**UW Medicine - Pathology**

400-11-01-25

Microarray Lot Testing Quality Control

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| Adopted Date: 1/2/2013  Review Date: 4/17/2013  Revision Date: |

PURPOSE

The purpose of this procedure is to verify the quality of new array lots and reagent lots for chromosome microarray analysis.

PROCEDURE

A. Policies:

The lot numbers and in-use dates for the components of array testing are documented in the Microarray QC Tracking tables (Z:\LabShared\Cytogenetics CGH\Array CGH\Array lab QC\QCtracking.xls). Critical assay components (defined below) will undergo lot testing and QC verification prior to the reporting of results. It is sufficient to document and verify acceptable performance (by supervisor review) of non-critical assay components (RapidRun Loading Dye, DNA ladders, agarose gels, 5X TBE buffer).

B. Material and Equipment

1. Agilent SurePrint CGH/CGH+SNP 4x180K Bundle includes array slides and all reagents and consumables
   1. SureTag Complete DNA Labeling Kit
   2. Oligo aCGH/ChIP-Chip Hybridization Kit
   3. OligoCGH Wash Buffers 1 and 2
   4. Backings for 4 array per slide
   5. SurePrint G3 Cancer CGH+SNP Kit 4x180K
   6. SurePrint G3 GGX CGH+SNP Kit 4x180K
2. Nimblegen CGH 135K Bundle includes array slides and all reagents and consumables
   1. Dual-Color DNA Labeling Kit
   2. Hyb Sample Tracking Control Kit
   3. Hybridization Kit
   4. Wash Buffer Kit
   5. CGX-3 Array
3. New versions of Cytogenomics Software

C. Procedure

1. The lot-to-lot verification.
   1. For each new shipment of reagent bundle with new lots, a residual DNA sample of a patient sample will be chosen and tested as usual using new lot reagents. All the components used in the assay will be verified as passing QC if the array data have SD<0.2 and the copy number changes detected concordant with the previous test of this sample.
   2. If new lots or shipments do not pass the QC metrics, the lot/shipment is not approved for use, and repeated test will be performed. If a lot/shipment test fails again, the technologist will contact the vendor for lot/shipment replacement.
   3. The test results are recorded and documented. Each QC test and the quality will be approved by lab director.
2. Testing new versions of Cytogenomics Software:

For each version update of Cytogenomics, a technologist will upload the designated original data files as listed below and compare the CNV results between the prior and the new version of software for any differences. All disconcordant result will be noted and resolved.

1. Normal male
2. Normal female
3. Abnormal female
4. Abnormal male

Written By: Director Approval:

(Signature and Date) (Signature and Date)

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**SIGNATURE PAGE FOR POLICIES AND PROCEDURES**

Procedure / Policy Title: Microarray Lot Testing Quality Control

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