

Development of a Bespoke External Quality Assessment Scheme for Heart Valves



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Introduction

Heart valves (HV) used for transplants should satisfy the criteria of posing no risk to patients, as they are considered 'life improving/life-saving'.

There are currently no standards or regulations in place for handling, testing and decontaminating heart valves for transplants, leading to variations in laboratory practises of tissue banks.

There is also a high discard rate of heart valves that can be transplanted due to failed microbiology.

No External Quality Assessment (EQA) scheme for microbiology of heart valve tissue banking currently exists.

The aim of the scheme will be to determine whether tissue banks can identify contaminants and successfully decontaminate the heart valves.

This project is a follow up from the work carried out by the Scottish National Blood Transfusion Service (SNBTS).

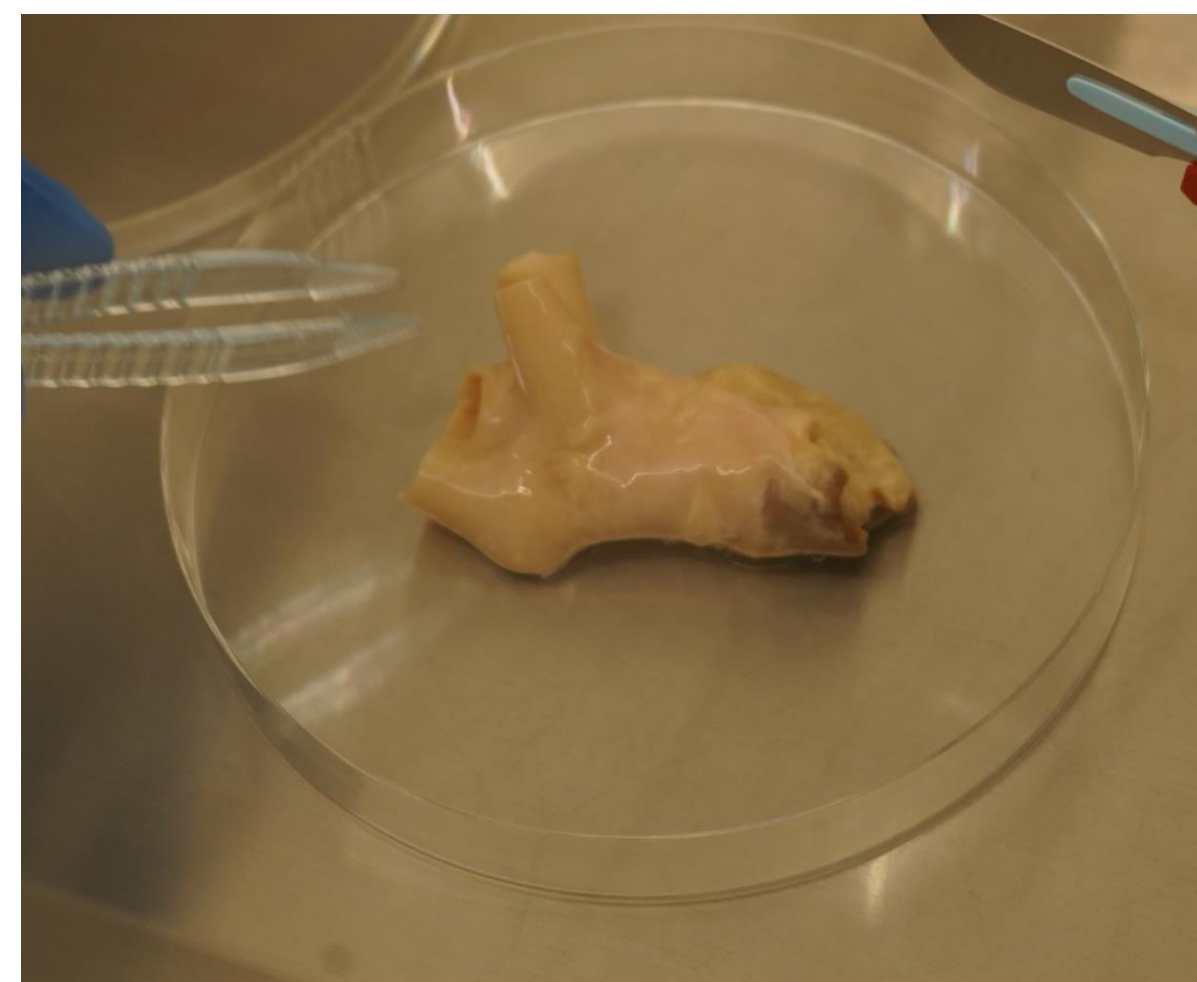


Figure 1: An image of one of the heart valves for inclusion within the scheme.

Methods

Hearts valves are handled in accordance with the Human Tissue Act 2004. All activities associated to manipulating HV were recorded on the UKHSA Laboratory Information System (LIMS) to be able to process the tissue in the laboratory.

The heart valves were processed in a MSC class II cabinet.

Sterility Checks

