**UW Medicine - Pathology**

400-08-01-01

Laboratory Quality Management Procedure

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| Adopted Date: 08/1991Review Date: 09/2005Revision Date: 05/03/11 |

PURPOSE

The purpose of the quality management program is to maintain the laboratory mission by reducing errors and improving critical functions. The laboratory mission is to provide accurate cytogenetic diagnostic services to the Northwest region in a timely, convenient and cost-effective manner. Educational community teaching as well as limited research are secondary goals.

PROCEDURE

### Quality Management Program Design

The QM program targets two areas: 1) the maintenance of accuracy by the prevention or reduction of errors and 2) the improvement of usefulness, timeliness and cost-effectiveness of the diagnostic services provided.

Both accuracy and improvement of services are addressed by: 1) Defining and monitoring critical values and variables. 2) Quality Control program which includes proficiency testing, QC reporting and which is outlined by the sections of this Technologist and laboratory personnel training.

### Critical Values

* + - 1. **Priority of case workup:** STAT bone marrow and baby bloods, amniotic fluid and chorionic villi have the first priority. All clinical obligations have priority over teaching and research.
			2. **Length of time for diagnosis:** If time to case sign out is consistently over target (see Cytogenetic testing workup guidelines), sending cases out for analysis is recommended (Corrective Action).
			3. **Growth:** Growth is recorded for each case in the GCS Microscopy *Growth* field by selecting 1-4 from the drop down list. Slow or poor growth should be noted in the GCS database in the *comments* field after each culture. Whenever growth failure occurs in 3 or more specimens of the same type during a period of 2 weeks, a thorough evaluation and investigation of the tissue culture system should be done. A record of all growth failures or contamination of specimens, including corrective action is kept (see *corrective action*)
			4. **Cell counts and karyotyping:** See Guidelines in each section (PB, AF, ETC for exact requirements for each sample type.
			5. **Analysis:** At least two technologists must be involved in the analysis of each case. Karyotypes are carefully reviewed and discussed by several members of the laboratory, including the technologist who fills out the report. A second technologist always checks the karyotype hard copy and initials and circles his or her initials. The faculty member on call who signs out the case reviews the karyotypes and performs analysis in a daily sign-out session.
			6. A minimum band level is expected for each case: See below. The band level is monitored for each case and reported.

**Band Level: Minimums**

* + - * + Amniotic fluid 400-500
				+ Chorionic villi 400-500
				+ Blood 550-650
				+ Bone marrow / solid tumor 300-400
				+ Solid tissue 400-500

Bands are routinely counted using the Vancouver method. In addition, to determine whether there are 850 bands, we use guidelines per E. Magenis [University of Oregon, Portland, OR; see ISCN (2009)

Xp21: splits into 2 bands

22q: 5 G-bands are visible

9q: distal band q33 of 9 shows a gray area in between

1q: middle dark band q31 splits into 3 bands

* + - 1. **Random breakage and rearrangement:** The acceptable level of random breakage and rearrangement is 1 in 300 metaphases. For individual case, it is 2 in 100 metaphases. For amniotic fluid specimens cultured in Amnio-max medium, it is 7 in 100 metaphases. Pseudomosaicism occurs in 2-3% of amniotic fluid cases.
			2. **FISH:** See FISH Validation procedure, SOP number 400-08-01-10.
			3. **Record Retention:** See Specimen Retention Policy, 100-02-01-20

REFERENCES

1. ISCN (2005): *An International System for Human Cytogenetic Nomenclature*: Recommendations of the International Standing Committee on Human Cytogenetic Nomenclature, eds., Shaffer, L.G., Tommerup, N., S. Karger, Basel, Switzerland, 2005.
2. Magenis, E., and Barton, S.J. Delineation of human prometaphase paracentromeric regions using sequential GTG- and C-banding. *Cytogenet. Cell Genet.* 45:132-140, 1987.
3. Specimen Retention policy, 100-02-01-20

Written By: Director Approval:

(Signature and Date) (Signature and Date)

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 Cytogenetics Supervisor