**UW Medicine - Pathology**

400-11-01-07

Reporting Array Results Procedure

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| Adopted Date: 10/12/09Review Date: 10/19/09Revision Date: 02/2010 |

PURPOSE

After microarray analysis and related studies such as FISH confirmation and G-banding confirmation are complete, ISCN diagnosis and a report can be generated using Genoglyphix software and loaded in Genetic Computer System (GCS) with the findings of the analysis and other relevant information.

PROCEDURE

### Equipment

* + - 1. Genoglyphix software from Signature Genomic Laboratories
			2. Genetic Computer System (GCS)

### Procedures

1. **Primary analysis:** The primary technologist's responsibility is to make sure that a case is analyzed completely and accurately in a timely fashion. After analyzing the oligo array data completely, go through the Array CGH Quality Assurance Checklist in the patient folder, initial and date all check marks under Primary Tech for the following list (see the procedure of Oligo Array Data Analysis using Genoglyphix Software for detail).
	1. Print PDF file for the plots and flagged regions, Karyogram, and Analysis Summary
	2. Initial "Case Reviewed" in Genoglyphix
	3. Label all pages by putting patient label on every piece of paper/stapled papers in the case folder.
	4. Note related studies. Check if any previous or concurrent cytogenetic studies have been performed under Login on the QA checklist
	5. Check all data analysis completed (including karyotype if concurrent)
	6. Give folder to second technologist if normal
	7. If abnormal, determine if G-banding or FISH confirmation is warranted. Do G-banding confirmation when the region of gain or loss is larger than 5 Mb. For smaller gain (> 300Kb) or loss using FISH confirmation. Order BAC FISH probe from Signature Genomic Laboratories and determine the locator FISH probe. For small suspected non-CNV gain and loss or any uncertainty, check with directors to determine if FISH or array confirmation is appropriate.
	8. If FISH test done, supporting FISH documentation must complete and accurate including a copy of packing slip from SGL BAC probe.
	9. Abnormal marked on folder as red **A**
	10. After related studies are done, click on the **Final Review & Report**, enter ISCN diagnosis for array result and FISH result, make sure all annotation for the gains and losses are complete and accurate, and click on save report.
	11. Open Genetic Computer System (GCS), load ISCN diagnosis for array result, FISH result, and/or G-banding result, and load correct report template.
	12. Print the GCS report
2. **Secondary analysis:** The second technologist reviews all work completed for any errors or interpretative differences for QA purpose.
	1. GGX analysis reviewed
	2. Mark "Case Completed" in Genoglyphix
	3. Related studies such as FISH results reviewed
	4. Interpretation and recommendations are adequate
	5. Click on the **Final Review & Report**, check ISCN diagnosis for array result and FISH result, make sure all annotation for the gains and losses are complete and accurate, click on save report
	6. Check if correct templates, ISCN nomenclature, and report are accurate and loaded in GCS.
	7. Sign out case on the board.

APPENDIXES

**Cytogenetics Laboratory**

**University of Washington Medical Center**

**Seattle, Washington**

**Appendix A: aCGH Sample Processing/Report Form**

**Sample Setup: PB\_\_\_ AF\_\_\_ CVS\_\_\_ POC\_\_\_**

Date Set-up: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_ Cytogenetics Study #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Case #: \_\_\_\_\_\_\_\_\_\_\_ Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Patient ID: \_\_\_\_\_\_\_\_ Gender: \_\_\_

Date Rec’d: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Draw Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_

Blood Sample Quality: Good, Hemolyzed, Clotted, Thick, Diluted, Dark

Tubes kept (number and type) Coagulation Type: Na heparin (green top)\_\_\_\_\_\_\_Volume \_\_\_\_\_\_\_\_\_\_\_

EDTA (purple top)\_\_\_\_\_\_\_\_\_\_Volume\_\_\_\_\_\_\_\_\_\_\_

Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Volume\_\_\_\_\_\_\_\_\_\_\_

No. of cultures set-up: routine A1 (5ml)\_\_\_\_\_\_ A2(5ml)\_\_\_\_\_\_ 72 hr/37°C w/ complete RPMI+PHA

Set up (for each culture, record the letter, culture time, and any mitogens):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Notes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**Sample Login in GCS & Genoglyphix (office staff)** Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_

\_\_\_\_Computer login GCS

\_\_\_\_check if any **previous or concurrent cytogenetic studies** have been performed.

* Case Accession # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* copies of past cytogenetic studies are placed in the patient folder

\_\_\_\_Print out multiple labels for files

\_\_\_\_Login Genoglyphix to add subject and full description of indications for testing

**Sample Harvest and Cytogenetics Confirmation Study: FISH\_\_\_\_ G-banding\_\_\_\_\_**

**Date harvested**: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_

**G-banding confirmation**: Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_

**FISH confirmation**: FISH probe ordered (probe name, color, date)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date FISH setup: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_

 FISH probe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Control probe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 FISH analysis Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Initial\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 metaphases\_\_\_\_\_\_\_ nuclei\_\_\_\_\_\_\_