- The hearts valves were checked for bacterial growth by inoculating and incubating a small section of the valve on CBA and two wells cut in the agar to fill with transport fluid.
- The plates were then incubated at 37°C for 24 hrs and checked for any bacterial growth.

Neutralisation of Antibiotics

- Neutralisation step was performed with two different neutralising agents. The neutralisation effect of Biomerieux DNP-F and BD Peds Plus TM/F Bottle were compared to determine the suitable neutraliser for the heart valves.
- The heart valves were incubated at 37°C for 1 hr in neutralising solution and plated with fully susceptible *Escherichia coli* and *Staphylococcus epidermidis* to check for zone of inhibition around the inoculated area.
- The zone of inhibition indicates the presence of antibiotics (Figure 2).

Keywords

Heart valves EQA, neutralisation of heart valves, tissue microbiology EQA, tissue bank EQA

Results

The heart valves did not contain organisms and were therefore considered sterile. No further work to decontaminate the heart valves was performed.

The heart valves treated with Buffered Peptone Solution with Neutralizers (DNP-F) and the BD Peds Plus™/F show slight reduction in the zone size in comparison to the control (Tables 1 & 2).

Results



Figure 2: The results obtained from the neutralisation step displaying clearance which indicates that the HV contained antibiotics. Top- two wells containing the neutralisation broth. Bottom- a small section of the HV.

