**UW Medicine - Pathology**

(400-08-01-12)

Reagent Quality Control

|  |
| --- |
| Adopted Date: 1/2/2013  Review Date: 4/16/2013, 8/26/2013  Revision Date: 4/16/2013 |

PURPOSE

The purpose of this procedure is to ensure that new reagent lots are properly checked for the ability to support cell growth and produce metaphases suitable for chromosome analysis.

PROCEDURE

A. Material and Equipment

1. Bright field microscope
2. Inverted phase microscope
3. Cell counter
4. New lots of media
5. QC score sheet (1 per lot of media)
6. 3 Samples with enough additional material to have an additional QC culture

B. Procedure- Suspension Cultures (NE and PB)

1. Use a patient sample that has additional material left after routine cultures, set up patient sample as usual
   1. Set up parallel A culture using the new lot of media and label as A1
   2. Repeat this process for a total of 3 different cases
2. Harvest, make slides and stain as usual
3. Count number of metaphases/interphase up to 1000 interphase cells (more as needed). Use 100x objective to count cells
   1. Mitotic Index (MI) is expressed as the number of metaphases/interphase cells (objective criteria)
   2. Note quality of metaphases, spreading and banding (subjective but do so in comparison to the old lot of media)
   3. Record results on the QC score sheet and give to the supervisor for final sign off and filing
   4. If the new lot has met all standards, in comparison to the media lot in use, media can be put into use when needed, after the final sterility check

C. Procedure- In-Situ (AF, TR, ST, CV)

1. Set up 1 parallel flask/case on 3 different cases
   1. Label flask as “QC test B”
2. Compare growth rate of new lot verses lot in use by observing growth rates daily for up to 5 days, unless flask becomes confluent before 5 days
3. Note results on the QC score sheet, give to supervisor for final sign off
4. If new lot has met all standards in comparison to the old lot, the new lot can be put into use after sterility check

RELATED DOCUMENTS

QC Media form

AmnioMax QC form

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Written By: Director Approval:

**UW Medicine - Pathology**

**Cytogenetics - UWMC**

**SIGNATURE PAGE FOR POLICIES AND PROCEDURES**

Procedure / Policy Title: Reagent Quality Control

Procedure / Policy Number: 400-08-01-12

|  |  |  |
| --- | --- | --- |
| **STAFF NAME**: (printed) | **STAFF SIGNATURE** | **DATE REVIEWED** |
| Chen, Xiaoqin |  |  |
| Darrin, Delores |  |  |
| DeHoogh-Grigsby, Debi |  |  |
| Donovan, Chris |  |  |
| Kraus, Jean |  |  |
| Liu, Yuhua |  |  |
| McInnis, Donna |  |  |
| Mohapatra, Itu |  |  |
| Morgan, Catherine |  |  |
| Pilger, Carrie |  |  |
| Staley, Rong |  |  |
| Stampalia, Ann |  |  |
| Villiers, Catherine |  |  |
| Vogel, Jared |  |  |
| Wang, Sharon |  |  |
| Waychoff, Emma |  |  |
| Whalen, Sara |  |  |
| Zhou, Yang |  |  |