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Report for QIS OQI as of 28/06/2022 11:02:57 AM

Report for QIS OQI -

20368 No Title Provided

OQI Details

Status Subject

Status | Closed Approved

AUDIT 8227: Enhancement of the MP II extraction platforms, including environment.

Points to be addressed from Audit 8227: 4.16-4.18, 4.23-4.27. Refer to hard copy Audit 8227 report (Cheng. Clausen & Muharam. 2008) in Quality Management DNA Analysis for full details.

- 4.16. The automated DNA IQ? protocols must be reviewed and further optimised to increase liquid handling performance (e.g. incorporate the use of different syringe sizes and tip types) with the assistance of a qualified PerkinElmer specialist (e.g. see points 2.4.13.7, 2.4.13.9, and resin transfer in points 2.5.9, 2.5.16). The optimised protocol should be tested and verified prior to routine use, as per current practice.
- 4.17. Further to 4.16, the applicability of a different magnet in order to minimise the need to manually secure the plate to the magnet should be investigated. Alternatively, a 96-deep well plate that is not prone to heat warping should be sourced.
- 4.18. The option for using pierceable film or septa on plates during the automated DNA IQ? protocol should be investigated (see point 2.4.13.14).
- 4.23. A process to change syringes more frequently at regular intervals should be implemented. Because of this, the process to calibrate or check new syringes will be time consuming and therefore alternative calibration or pipetting verification systems should be sourced (e.g. Artel MVS).
- 4.24. The BSD Duet 600 instrument can be moved to a different location in order to decrease human traffic and increase the amount of working space available around the MP II extraction platforms. A portable biohazard hood can be introduced into Room 6125 to enable some sample processing outside of the MP II hoods (e.g. manual addition of DNA IQ? resin).
- 4.25. Investigate the use of a tip catcher that is made of a material not prone to rusting (e.g. plastic).
- 4.26. The procedure for washing and drying the MPII tip chutes must be reviewed (see point 2.4.13.18). Designate a rack position or location for drying of the tip chute and tip catcher, separate from the rack used for reagent troughs. Furthermore, a spare tip chute can be made available for each MPII, therefore used tip chutes can be allowed to decontaminate in a Decon bucket to fully decontaminate the tip chute, without compromising throughput of the MPII.
- 4.27. The cleaning regime of the MPII, including surroundings and enclosure (e.g. top of MPII hood), must be reinforced.

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Source of OQI Audit
Date Identified 11/08/2008

OQI Creator Contact Details

Organisational Unit/s
Service/s
Amy CHENG
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Site Location/s | Coopers Plains

Investigator/ Actioner Contact Details

Actioner Allan MCNEVIN
Organisational Unit/s Analytical
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Investigation Details

Investigation Completed
Investigation Details

Root Cause Type | Procedure/Method/Process 20/08/2008 Audit finding 4.16. Use of the automated DNA IQ extraction procedure has been temporarily placed on hold and a return to the routine use of Chelex for DNA extractions has been put into place whilst improvements are made to the automated DNA IQ procedure. The automated DNA IQ extraction procedure has subsequently been reviewed by a PE specialist and a number of changes to the protocol were made, namely: - Changes to pipetting speeds, transport air gaps. aspirate & dispense heights, System air gaps - Mixing / washing steps - Resin addition Some preliminary testing of the improved protocol has shown no evidence of pipetting problems (e.g. droplet formation). Additional changes have been made to remove pipette mixing and mixing with the integrated DPC shaker and replace with off-deck mixing using an eppendorf mixmate. Preliminary testing using this last change has also shown a significant improvement in DNA recovery. The improved protocol will undergo extensive verification including (but not limited to) various cross-contamination checks using both concentrated commercial DNA and mocked samples. Additionally, as a precautionary measure, re-introduction of automated DNA IQ extractions will be done in a stepwise manner involving the processing of reference samples initially until satisfaction as to the quality of the procedure can be reached. All verification findings (including the detailing of what improvements have been made) will be recorded in the prescribed manner. Audit finding 4.17. Several alternate magnets have been trialled previously (e.g. Promega Magnabot magnets) and recently an Ambion magnet was trialled with positive results. This magnet will be incorporated into improvements to be tested as part of changes made noted above. Audit finding 4.18. Peirceable septa mats & pierceable films are not viable options for use during processing of the automated process. Peirceable septa mats are prone to becoming stuck to disposable tips, especially larger size tips (e.g. 175?L) and especially in the wells adjacent to the edges of the 96-well plate. Pierceable films are not preferable as liquid can be left on the edge of the hole produced from piercing after tip retraction and flicking of liquid can then occur during subsequent pipetting steps. Information sourced from other laboratories is that plates are not covered during an automated extraction protocol. However, the use of a septa mat during the off-deck mixing step is being considered and will be tested as part of the verification procedure noted above. Additionally septa mats will be used (and tested) to replace the use of adhesive plate seals for the storage of lysates prior to automated extraction. Audit finding 4.23. A business case for the purchase of an ARTEL MVS had previously been

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> submitted and rejected. This will be re-visited with a view to performing more regular performance checking. This will also allow for throughput efficiencies to be maintained if more regular syringe replacement occurs. Additionally, 1mL syringes have been used to replace the 500uL syringes. Due to the reduced number of draws (up and down pumps of the syringes) with 1mL syringes, this will extend syringe life-cycles. 1mL syringes will be used throughout the verification undertaken as outlined above.

Preformed By | Quality Information System

Action Details

Action Complete Title

Action Fix Type | Resources Audit finding 4.24. 26/09/2008 Action Description Current laboratory space limits the possibilities of moving of the BSD duet,

however one option not yet investigated (but not likely to be possible) is moving of the BSD duet to room 6122. This will be investigated in conjunction with the Operational Supervisor and the Managing Scientist. Addition of resin to the deep-well plate has been incorporated into and will be included in the verification of the improved protocol (as noted above) negating the problems associated with having the operator add the resin. Audit finding 4.25. An alternate plastic tip-catcher is currently being sourced. Audit findings 4.26 & 4.27. Cleaning regimes and procedures have been discussed in the Analytical team meeting. This included appropriate cleaning of the tip chutes etc. It was felt that if cleaning was sufficient, the placement of reagent troughs and tip chutes adjacent to each other is not a contamination risk, therefore emphasis on correct cleaning procedures was the most important aspect. The top of the MPII hood has not been cleaned previously (routine cleaning of the top of the biohazard cabinets is also not carried out), however a suitable cleaning tool to access this area is being sourced.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status Follow-up Status Comment

Accepted

8/12/2008 2:48:48 PM Amy CHENG:

Points in this OQI will be reviewed in an audit within 8 weeks after reimplementation of DNA IQ (date to be decided), followed by another audit 6 months later. These points are: 4.16, 4.23, 4.24, 4.25, 4.26, 4.27.

Approver Approval/ Rejection Date Approval/ Rejection Comment

11/12/2008

11/12/2008 12:00:00 AM Paula TAYLOR:

No comment was recorded

Associations

Module Audit QIS Record | DNA Extraction Process (DNA IQ)

QIS Record Number | 8227 Associated Version

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Status Closed Current Version Migrated Data from QIS
Association Description

Records

No Records found

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