Neutralisation Step using *E. coli*

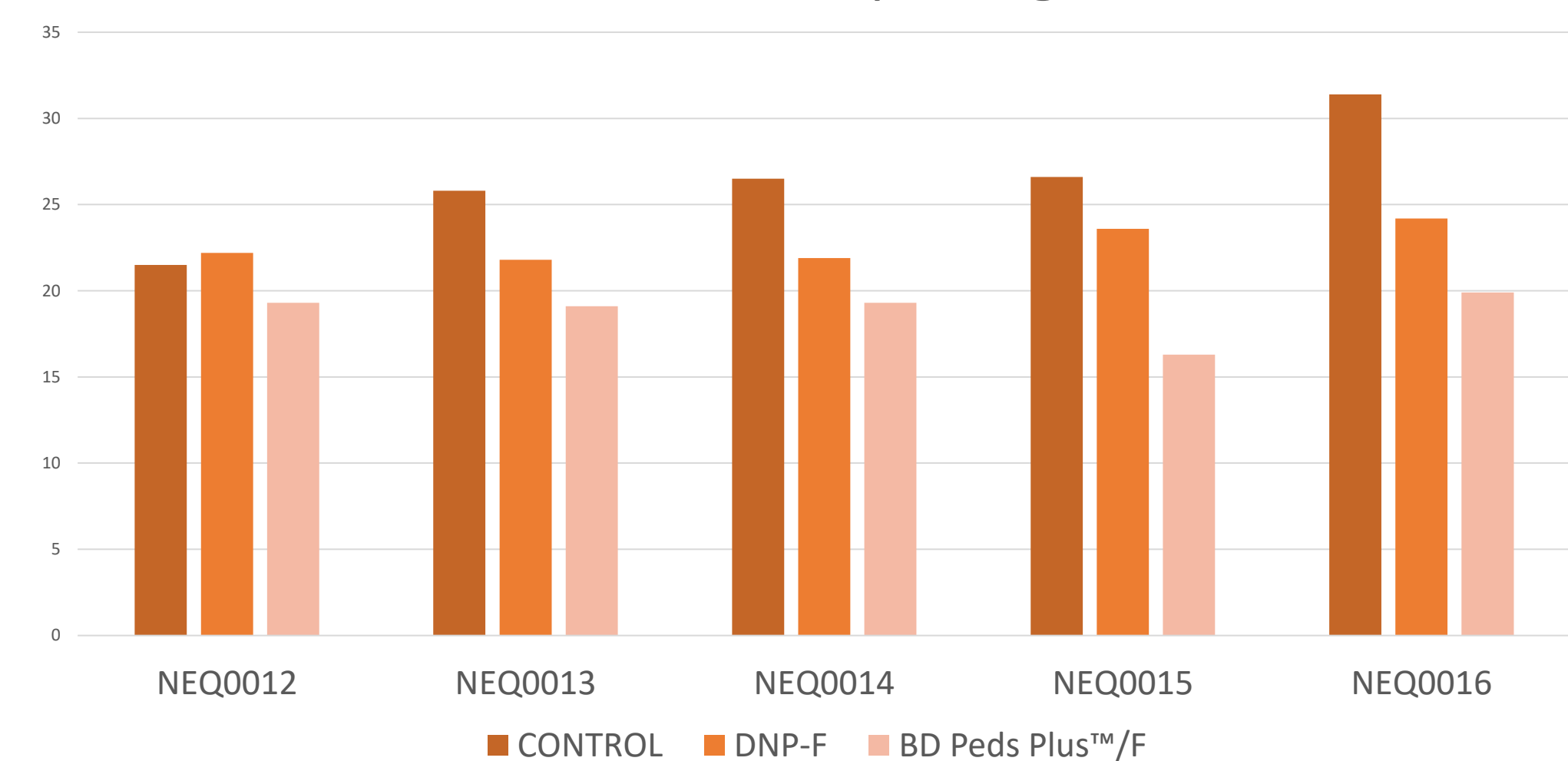


Table 1: Results of the neutralisation step performed on *Escherichia coli* that failed to fully neutralise the antibiotics present in the HV. Comparison of the neutralisation between Control, Biomerieux DNP-F BD Peds Plus TM/F bottle

