

**EV0017**

**ePoster Viewing**

**HIV/AIDS (incl anti-retroviral drugs, treatment & susceptibility/resistance, diagnostics & epidemiology)**

### **Laboratory evaluation of the Alere HIV Combo point-of-care test**

Hitesh Mistry<sup>\*1</sup>, Maximillian Habibi<sup>2</sup>, David Muir<sup>2</sup>

<sup>1</sup>*Imperial College Healthcare NHS Trust, Charing Cross Hospital, Infection and Immunity, London, United Kingdom*

<sup>2</sup>*Imperial College Healthcare NHS Trust, London, United Kingdom*

**Background:** The Alere HIV Combo is a small strip format point-of-care (POCT) test that detects both HIV-1/2 antibodies and non-immunocomplexed HIV-1 p24 antigen providing results in 20 minutes. This test therefore has the potential to identify HIV infection earlier than antibody-only tests. To determine suitability for use as routine HIV POCT, an evaluation using stored serum was performed in the Infection and Immunity laboratory at Imperial College Healthcare NHS Trust (ICHNT).

**Material/methods:** Frozen archive serum samples from patients tested for HIV serology were identified, the original result was noted and the samples tested in batches using both the Alere HIV Combo and the current standard HIV confirmation assay at ICHNT, the bioMérieux VIDAS HIV Duo Ultra 4<sup>th</sup> generation HIV-1/2 antigen antibody combination assay.

**Results:** A total of 99 HIV seropositive and 20 HIV seronegative samples were collected. No sample tested gave an indeterminate result using the Alere HIV Combo. 96 out of 99 known HIV seropositive samples gave a positive result using the Alere HIV Combo (sensitivity for HIV infection at any stage = 97%). All 3 samples that gave a negative result using the Alere HIV Combo had originally, as well as on repeat testing, been determined to have HIV-1 p24 antigen-only detectable by VIDAS. No HIV-negative sample gave a positive result using the Alere HIV Combo (specificity = 100%). The observed positive predictive value (PPV) of the Alere HIV Combo for identifying HIV infection was therefore 100% and the negative predictive value (NPV) was 87%.

**Conclusions:** The Alere HIV Combo is a simple to use, rapid test capable of reliably identifying established HIV infection when using frozen archive serum. Deployment of this test at the point of care however, where fresh finger-prick whole blood samples are used, will require further evaluation.