**UW Medicine - Pathology**

400-08-01-02

Correction of Laboratory Errors Procedure

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| Adopted Date: 08/1991Review Date: 09/2005Revision Date: 02/2013 |

PURPOSE

The purpose of this section is to outline procedures to detect and avoid errors and corrective actions to use when errors are detected.

PROCEDURE

### Detection of Laboratory Errors

* + - 1. The faculty member signing out the case reviews all aspects of the case, which includes the accuracy of the work documentation, the patient name and other identifiers and the accuracy of the diagnosis. This is recorded on the Daily feedback checklists (AKA SALMON)
			2. The office personnel review the computer-generated draft of the clinical report for spelling, grammatical, transposition of information and procedural errors before returning the (corrected if necessary) report to the faculty member for signature.

### Corrective Action

Any problem arising in the laboratory needs to be discussed among technologists, supervisor and faculty member signing out. Internal QA reports and “Salmon Sheets” are ***required*** to be used to track culturing and harvesting conditions, for help in troubleshooting, errors, or unexpected results. Documentation of errors or unexpected results should be included in the GCS database, if case related. Any corrective action (if case related) should be reviewed by the directors and recorded in the GCS database under “Comments-various.” If a problem is not case related, QC summary sheets are used for recording incidents and stored in the Media and Quality Control notebook. Errors are reviewed by supervisor and/or directors regularly via data extracts from GCS and QC summary sheet notebook

1. **Length of time for diagnosis:** Because good patient care requires timely and accurate results, technologists and other laboratory personnel can work when needed. Healthcare providers should be notified of delayed reports.
2. **Growth:** Cell proliferation should be monitored to see if the lack of growth is due to subjection of the specimen to unfavorable environment, e.g., long transportation time, extreme temperatures, syringe containing toxic chemicals, saline as transportation media, etc. Secondly, technologists should check the tissue culture system. For example:
	1. Is there any new component introduced to the system, e.g., new lot of serum, media, detergent, chemical reagents, plasticware, etc.? If true, cloning efficiency tests should be set up to compare the new lot with the old lot or a different lot.
	2. Check accuracy of incubators.
	3. Check for mycoplasma contamination
	4. If specimens show elevated breakage and/or random rearrangements, one should check:
		1. Has the patient been subjected to chemotherapy, radiation or diseases such as Ataxia telangiectasia, leukemia, etc.?
		2. Was the specimen handled correctly during shipping?
		3. Is a new lot of serum or medium being used?
		4. Is there any mycoplasma and/or virus contamination?
	5. Recording: Unexpected slow or no growth should be recorded in the GCS database in the comments field after each culture (in culture screen). For each case growth should be assessed qualitatively and given a selection under Growth in the GCS database (Good, Poor, Fail). Results of troubleshooting and corrective action should be recorded in the GCS database under “Comments: Various” for each case affected. The report "Poor Growth Report" is printed and reviewed by Lab Manager and/or Director monthly. Quality failures and QA information not related to individual cases are recorded on the QC Summary sheets provided on each side of the lab. The QC Summary Sheets are reviewed by Lab Mgr.and/or Director monthly.
3. **Quality of banding**
	1. G-banding: repeat procedure, changing trypsin time and concentration, preparing new trypsin or Wright's stain.
	2. Other bandings: Prepare new stain and pretreatment solution and repeat staining.
	3. Check hypotonic and fixative (harvest may need to be repeated). Check microscope, image analysis system and photography.
4. **FISH**--See FISH Validation procedure, SOP number 400-08-01-10.
5. **Molecular analysis**
	1. Failure to obtain a product in control lane: repeat with new primer dilution and reagents. Check temperature of PCR machine using radiant temperature gun or call Scientific Instruments.
	2. Contaminating bands: repeat reactions with new reagents. Increase annealing temperature. Keep area clean.
	3. Length of time for Y-primer PCR results should be no longer than 15 days.
6. **Recording of Errors:** If an error in the processing, analysis or diagnosis is detected by the faculty signing out, they will immediately consult with the technologist(s) who carried out the analysis to determine the cause of the error and, if necessary, take corrective action. Errors discovered by technologists should be brought to the supervisor’s attention for analysis and correction. If the laboratory is notified of an error by a provider (physician, other cytogenetic lab, etc.), a thorough reexamination of karyotypes and all information on the case is undertaken. An amended or addendum report may be issued (see #7 below).

Details of each error (with corrective action taken) must be recorded by either faculty and/or technologist in one of three areas: 1) On the QC summary sheets found on each side of the lab. These are reviewed by the supervisor monthly and compiled into the QC notebook. 2) Any case related error information is kept in the CGS database under the “Comments: Various” section of the case. A report is run quarterly for review and inclusion in the QA notebook. 3) A UWMC/PSN incident report (<https://psn.medical.washington.edu/default.aspx> ) should be submitted if the error could affect patient care or laboratory liability. Incident reports are reviewed annually.

1. **Amended and addendum reports:** Errors detected on final reports are corrected in the GCS system and a new, clearly marked amended report is issued. If additional analysis is done on a case, an addendum report will be issued. Possible causes of failure of cases are indicated on the final report (e.g., time in transit, etc.) A report of all the amended and addendum cases is run yearly from the CGS database for inclusion in the QC notebook (located outside of AA108E).
2. **Autoclave and sterility failures**: Upon notification of test failure, the autoclave is taken out of use by supervisory personnel. The cycle is checked for proper temperature and pressure settings, tested to record Temperature and Pressure during a new test cycle and adjustments made if needed. Operations and Maintenance (543-3010) is called if any problems are noted. Another test run is done and verified by test strips as passed before autoclave can be used again. All failures and corrective actions are recorded in QC summary sheet. Culture contamination is recorded in the comments section of the individual culture in the GCS database. (Table: CULTURE, Field: COMMENTS) see VI.CULTURE AND LABORATORY STERILITY/CONTAMINATION

Written By: Director Approval:

(Signature and Date) (Signature and Date)

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 Cytogenetics Supervisor