

Report for QIS Audit as of 17/08/2022 8:45:48 AM

Report for QIS Audit -

9642 DNA IQ follow up audit

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Audit Details

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| Date Audit Performed | 24/08/2009 |
| Audit Type | OQI Follow up |
| Audit Status | Closed |
| Audit Subject | Review the changes made to the DNA IQ process for improvements in quality of results |
| Audit Objective | Check that the changes made to the DNA IQ program sufficiently improve the quality and reliability of results. |
| Audit Scope | The new DNA IQ program v6.3 run on Extraction MultitPROBEs A and B, using reference samples in checkerboard patterns |
| Audit Criteria | Nil contamination, SOP compliance |

Audit Outcome

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| Audit Findings | <p>1. Abstract</p> <p>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.</p> <p>2. Aim</p> <p>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.</p> <p>3. Background</p> <p>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</p> |
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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 IQTM 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 than 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

The auditors would like to thank all DNA Analysis staff involved in the audit for their time, assistance and cooperation.

Contact Comments

1. The addition of a formula to determine reagents amounts in Section 4 of the SOP.
This point will be addressed in the next revision of the SOP 24897, it has been added as a comment and communicated to the appropriate staff and will be included as an appendix in the future.

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 μ L would be more appropriate.
This point will be addressed in the next revision of the SOP 24897; it has been added as a comment and communicated to the appropriate staff.
3. Update the AUSLAB Off-Deck Lysis worksheet to state 40% Sarcosyl instead of 20%.
A change request will be submitted to LISS for amendment of this mistake.
4. The addition of the specific methods for transferring the substrate to the spin basket to the SOP.
This was discussed at length previously amongst the Analytical team and a decision was made to include both methods; as each was valid and an operator was free to choose a method that they would most prefer using.
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.
This point will be addressed in the next revision of the SOP 24897; it has been added as a comment and communicated to the appropriate staff.
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.
Whilst the current manual de-capping of Nunc tubes is inefficient the procedure has been redesigned to minimise the potential for cross contamination. Given the success and increase in efficiency of de-capping with the Pre-PCR automated de-capper; additional de-cappers are a priority but current budget constraints prohibit DNA Analysis purchasing additional units at this time. As noted in the following response, purchase and implementation of improved cabinets has been delayed due to budgeting issues as well
7. Investigate ergonomically designed cabinet doors for the MultiPROBE II platforms. The current cabinet doors are a Workplace Health and Safety concern.
New cabinets have already been applied for and are expected to be delivered during the move to block 3. The Perspex doors slide along a metal channel, to make sliding of the doors easier for the time being – soap will be used on the metal channels. Improved cabinets have not been sourced prior to this date due to budget restrictions.
8. The SOP requires the addition of the tube to batch paperwork sequence checking step.
This point will be addressed in the next revision of the SOP 24897; it has been added as a comment and communicated to the appropriate staff.
9. Implement weekly cleaning of the Flush Wash G13 reservoir.
This will be discussed at an Analytical meeting to determine if cleaning or renewing of the reservoir is necessary.
10. Investigate the bubbles/droplets on the outer surface of the disposable tips.
This has been investigated as part of the DNA IQ re-implementation project. The surface of the conductive tips attracts small droplets/bubbles of the lysis buffer through static attraction. There is a low risk that these small droplets/bubbles will separate from the end of the tip. The step where the droplets/bubbles remain adhering to the conductive tips is a post dispense step in the store plate. The store

plate is discarded after the extraction and there are no consumables between the plate and the tip chute where the tips are discarded. The instrument does not pass over any labware that may be contaminated by the adhering bubbles/droplets.

The droplets observed adhering to the fixed tips after the addition of resin to the lysate plate is of minimal risk. The tips dispense well above sample and do not contact sample. The droplets are clean reagent adhering to the tip. There is minimal risk of contamination occurring as a result of adhering reagent to the tips.

11. Elaborate on the prompts in the SOP. This will make the SOP easier to follow for operators.
This will be discussed at an Analytical meeting to determine which prompts require elaboration. It has been added as a comment in QIS for revision in the next version of the document.

12. Investigate an alternative tip chute to prevent tips flicking out after being discarded from the fixed tips.
Alternative tip chutes are currently being investigated with a view to purchase of a plastic based chute that could be easily decontaminated without corrosion. The tips observed flicking out of the tip chute on extraction platform A were as a result of incorrect tip chute dispensing position calibration. This has been addressed and no further tips have flicked out of the tip chute. This issue was previously addressed on extraction platform B and no tips have been observed flicking out of the tip chute.

13. Investigate a more appropriate way to perform the weekly maintenance rather than to remove the shaker component every week. The shaker must be removed from the deck during the weekly maintenance as the eight tip arm and gripper would crash into it during the random arm movement test. Quotes have been requested from the manufacturer (PerkinElmer) for an expansion deck and new shakers that would be smaller in size and easier to move. Once the quotes have been assessed against the current budget a decision to replace the DPC shaker will be made. Appointments/intervention by appropriate staff for the removal of the DPC shaker will be sent to ensure that staff who cannot remove the DPC shaker easily will not have to.

Associations

| | |
|--------------------------------|---|
| Module | Document |
| QIS Record | Automated DNA IQ Method of Extracting DNA from Reference and Casework samples |
| QIS Record Number | 24897 |
| Status | Superseded |
| Association Description | Samples |
| Associated Version | 5.0DNA IQ Method of Extracting DNA from Casework and Reference |
| Current Version | |

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| Module | OQI |
| QIS Record | From Audit 9642: Tip chute on Platform A |
| QIS Record Number | 23913 |
| Status | Closed Approved |
| Association Description | discarded. |
| Associated Version | The used disposable tips flick out of the tip chute on Platform A when being |
| Current Version | |

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| Module | OQI |
| QIS Record | From Audit 9642: The manual de-capping tool |
| QIS Record Number | 23912 |
| Status | Closed Approved |
| Association Description | The manual de-capping tool is non ergonomic and is a |
| Associated Version | |
| Current Version | |

potential source for contamination.

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| Module | OQI | | |
| QIS Record | From Audit 9642: The cabinet doors are not fit for purpose | | |
| QIS Record Number | 23911 | Associated Version | The cabinet doors are non ergonomic and are not fit for purpose. They are heavy, difficult to move and inefficient, and are a Workplace Health and Safety concern. |
| Status | Closed Approved | Current Version | |
| Association Description | | | |
| Module | Audit | | |
| QIS Record | DNA Extraction Process (DNA IQ) | | |
| QIS Record Number | 8227 | Associated Version | Process Audit of the Automated DNA IQ System (including Off-Deck Lysis) |
| Status | Closed | Current Version | |
| Association Description | | | |

Records

No Records found

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