Report for QIS OQI as of 28/06/2022 11:02:26 AM

Report for QIS OQI -

20367 No Title Provided

OQI Details

Status	Closed Approved
Subject	AUDIT 8227: Automated DNA IQ? process, including documentation. Points to be addressed from Audit 8227: 4.10 ? 4.15, 4.19 ? 4.22. Refer to hard copy Audit 8227 report (Cheng, Clausen & Muharam, 2008) in Quality Management DNA Analysis for full details. 4.10. In-tube sample submissions to the Analytical Section must contain the appropriate amount/length of sample in the first instance, in order to eliminate the need for reprocessing and reduce the risk of contamination. 4.11. If proceeding with a checkerboard format for DNA extractions, the method for preparing the water blanks must be reviewed and standardised (see point 2.2.3). 4.12. Standardisation of the method for transferring substrates to spin baskets should be considered (see 2.2.6). 4.13. Investigate the isolation of all DNA IQ? reagents and off-deck lysis protocols in one working area. The authors are aware, however, that the current physical design of the DNA Suite may not allow this. 4.14. Investigate the advantages of separating the DNA IQ? SOP (QIS 24897) into two separate documents, e.g. off-deck lysis (including STORstar) and automated DNA IQ?, and implement as appropriate. The SOP needs to be updated to reflect changes and correct minor errors (e.g. see points 2.4.7, 2.4.13.2, 2.4.13.13). 4.15. Finalise configuration of the appropriate AUSLAB worksheets for use throughout the DNA IQ? method, so that operators are using the correct worksheets and are able to record all of the necessary batch details in designated fields. 4.19. A procedural checklist should be considered for each protocol so that individual operators can keep track of each specific step as they are performed. This checklist can be added as an appendix to SOP?s in QIS that can be printed out by operators prior to performing the procedure. Alternatively, the checklist can be configured in AUSLAB and printed out together with the batch worksheet. 4.20. Checking of calculation results for reagent volumes by a different operator should be introduced, as should the dispensing of reagents into the correct troughs. 4.21. The use of ?working? containers and aliquots should be enforced where appropriate so that the possible contamination of stock solutions is minimised. 4.22. Appropriate calibrated volumetric devices should be sourced to measure the volume of critical reagents such as TNE buffer.
Source of OQI	Audit

Date Identified	11/08/2008

OQI Creator Contact Details

Creator	Amy CHENG
Organisational Unit/s	Analytical
Service/s	
Site Location/s	Coopers Plains

Investigator/Actioner Contact Details

Actioner	Allan MCNEVIN
Organisational Unit/s	Analytical
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Site Location/s	Coopers Plains

Investigation Details

Investigation Completed 21/08/2008 **Root Cause Type** Procedure/Method/Process

Investigation Details

Audit finding 4.10. The submission of appropriate samples to the Analytical section for DNA extraction is an ongoing issue due to changes to internal and external procedures that is routinely managed by feedback between the Analytical and Evidence Recovery senior scientists. Audit finding 4.11. This troubleshooting measure was implemented at the same time as the audit was conducted, and as such no standard procedure had been put into place. Verbal instructions to team members had been to use a specific procedure, however as it had not been previously performed it had to be assessed and amended as necessary at the moment of use. It will not be a permanent fixture to processes, however were it to be required to become so a defined process would be included into appropriate SOP?s. Audit finding 4.12. For the DNA IQ off-deck lysis procedure, the use of Forceps to move substrates to spin baskets is intended to be the standard protocol. Forceps to be sterilised between samples by immersion in 10% Bleach, followed by 70% ethanol followed by flaming in Bunsen. It must be noted that the method for using ?twirling? sticks used by some operators is in routine use for Chelex extractions and has not been considered previously to be a quality issue. Forceps have been found by the Analytical team to be not suitable due the larger amount of liquid contained within the reaction tube. Audit finding 4.13. Moving of fridges and freezers will be considered, however as noted, current lab design does limit the options available and this was considered when current processes were implemented. The current laboratory limitations have been noted and will be considered by the laboratory redesign project team. Audit finding 4.14. Splitting of the SOP had been previously discussed amongst the Analytical team and rejected. Although it is agreed that the SOP is somewhat large, the processes are interdependent and follow-on one from the other and there would be a requirement to cross-reference the SOP's. Additionally as the procedures overlap, if the SOP is split there is an increased risk of one SOP being updated and related portions being missed whilst updating the other SOP causing confusion. As part of discussions, Analytical staff were reminded that relevant portions of a SOP can be printed and retained in specific work areas (and marked appropriately) without necessarily printing the whole SOP. Minor changes have been added as comments to QIS and will be included in the next revision of the SOP (awaiting full determination of procedural changes). Additionally the minor changes have been discussed in the Analytical team meeting. Audit finding 4.15. At the time of the audit, AUSLAB had been notified of the urgency of the outstanding job. Additionally, an appendix was included

	into the active SOP for printing as a worksheet for recording of reagents etc. as a work-around.
Preformed By	Quality Information System

Action Details

Action Complete	24/09/2008 **Action Fix Type** Changed ProcessAudit finding
Title	
Action Description	4.19. Procedural checklists have been previously discussed in the Analytical team meeting and it was felt by team members that these would not provide any additional benefit. For all procedures (not only those relating to DNA IQ), a return to the pre-batch functionality system of printing the method from the SOP and attaching it to every worksheet will be reconsidered. This would require some re-configuration of SOP? s to make them amenable to printing of procedural steps, but this is not an obstacle. Further discussion as to the best approach will be conducted within the analytical team. Audit finding 4.20. After discussion with Analytical team the suggestion to check calculations was rejected. The need for attention to detail for all areas of performance (including calculation of reagent volumes and aliquoting of reagents) has been emphasized. The only way to check if the correct reagent has been added to the correct trough is for a second operator to oversee the first operator actually performing the task and this is not practical. The calculations involved are relatively simple and as such emphasis on the need for care has been re-iterated. During many procedures performed in any laboratory each scientist performs critical tasks without constant supervision. This is a position requirement and staff are trained to, and are expected to be able to, operate without direct supervision. Additionally all of these elements (reagent calculations and setting up of the automated deck including reagent addition) is included as part of training, and a trainee has to be deemed competent in these skills to complete their training. Audit finding 4.21. The use of working containers and aliquots was re-emphasised during the Analytical team meeting 18/8/2008. This is standard practice throughout all procedures in the Analytical section. Audit finding 4.22. Whilst the use of volumetric measuring cylinders is best practice, no glassware is currently routinely calibrated within DNA Analysis. As the only volume measured without a pipette was 53mL and to this volume no more than 1.5mL is added with pipettes, the error in measurement from the clean plastic-ware used to measure 53mL was deemed to be acceptable. The method was validated using the procedure observed at the time of the audit. A bottle-top dispenser will be investigated as an alternative however.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	8/12/2008 2:45:53 PM Amy CHENG: Points in this OQI will be reviewed in an audit within 8 weeks after re-implementation of DNA IQ (date to be decided), followed by another audit 6 months later. These points are: 4.12, 4.15, 4.19, 4.21, 4.22. With regards to 4.22, the procedure will be to use a 50mL Combitip and Multipette Stream to measure the correct amount of buffer required.
Approver	

Approval/ Rejection Date	11/12/2008
Approval/ Rejection Comment	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**	Migrated Data from QIS version 1
Status	Closed	**Current Version**	
Association Description			

Records

No Records found

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