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Audit 9642: DNA IQ Method of Extracting DNA from Casework and Reference Samples Audit

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1. Abstract

A follow-up internal audit was performed on the DNA IQ method for extracting DNA from Casework and Reference Samples. The purpose of this audit was to maintain the continuous high quality standards within the DNA Analysis laboratory.

2. Aim

To determine if the DNA IQ extraction process is fit for purpose as well as to ensure that the recommendations from Audit 8227 have been implemented.

3. Background

Through the laboratory quality system (OQI process) a number of adverse quality events were identified on the MultiPROBE® II platforms. Three OQI's (19349, 19477, and 19768) had previously been raised to address contamination events, which were investigated in Audit 8227. This is a follow-up audit to ensure quality measures that were suggested have been implemented successfully. Audit findings and recommendations are outlined in this report.

4. Findings and Observations

Observations from the Off-Deck lysis process are outlined below:

- Table 2 – Table of Reagent Volumes, on Page 5 of the SOP (24897 Automated DNA IQ™ Method of Extracting DNA) is unclear. The table lists reagent volumes all in mL, most of the reagent volumes required are less than 1mL. The addition of a formula to determine reagent volumes would assist in the event of non-standard batch sizes.
- The Auslab OFF-Deck Lysis worksheet has 20% Sarcosyl, this should be 40%. As a result the operator is required to amend the volume on the worksheet.
- The process of transferring the substrate to the spin basket is not defined. Operators can do this in 2 different ways.
- The preparation of the plate map using the BSD program for the validation configuration of batches i.e. Soccerball, is not mentioned in the SOP at all.
- Staff were using a draft copy of the SOP

Observations from the MultiPROBE II element of the automated extraction process are outlined below:

- In the new deck arrangement, the reagents are placed at the back of the deck. This was identified as a possible Workplace Health and Safety concern as the operators are required to lean over the entire platform in order to place the reagents in the reservoirs.
- It was observed that whilst filling the reservoir, some lysis buffer was spilt onto the shaking platform.
- There were bubbles present on the meniscus of the resin after addition to the reservoir; the operator was required to pipette mix to reduce the bubbles.
- The Schott bottle containing Lysis Buffer + DTT was not labelled.
- Section 4.4 DNA IQ Resin, Point 3 was not performed at this stage, as the tube was inverted just prior to transferring reagent into container on platform.
- The second operator performed a platform check before commencing run to ensure everything is in the appropriate position.
- The cabinet doors are not ergonomically designed. This is a Workplace Health and Safety concern as they are difficult to open, and they must be removed monthly to enable environmental cleaning. It is also difficult to manoeuvre the uncapped nunc tubes to a new position on the deck after uncapping due to the cabinet doors.
- The manual de-capping process is inefficient, time consuming and has the potential to be a possible source of contamination. The operator is required to use their finger to remove the cap off from the end of the de-capper. Some operators are uncomfortable with this manual de-capping process. De-capping manually can also be difficult due to the position of the cabinet. The de-capper can only be placed in the corner of the cabinet, making it difficult for operators to utilise.
- In the SOP, a specific de-capping order is mentioned; however it was observed that not all operators perform the task in this order.
- Some operators are concerned with the shaking of the slicprep plate on the magnet. It has been observed by some operators to dislodge occasionally.
- The sequence checking of the first and last nunc tube samples of both sets of tubes to the batch paperwork is not included in the SOP.
- The reservoir ‘F/W G13’, where the fixed tips are rinsed with nanopure water is only cleaned monthly during environmental cleaning. There is a potential for a contamination event to occur.
- Bubbles/droplets were observed on the outer surface of the disposable tips. This was observed on both 1mL and 125uL tips, after dispensing both the resin and the lysis buffer.
- It was sometimes difficult to follow the SOP as some steps are only outlined in the prompts on the computer program running the MultiPROBE II. These prompts are only mentioned in the SOP as ‘Follow the directions as

outlined in the user prompt', and the specific step details are not mentioned at all.

- During the transfer of lysates to the slicprep, some of the tubes are temporarily lifted from their position. No tubes were completely removed from their position.
- The seal on the slicprep plate was not completely sealed on one corner after sealing with the heatsealer.
- It was observed that during the wash stage, a 1mL tip flicked out of the tip chute after being discarded by the fixed tip. One operator has witnessed this occurring 2 times out of 4 runs.
- A 125uL tip could not be removed automatically from the fixed tip on 2 occasions. The operator was required to remove them manually.
- There is currently a check at the end of the extraction process to ensure there is no lysate left in the original nunc tubes. This step may be more useful if performed before the extraction process.
- A new magnet is now being used. The plate now sits on the magnet with no operator intervention.
- It was observed that the de-capper on Platform A has begun to rust.
- The shaker component needs to be removed from the deck every Friday in order to perform weekly maintenance on the Monday. This could be a Workplace Health and Safety concern as the shaker is heavy and is difficult to manoeuvre with the current cabinet doors.

5. Summary

Overall, the recommendations of Audit 8227, Process Audit of the Automated DNA IQ™ System (including Off-Deck Lysis) have been addressed. Some sections are still to be addressed and have been included in this audit's recommendations. Further improvements were identified during this audit and have been outlined below.

6. Recommendations

There have been several places identified where improvements can be made. These are outlined below:

1. The addition of a formula to determine reagents amounts in Section 4 of the SOP.
2. In Table 2 in the SOP, change the reagent volumes to appropriate measurements. Currently all volumes are listed in mL, but for most of the reagents uL would be more appropriate.
3. Update the Auslab Off-Deck Lysis worksheet to state 40% Sarcosyl instead of 20%.

4. The addition of the specific methods for transferring the substrate to the spin basket to the SOP.
5. Addition of the method for the preparation of the BSD plate map for the validation configuration of batches i.e. Soccerball to the SOP.
6. Consider acquiring an automatic de-capping machine. The manual de-capping method is inefficient, difficult in the current cabinet and has the potential to cause contamination events.
7. Investigate ergonomically designed cabinet doors for the MultiPROBE II platforms. The current cabinet doors are a Workplace Health and Safety concern.
8. The SOP requires the addition of the tube to batch paperwork sequence checking step.
9. Implement weekly cleaning of the F/W G13 reservoir.
10. Investigate the bubbles/droplets on the outer surface of the disposable tips.
11. Elaborate on the prompts in the SOP. This will make the SOP easier to follow for operators.
12. Investigate an alternative tip chute to prevent tips flicking out after being discarded from the fixed tips.
13. Investigate a more appropriate way to perform the weekly maintenance rather then to remove the shaker component every week.

7. OQI's that will be raised from this audit:

1. OQI 23911: The cabinet doors are non ergonomical and are not fit for purpose. They are heavy, difficult to move and inefficient, and are a Workplace Health and Safety concern.
2. OQI 23912: The manual de-capping tool is non ergonomical and is a potential source for contamination.
3. OQI 23913: The used disposable tips flick out of the tip chute on Platform A when being discarded.

8. Acknowledgements

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