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Validation of the Cepheid GeneXpert for detecting Ebola virus in semen and cervicovaginal fluid

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Background & Aim: After the period of sustained Ebola virus transmission during the 2013-2016 epidemic, sporadic clusters of Ebola virus, linked to the persistence of virus in body fluids of Ebola survivors, were reported in West Africa. The persistence of Ebola virus (EBOV) in body fluids other than blood, including semen, and the documentation of at least one case of sexual transmission led the World Health Organization (WHO) to recommend that men who have survived Ebola virus disease (EVD) refrain from unprotected sexual intercourse for at least 12 months, following recovery or until their semen is confirmed to be EBOV-free. However, there is no fully validated assay for EBOV detection in fluids other than blood. Given the public health implications of viral persistence in the semen of male survivors we have validated the detection of EBOV RNA in semen using the Cepheid Xpert Ebola Assay.

Methods: Whole semen samples were obtained from uninfected donors and spiked with inactivated EBOV virus to generate a series of samples containing 100-100,000 copies/mL of EBOV. Each 100 uL sample was lysed in the 2.5 mL lysis buffer provided in the test kit, incubated for 10 minutes, and then treated with dithiothreitol (DTT) followed by another 10-minute incubation. One positive control (containing both GP and NP targets) and one negative control (human serum) from the SeraCare Control Bundle was tested each day that testing occurred. All samples were tested using the Cepheid Xpert Ebola Assay on the GeneXpert Dx System.

Findings: The Cepheid Xpert Ebola assay had a limit of detection of 1000 copies/mL in semen and 275 copies per mL in blood. Limits of detection increased with longer intervals between collection and testing. However, acceptable results were obtained up to 72 hours after specimen collection. Un-spiked blood and semen donor samples (n=40 and 50, respectively) were all undetected. All positive and negative controls were valid, and there were zero false positives (negative controls with positive results) and zero false negatives (positive controls with negative results) for either instrument.

Interpretation: Similar to its performance characteristics in blood, the Cepheid Xpert Ebola assay on the GeneXpert Dx System is accurate and precise for detecting EBOV in whole semen. Testing of these fluids conducted within 72 hours of specimen collection was acceptable for all samples down to the limit of detection, but specimen-specific extraction controls are necessary. A validated assay for EBOV RNA detection in semen informs the care of male survivors of Ebola, as well as recommendations for public health.

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