Neutralisation Step using *S. epidermidis*

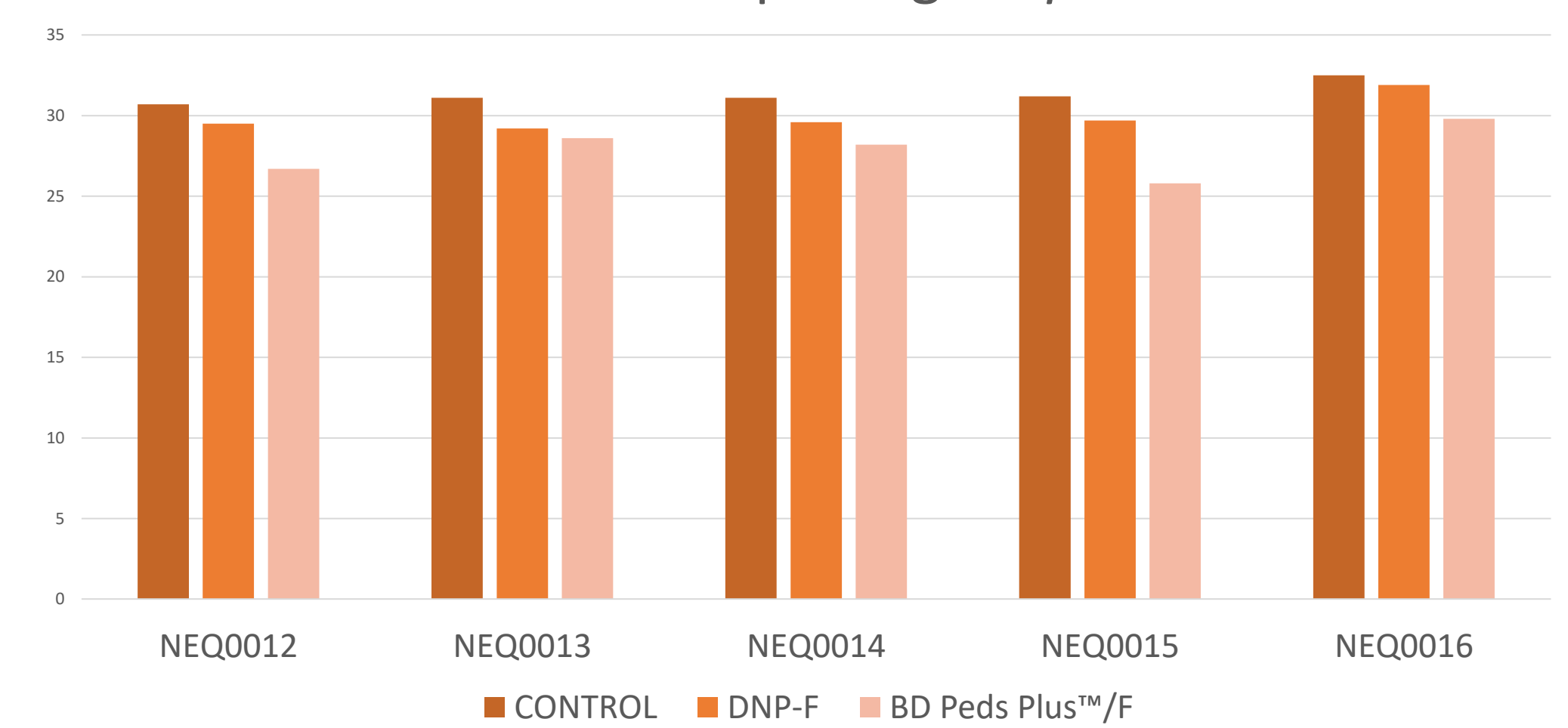


Table 2: Results of the neutralisation step performed on *Staphylococcus epidermidis* that failed to fully neutralise the antibiotics present in the HV. Comparison of the neutralisation between Control, Biomerieux DNP-F BD Peds Plus TM/F bottle

Discussion/ Conclusion

The neutralising agents in Biomerieux DNP-F and BD Peds Plus TM/F bottles have not effectively neutralised antibiotics in the HV, possibly due to insufficient contact time. Further validation will be carried out to determine the correct time required for neutralisation.

On successful neutralisation of the HV, the HV will then be spiked with bacteria and will be distributed as a specimen in a pilot study scheduled for November 2023.

The pilot study is firstly performed to determine the protocol is suitable and results are reproducible in tissue banks. Following successful delivery of the pilot, the scheme will then be launched.

Reference

Jashari R. Transplantation of cryopreserved human heart valves in Europe: 30 years of banking in Brussels and future perspectives. *Cell Tissue Bank*. 2021 Dec;22(4):519-537. doi: 10.1007/s10561-021-09902-2. Epub 2021 Feb 2. PMID: 33532987; PMCID: PMC7853167.
Zahra, S., Galea, G., Jashari, R. et al. Significant variation in heart valve banking practice. *Eur J Clin Microbiol Infect Dis* **38**, 1491–1498 (2019). <https://doi.org/10.1007/s10096-019-03577-0>
Zahra, Sharon et al. "Validation of microbiological testing in cardiovascular tissue establishments: results of a second international quality-round trial." *European Journal of Clinical Microbiology & Infectious Diseases* **38** (2019): 1481 - 1490.

Acknowledgements

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