recommendations and adhere to acceptable regulatory and legal standards.

Twenty two laboratories were invited to compete for the selection of the clinical site. Seven laboratories decided to compete. The University of Yaounde' won the selection because of the above criteria and the amicable relationship developed between the selection team and Professor Mbopi-Keou, the chair of Laboratory Medicine at the University of Yaounde'.

The clinical trial led to product improvements

EMD Millipore initiated the clinical trial at the University of Yaounde' in March, 2014. Initial testing revealed a requirement that the product be made rugged to endure fluctuations in African electricity and also tolerate extreme heat and humidity found in the equatorial regions.

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Over the next few months, new design and parts were developed for the Muse Auto CD4/CD4% system. The University of Yaounde' tested new prototypes and provided quality data and feedback. The result became the new, exciting Muse Auto CD4/CD4% system. After a successful clinical trial, a CE-IVD mark was declared. EMD Millipore officially released the instrument for commercial sale in October, 2015.

The clinical evaluation at the University of Yaounde'

The clinical trial of the Muse Auto CD4/CD4% system proved the Muse Auto CD4/CD4% system to meet or exceed the standards for laboratory use in hospitals, clinics, and ambulatory care. Results from the University of Yaounde' demonstrated the Muse Auto CD4/CD4% capable of counting positive CD4 cells in cytopenic specimen. T cell count recovery can be seen at lower count levels with employment of the Muse Auto CD4/CD4% system. The Muse Auto CD4/CD4% system is ideal for establishing the T cell baseline required by WHO protocol for before and after anti-retroviral therapy (ART).

The staff in Professor Mbopi-Keou's laboratory is composed of professional medical technologists and pathology interns. The team in the laboratory followed the approved protocol. All legal and regulatory requirements were met. The data from their evaluation is now incorporated into EMD Millipore's clinical file for CE-IVD submission. It was an honor and a pleasure to conduct the clinical trial at the University of Yaounde'.

Take a closer look!

Merck is committed into expanding sales into emerging economies. Substantial investment has been provided to develop and support new technologies for the developing world. The Muse Auto CD4/CD4% system is an initial offering designed for this market. Please evaluate the Muse Auto CD4/CD4% system for your laboratory. Contact your local Merck representative for additional information.

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Conflicts of Interest

None.

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