AUDIT CHECKLIST

TYPE of AUDIT: PROCESS

AREA / ACTIVITY: DNA Analysis FSS
Automated DNA IQ Method of Extracting DNA from Reference and Casework Samples (QIS 24897 R3)

AUDIT NUMBER: 8227

AUDIT CONTACT: Allan McNEVIN	AUDITOR: Iman MUHARAM, Amy CHENG, Peter CLAUSEN	DATE:15/07/2008 – 18/07/2008	Page 1 of 7

Audit Objective	To identify steps in the protocol where potential for quality breakdowns are present, or where areas of improvement will benefit the protocol.
Audit Scope	Whole process (including off-deck lysis and STORstar).
Audit Criteria	

Consider the following headings: Inputs; Documents; Quality Control; Proficiency Testing; Equipment; Calibration; People; Safety; Environment; Records; Reports; Outputs; Performance Objectives.

Procedure Reference	Question/Requirement	Compliance	Observation	OQI #
	BACKGROUND: *Concerns have been raised in relation to OQI's 19477, 19768 and 19349 where initial investigations appear to indicate well-to-well cross contamination during automated extraction using the DNA IQ™ system. Investigations performed to date have not been able to identify the cause of the contamination.* ***RISK:*** *Well-to-well cross contamination events compromise sample integrity, therefore potentially causing loss in evidential value for affected samples.* *Representation of areas to be audited:* • *Off-Deck Lysis (with retained supernatant)* • *Off-Deck Lysis (without retained supernatant)* • *STORstar of lysates into ABgene plate* • *STORstar of Nunc tubes into rack* • *Automated DNA IQ (reference)* • *Automated DNA IQ (casework)* • *Training records 1x* • *Documentation (diaries, maintenance logs)* • *Calibration records (pipetting)* • *Service records (instruments)* ? monitoring records			

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	Equipment and environment: ▪ *Criticality to the process/result* ▪ *Space requirements* ▪ *Unique identification of equipment* ▪ *Validation* ▪ *Location of necessary manuals and/or instructions (are these controlled)* ▪ *Environment and cleanliness* ▪ *Calibration* ▪ *Maintenance* ▪ *Adequacy of special services (UPS, ventilation, air conditioning, access to sink, etc)* ▪ *Safety hazards*			

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	Evaluation of the Process: ▪ *Is the environment adequate for the process?* ▪ *What is the possibility of contamination of or by a sample?* ▪ *What are the safety hazards and adequacy of handling procedures?* ▪ *Are the acceptance criteria in the method adequate?* ▪ *How are changes to the process investigated, implemented and managed?* ▪ *How is the process reviewed and improved?* ▪ *How are problems identified?* ▪ *How are problems recorded?* ▪ *Is AUSLAB being used effectively?* ▪ *Is the OQI system being used effectively?* ▪ *What is not working well?* ▪ *What is the degree of client satisfaction with the current process?*		are they checked, when?	

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	Interaction with other areas: ▪ *What is the process for communicating problems?*			

SIGNATURE:_____