BacT/ALERT

Simple changes, positive outcomes

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Introduction

The Scottish National Blood Transfusion Service (SNBTS) collects processes and supplies blood components to hospitals all around Scotland. SNBTS ensures that the transfusion needs of patients in Scotland are met, by providing safe, high quality blood components.

BacT/ALERT 3D is used to screen platelets for bacterial contamination. All BacT/Alert tests remain active in the system throughout the component shelf life and any positive BacT/ALERT (figure 2) is further investigated. When a BacT/ALERT bottle flags as positive the bottle is sub cultured onto blood agar plates and incubated for a further 7 days. Processing initiate a recall to return all available components associated with a positive for further testing. On return these are set up on BacT/ALERT 3D to identify the bacterium and source of the potential contamination. A false positive is an initial screen positive that does not grow any bacteria when sub-cultured onto plates.

SNBTS have experienced a higher false positivity rate than other services. In 2018 up to December we had 62 false positives. The repercussions of this is increased workload, increase in staff time dedicated to dealing with false positives (laboratory, Quality and medical staff) repeat and follow up testing, increase in consumables use. This also impacts on patients who may have received components from false positive donations. See Figure 3 for Positive BacT/ALERT workflow.

Our historic loading strategy was to load both aerobic and anaerobic bottles randomly within all available drawers and incubators, which can lead to drawers being opened several times throughout a day. This will lower the incubation temperature multiple times in a day. The new loading pattern suggested from the BacT/ALERT users group was to fill one drawer to its full capacity and not open again for 48 hours to maintain a consistent temperature inside the drawer.

Donation testing implemented the new loading pattern December 2018 and has been monitoring all results which are presented here.

Figure 1 – BacT/ALERT 3D system.

Method

A review of testing totals was carried out to determine if the new capacity could be accommodated within the existing equipment with no impact on business as usual. This was used to formulate the proposed new loading pattern.

A total of 30 tests (2 bottles per test, one aerobic and one anaerobic) would be loaded into 1 drawer (figure 1) from the batch of platelets sent for testing. If the batch of tests exceeded 30 then another drawer would be used to accommodate the extra tests. Once a drawer had been used, no matter the number of bottles loaded into it, the dedicated drawer would not be opened for 48 hours.

Due to the need for extended testing periods for recalls and query transfusion reactions an incubator drawer would be allocated specifically for those tests; Drawer 3D and 6D in system 1 and 2 respectfully.

Due to the 6 day incubation period and the reduced number of platelets to test on Monday's and Tuesday's, the number of incubator drawers available to use from both systems is enough to adopt the new loading pattern.

With each batch of tests a growth control is used. To incorporate the new loading pattern the growth control must be loaded into a separate drawer as it gets unloaded the following day, thus avoiding opening a drawer within the 48 hour time frame. As the growth control bottles are unloaded in the morning this will free up another drawer for routine use. If in doubt the drawer set aside for longer incubation periods may be used without any detrimental impact.

Results

The number of Apheresis and pooled platelets tested on BacT/ALERT per month, along with the number of 'False Positives' were recorded and compared for the three months prior to the new loading pattern starting, Figure 4.

Month	No. Aph Plts	No. False Positives	%	No. Plt Pools	No. False Positives	%
Sept	596	3	0.50%	802	6	0.75%
Oct	560	3	0.54%	985	12	1.22%
Nov	568	3	0.53%	956	3	0.31%

Figure 4 – Data three months prior to new loading pattern.

The new loading pattern was initiated on the 1st of December 2018, however as the system was in a transition phase between old and new loading and staff were becoming familiar with the new loading pattern, this month's data is not used as part of the initial comparison.

The number of both Apheresis and pooled platelets tested are similar for both the three months pre and post new loading, however there is a significant reduction in the number of 'false positives' from both components. Figure 5.

Month	No. Aph Plts	No. False Positives	%	No. Plt Pools	No. False Positives	%
Jan	566	0	0.00%	908	0	0.00%
Feb	484	1*	0.21%	866	0	0.00%
March	601	0	0.00%	869	0	0.00%

Figure 5 – Data three months post loading
* Part of media QA Validation

The false positive in February 2019 was as a result of a media qualification which involves testing known bacteria, and suitably spiked BacT/ALERT bottles are loaded throughout the system. The loading of media QA validations will be reviewed and amended to prevent the occurrence of machine generated 'false positives'.

Figure 2 – showing BacT/ALERT positive bottle

Conclusion

Based on the data it has been concluded that the change in loading strategy has had a significant impact on the false positivity rate.

Further to the conclusion the question was raised if the change had any impact on the underlying genuine confirmed positivity rate. Figure 6 illustrates 2017, 2018 baseline data for comparison with post change. No detrimental impact on detection of true positives has occurred.

The consequences of false positives are:

- Increased cost associated with unnecessary repeat and follow-up testing.
- Staff time required to perform this testing and recall
- Reduced impact on patients who may have received components from false positives.

Going forward the implementation of the new loading pattern will significantly reduce false positives and all associated consequences.

	Apheresis Platelets				
Period	Total Aph tested	Initial Pos (%)	False Pos (%)	Ind Pos (%)	Conf Pos (%)
2017	9463	59 (0.62)	32 (0.34)	25 (0.26)	2 (0.02)
2018*	7786	51 (0.66)	39 (0.50)	9 (0.12)	3 (0.04)
Dec	598	1 (0.17)	0 (0)	1 (0.17)	0 (0)
Jan	566	1 (0.18)	0 (0)	1 (0.18)	0 (0)
Feb	484	2 (0.41)	1 (0.21)	1 (0.21)	0 (0)

	Platelet Pools				
Period	Total pools tested	Initial Pos (%)	False Pos (%)	Ind Pos (%)	Conf Pos (%)
2017	4555	32 (0.70)	18 (0.40)	8 (0.18)	6 (0.13)
2018*	6851	42 (0.61)	23 (0.34)	14 (0.20)	5 (0.07)
Dec	965	2 (0.21)	0 (0)	2 (0.21)	0 (0)
Jan	908	3 (0.33)	0 (0)	1 (0.11)	2 (0.22)
Feb	866	3 (0.35)	0 (0)	3 (0.35)	0 (0)

Figure 6 – Baseline data for comparison.
* Dec 2018 data removed from annual total and presented separately.

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Figure 3 – Process of dealing with BacT/ALERT positive.