VALIDATION OF IMMUNOASSAYS FOR THE USE WITH CADAVERIC SPECIMENS FROM TISSUE DONORS

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SETTING THE GROUND

Cadavers are the main source of organs and tissues: this introduces the risk of transmission of donor-derived infections for the transplantation recipient. By contrast, very few assays are specifically validated for the use with cadaveric specimens.

Changes to blood composition following death occurs: haemolysis, proteolysis, presence of clots due to absence of heartbeat may influence test results. Then a specific validation study is required.

Guideline recommended by the Paul-Ehrlich-Institut (May 2014) for the use of immunoassays for the release of tissues for transplantation was followed: “Proposal for the validation of anti-HIV-1/2 or HIV Ag/Ab combination assays, anti-HCV assays, HBsAg and anti-HBc assays for use with cadaveric samples”.

THE APPROACH

“Although specificity has previously been considered a problem in the screening of cadaveric samples, we believe that ensuring sensitivity is more important”. (Kitchen AD – Newham JA, Cell Tissue Bank. 2011 May; 12(2): 117-24).

Eliminating False Negative results is of much concerns, as it increases safety for organ recipients.

Special care should be used during collection and separation procedures (i.e. centrifugation) to ensure the suitability of cadaveric specimen.

Spiked samples incubated at Room Temperature prior to testing to enhance potential inhibitors that can affect results.

Samples within 24hrs from last heartbeat.

Spike volumes do not exceed a tenth of the sample volume.

Guideline asks for accuracy and precision assessment.

Accuracy: student’s t-test is used to calculate statistical difference between pre and post-mortem populations, at same level of reactivity (neat excluded).

Precision: by testing one cadaveric specimen and one living donor with low positive reactivity in 6 replicates.

RESULTS AND DISCUSSION

Outcomes: No difference in sensitivity performance is expected between pre and post-mortem sample testing. Results of the study will be included in Instruction for Use.

DILUTION TEST

The qualification of testing is expected to be completed by the end of 2015 including Hepatitis and Retrovirus assays on LIAISON® automated analysers.

CONCLUSIONS

No significant differences are observed when testing cadaveric specimens versus living donors. LIAISON® assays ensure reliable data, showing suitable performance in the determination of Treponema, Chagas and HCV specific antibodies in serum/plasma cadaveric specimens. This option improves the potential of the LIAISON® fully automated solution for the detection of Treponema, Chagas and HCV antibodies and of all other DiaSorin markers for infectious disease panel including Hepatitis and Retroviruses which are under evaluation.

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