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LONDON, UK (GlobalData), 26 July 2012 - **IntelligentMDx** received EU approval of their new diagnostic test, IMDx HSV-1/2, which **detects** the presence of **HSV** **nucleic** **acids** and differentiates between **Herpes** **simplex** virus **1** and **2** (HSV-1 and HSV-2). The IMDx HSV-1/2 is designed to complement the use of the Abbott m2000 RealTime system, manufactured by Abbott Molecular, a subsidiary of Abbott Laboratories. The new diagnostic test can be used to detect HSV DNA in both male and female genital or oral lesions and cerebral spinal fluid, according to a press release by IntelligentMDx on 19 July, 2012.

Herpes simplex virus, or HSV, of the Herpesviridae family, has a prevalence of infection of approximately 16.2% worldwide (CDC). HSV-2 has been shown to frequently cause genital herpes when transmitted sexually, contributing to its status as a sexually transmitted infection (STI). According to the World Health Organization (WHO), herpes may occasionally be caused by HSV-1 in addition to HSV-2, which indicates a need to not only diagnose HSV infection, but also provide an efficient differential diagnosis between the two types of HSV for appropriate treatment. HSV is characteristic in its ability to maintain latency in the human host, while evading the immune system, and eventually causing sporadic reactivation that results in genital lesions, sores, fever and swollen glands. While the dissemination of the disease is primarily through sexual intercourse, HSV can also be passed along from mother to child, leading to a significantly high morbidity in untreated infected infants (WHO).

According to the statement released by IntelligentMDx, IMDx HSV-1/2 allows clinicians to test up to 94 samples from patients in less than 6 hours, while requiring minimal processing of the test samples. In addition, the statement also mentioned that the test boasts 100% sensitivity

and an average of 98% specificity in the detection of HSV-1 and HSV-2 when compared to existing culture and molecular reference methods, which struggle to maintain sensitivity after initial infection. Also, Dr. Alice Jacobs, the Chairman and CEO of IntelligentMDx, cited that fast and automated workflow solutions such as IMDx HSV-1/2 and Abbott's m2000 system, promise to aid clinicians in their attempt to move towards quicker and more efficient diagnostic testing. The IMDx HSV-1/2 marks the fourth test developed by IntelligentMDx, with other tests designed to diagnose Streptococcus, drug-resistant Enterococci, and Clostridium difficile.

A large portion of the herpes virus disease burden remains in low-income countries, with disproportionately large numbers of infected individuals residing in areas of sub-Saharan Africa, where statistics reveal infection in 70% of women and 55% of men (WHO). For these individuals and the governments of these afflicted countries, the need for a multiplexed point-of-care (PoC) device designed to detect and diagnose multiple pathogens is crucial. The tests developed by IntelligentMDx undoubtedly seek to provide solutions to this large and growing market. These tests also help create a push towards the development of drugs and other therapies that may be used to cure individuals suffering from infection.

To date there are no cures for HSV infection, with the majority of treatments focused on reducing outbreaks and decreasing the likelihood of viral reactivation (CDC, January 2011). Well-designed diagnostic tests work to highlight market needs, and often act as an impetus to new therapeutic research. A study conducted by GlaxoSmithKline and the National Institute of Allergy and Infectious Diseases (NIAID) concluded that the vaccine Havrix, developed against herpes, did not provide any immunization against HSV-2 and only limited immunization against HSV-1. In light of the slow progress towards providing a cure and the availability of solely palliative treatments, the market is poised for a company to enter and capitalize on its first-mover advantage. However, any true cure or prophylactic would be required to provide dual coverage against HSV-1 and HSV-2 to adequately address the unmet needs of this market, which may slow down research and development. With a new wave of diagnostic companies, such as IntelligentMDx, we see the industry acclimating to a shift, where diagnostic solutions will help outline and segment populations for targeted treatment. Therefore, it is likely that this approach will define the paradigm in the fight against infectious disease for high- and low-income countries, alike.