

Report for QIS OQI as of 7/12/2023 10:33:40 AM

Report for QIS OQI -

11401 No Title Provided

OQI Details

Status	Closed Approved
Subject	<p>I am concerned that we (Forensic Biology) are in breach of both NATA regulations and section 95A of the Evidence Act describing the conditions of the DNA evidentiary certificate.</p> <p>According to this legislation we are unable to write DNA certificates given that it has been 'proven' that Quantifiler is not accurate. Section 95A part 8 states "Any equipment used in testing the thing at the laboratory is to be taken to have given accurate results in the absence of evidence to the contrary." The repeated suspicions and concerns of staff directed to supervising scientists, dating back to Quantifilers implementation in April, regarding the accuracy of this quantitation process have finally been verified by the recent study presented in the staff meeting on 5 January 2005.</p> <p>Secondly, NATA requires that all equipment is validated for forensic sampling. There is no evidence that a validation was ever conducted for this equipment (or a cost-benefit assessment that the equipment would actually be suitable for our requirements). The Appendix of our Statutory Declaration states statements are prepared in accordance with the requirements of NATA. Clearly NATA guidelines in this instance have been breached when a critical instrument in the DNA analysis procedure has not been validated and further proven to be inaccurate. I question if we are breaching the Justices Act when we sign statements which declare all information in the forgoing pages are accurate to the best of the scientists knowledge.</p> <p>Furthermore, the consequences of this change in process without a pre-assessment and validation have lead to the dramatic increase in reworking samples and hence an overwhelmingly high financial cost, and an inefficiency in reporting results within reasonable turn around times.</p> <p>I suggest an independent auditor review DNA master, the DNA workbook, and other OQI's relating to inconsistent DNA profiles, all indicative of an ineffective system / equipment that significantly increases costs because of inadequacies in validations and scientific knowledge in managing the processes appropriately.</p>
Source of OQI	Internal Problems (QHPSS)
Date Identified	12/02/2005

OQI Creator Contact Details

Creator	[REDACTED]
Organisational Unit/s	DNA Analysis
Service/s	
Site Location/s	Coopers Plains

Investigator/Actioner Contact Details

Actioner	Vanessa IENTILE
Organisational Unit/s	DNA Analysis
Service/s	
Site Location/s	Coopers Plains

Investigation Details

Investigation Completed	28/02/2005	Root Cause Type	OtherQuantitation is used to estimate the amount of DNA in a sample. This is used to calculate an appropriate volume to obtain a DNA profile from Profiler Plus. Quantifiler was introduced to replace the Quantiblot system which was labour intensive, time consuming and did not identify degraded DNA or potential inhibitors. Quantifiler is a Real Time PCR system that allows identification of potential DNA inhibitors but is still an estimation of the amount of DNA. Quantifiler was installed in April 2004 and initial validation studies were performed. Updates on the installation, validation and implementation process were discussed at staff meetings and minuted between Feb & May 2004. Quantifiler was chosen over other RT PCR systems because of its internal positive control that allows identification of potential inhibitors. After implementation it was expected that the number of reworked samples would decrease. In March, April 2004, the 3100 was implemented for crime scene samples. This instrument is more sensitive than the previously used 377 and validation was completed to establish new reporting thresholds. A review of results indicated that the repeat rate had not decreased but it was uncertain whether this was as a result of the Quantifiler, the sensitivity of the 3100, the new reporting thresholds or other optimisation issues relating to TE buffer. A project was started to review these procedures and this process is ongoing. A project page was created detailing the testing and results for these projects as well as the changes implemented as a result. Part of the ongoing process reviews is to continue to monitor the repeat rates as an indication of the system function.
Investigation Details			
Performed By			Quality Information System

Action Details

Action Complete Title	16/05/2005	Action Fix Type	Report/Result
		Action Description	The ongoing process reviews and changes can be accessed via http://qhps.health.qld.gov.au/qhss/forensic-sciences/FSEP/forensic_biology_projects/dna-process/default.asp An audit of the validation and ongoing improvement processes will be scheduled to monitor these improvements. NATA Requirements - the quantifiler procedure is a validated protocol and no variations to the protocol were made when the process was introduced into the laboratory. The protocol was compared against the previous procedure using known samples and the data was reviewed to ensure that the performance was reproducible and comparable to the method it was replacing. The raw data was reviewed and the findings were discussed in team meetings. The raw data was available for other staff to review. Inaccuracy of results - The purpose of forensic biology is to obtain DNA profiles for comparative purposes. Quantitation is used to estimate the amount of DNA template required to optimise the PCR process. Each DNA profile is evaluated against acceptance criteria based on standard protocols and in house validation. Samples that do not meet the acceptance criteria are repeated. The quantitation result itself is not reported. Any quantitation method is an estimation of the amount of DNA present and the outcome of variations in the quantitation may

result in too much or too little DNA being added to the PCR process. Large variations would cause the DNA profiles to fail the acceptance criteria and these would not be reported. Evidence Act - an evidentiary certificate issued under the evidence act states that the reporting analyst has reviewed the results and can assure the court that the appropriate quality procedures were followed including other analysts following the SOPs/methods. The quantifier method used is the standard protocol and is documented in QIS. All analysts performing this method follow the SOP. As mentioned before there is no indication that the DNA profiles reported by the laboratory are inaccurate. All quality control samples have given expected results including external proficiency test samples. Full details of the external review into the validation and quantifier procedure are expected to be released and available to all staff in late June.

Task Details

No Tasks found

Follow-up And Approval

Follow-up Status	Accepted
Follow-up Status Comment	<p>4/07/2005 4:22:41 PM [REDACTED]:</p> <p>The follow-up has been performed by Sharyn Nilsen - Principal Quality Advisor as [REDACTED] is no longer an employee of QHPSS. The above investigation does not directly address whether NATA requirements or the Evidence Act have been breached. It does also not address the issue of inaccuracy of the results. All have been discussed at length and assurances have been given that none of these are an issue. However, I would appreciate more detail in the OQI record itself. SN 02-03-05 Actions and response appropriate SN 04-07-05</p>
Approver	Robyn KELLY
Approval/Rejection Date	28/08/2005
Approval/Rejection Comment	<p>28/08/2005 12:00:00 AM Robyn KELLY:</p> <p>28 August 2005 - As mentioned above an external review of the quantifier validation/implementation has been undertaken, and this review report and two subsequent independent reviews of the report have been published on QHSS intranet for all staff to review. The reports reconfirm that the system was validated consistent with NATA guidelines and that there is no evidence of any DNA profiles reported by the lab have been inaccurate. Staff have been invited to comment on the review findings to the Chief Scientists Biology, and the ongoing findings re quantifier and reworks are being discussed in team meetings, as well as being actioned through the FSBEP project breakthrough teams. It is worthy of note that several other states have now sought information from QLD on their validation and the application of quantifier in a routine laboratory, and SA,WA and NSW are all starting to use this routinely to replace quantiblot. Also of note is an article published in the July 2005 edition of J Forensic Sciences outlining successful validation of quantifier.</p>

Associations

No Associations found

Records

No Records found

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