



Paris, 7 October 2015

## **Rapid diagnosis of Ebola: the eZYSCREEN<sup>®</sup> test proves itself in the field.**

**Announced at the end of 2014 during the final phase of research and development, the rapid diagnostic test for Ebola virus disease developed by the French Atomic Energy Commission (CEA), with support from the Inserm Jean Mérieux P4 high-level biological containment laboratory (Lyon), has been assessed in the field, including in Guinea, over a period of several months. This assessment now allows the test to be CE marked, leading to its authorisation for use as a diagnostic tool. The eZYSCREEN<sup>®</sup> test will thus help to enhance the available means of control, particularly by detecting residual sporadic cases among symptomatic patients, or by post-mortem identification.**

The rapid diagnostic test for Ebola, developed in the public health emergency of 2014 and 2015 by a team from the Life Sciences Division (DSV) of CEA, with support from the Inserm Jean Mérieux P4 high-level biological containment laboratory (Lyon), allows diagnosis of the disease within 15 minutes, using a few drops of blood or serum. An agreement has been drawn up with the Vedalab company (Alençon), which manufactures it.

In contrast to laboratory tests, this easy to use field test does not require sophisticated instrumentation or even electricity, and can be used by non-specialist staff. The result is read directly and visually. Storage for eight and a half months at 30°C, and for 14 days at 45°C, did not affect its performance, proving its high robustness and stability.

The eZYSCREEN<sup>®</sup> test was assessed under real conditions, including in the Ebola Treatment Centres in Coyah and Forécariah in Guinea (French Red Cross), and part of the analyses were also conducted in Donka National Hospital (Conakry, Guinea). These studies ended in August 2015. The rapid test shows excellent specificity, eliminating almost any risk of false positive results, and an appropriate degree of sensitivity for its intended use, i.e. to very rapidly identify the maximum number of cases possible *in situ* with a view to preventing epidemics.

These results enabled CE marking of the eZYSCREEN<sup>®</sup> test for Ebola, which is essential for its use during the sporadic cases that continue to occur in Guinea and Sierra Leone. The objective is to be able to avoid the start of a new large-scale epidemic outbreak.

Discussions are underway between CEA and diagnostics industries in order to allow the widest possible distribution of the test.

For this body of work, the Technological Innovations for Detection and Diagnosis (Li2D/DSV) Laboratory in the CEA Marcoule Centre has just received the Societal Resilience Trophies Technological Innovation Prize for 2015, awarded by the French High Committee for Civil Defence.

### **CE Marking**

*“CE” marking was established within the framework of European legislation. It indicates that the product conforms to the community requirements incumbent on the manufacturer of the product. It must be affixed before a product is placed on the European market.*

*With respect to eZYSCREEN<sup>®</sup> tests for rapid diagnosis of Ebola virus disease, their conformity with European Directive 98/79/CE for in vitro diagnostic medical devices is confirmed by the issuance of a declaration of conformity by the manufacturer (Vedalab) on 2 October 2015.*

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### **Press Contacts**

Tuline LAESER – Tel.: +33 (0)1 64 50 20 97 / Email: [tuline.laeser@cea.fr](mailto:tuline.laeser@cea.fr)