**Cytogenetics Laboratory** Case #: Patient ID:

**University of Washington Medical Center** Patient Name:

**Seattle, Washington** Gender:

**Appendix B: Oligo Array CGH Patient Work Form**

**DNA Isolation/QC**

Date Rec’d: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ DNA extraction: Date\_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_

EDTA (purple top) #\_\_\_\_\_\_\_\_\_\_Volume\_\_\_\_\_\_\_\_ Amount of sample used for extraction: \_\_\_\_\_\_\_\_\_

NanoDrop readings: [DNA] ng/ul\_\_\_\_\_\_\_\_\_\_A260/280\_\_\_\_\_\_\_\_\_A260/A230\_­­­­­\_\_\_\_\_\_\_\_­­­­ Initial: \_\_\_\_\_\_

**DNA Labeling**

Labeling reaction set-up: Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_

Patient DNA(cy3):\_\_\_\_\_\_\_\_\_\_\_\_ng per reaction

Control DNA(cy5): \_\_\_\_\_\_\_\_\_\_\_ng per reaction (gender matched)

Post-labeling: Patient DNA(cy3): NanoDrop: [DNA] ng/ul\_\_\_\_\_\_\_\_ x ­­­­\_\_\_\_\_\_\_ul = ug

Control DNA(cy5): NanoDrop: [DNA] ng/ul\_\_\_\_\_\_\_\_ x ­­­­\_\_\_\_\_\_\_ul = ug

**DNA Hybridization**

Hybridization set-up: Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_

Tracking Control: \_\_\_\_\_\_\_\_ Bay #: \_\_\_\_\_\_

*Set-up check:*

1. \_\_\_\_\_ Patient name correct on sample
2. \_\_\_\_\_ Accession number correct on sample
3. \_\_\_\_\_ Slide barcode number correct
4. \_\_\_\_\_ Hybridization solution added to correct fill port

Post-hybridization wash: Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_

Experiment file name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Scanning and Data Processing** Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_

Scan Image File names (barcodeA0x\_532/635.tif)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_532.tif \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_635.tif

Image quality: good, average, poor (bright, uneven, dim, blank, bubbles, missing array features, wash artifact, dust, scratches, fingerprints, others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

Alignment score (<0.2): 532 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 635\_\_\_\_\_\_\_\_\_\_\_\_\_\_ STC match\_\_\_\_\_\_\_\_\_

Data QC on Genoglyphix: SD\_\_\_\_\_\_\_good, average, poor (noisy, telomere chatter, others\_\_\_\_\_\_\_\_\_\_\_\_)

Data reviewed on Genoglyphix (& inform techs for case review): Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Initial: \_\_\_\_\_\_

**Cytogenetics Laboratory** Case #:

**University of Washington Medical Center** Patient Name:

**Seattle, Washington** Gender:

**Appendix C: aCGH Case Review Work Form**

**Primary Tech:** Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_\_

1. \_\_\_\_\_ PDF, Karyogram, and Analysis Summary are printed
2. \_\_\_\_\_ Initial “Case Reviewed” in Genoglyphix
3. \_\_\_\_\_ Labels on all pages
4. \_\_\_\_\_ Related studies noted (ie. Karyotype study AF10-19)
5. \_\_\_\_\_ All analysis completed (including karyotype if concurrent)
6. \_\_\_\_\_ Give folder to second checker if normal
7. \_\_\_\_\_ If abnormal, determine if FISH confirmation or G-banding confirmation is warranted
	* \_\_\_\_\_ G-banding confirmation
	* \_\_\_\_\_ FISH probes: locator \_\_\_\_\_\_\_\_\_\_, BAC probe \_\_\_\_\_\_\_\_\_\_ order by date \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_
	* \_\_\_\_\_ FISH confirmation (Vysis/BAC FISH test)
8. \_\_\_\_\_ Abnormal marked on folder as **A**

**Secondary Tech:** Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_ Initial: \_\_\_\_\_\_\_

1. \_\_\_\_\_ GGX analysis reviewed
2. \_\_\_\_\_ Mark “Case Completed” in Genoglyphix
3. \_\_\_\_\_ FISH results reviewed if necessary
4. \_\_\_\_\_ Interpretation and recommendations
5. \_\_\_\_\_ Print out the GGX final report
6. \_\_\_\_\_ Correct templates, ISCN nomenclature, and report are accurate and load in GCS

**Interpretation**

1. Normal \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ microarray analysis.
2. Genetic counseling is warranted.
3. Note: Results were discussed with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_
4. Parental chromosome analyses are warranted to determine if this was inherited from a parental rearrangement or a *de novo* event.

\_\_\_\_\_ Family follow up by G-banding

\_\_\_\_\_ Family follow up by FISH

\_\_\_\_\_ Family follow up by array

Abnormal/Atypical report:

**Cytogenetics Laboratory**

**University of Washington Medical Center**  Run Date\_\_\_\_\_\_\_\_ Tech\_\_\_\_\_\_

**Seattle, Washington**

**Appendix D: aCGH Patient DNA Labeling Worksheet**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **case number** |  | **Nanodrop** | **total volume 20 ul** | **total volume 40 ul** |
|  | **Patient ID** |  **Gender** |  **DNA [ng/ul]**  | **ul DNA** | **ul H2O** | **ul DNA**  | **ul H2O**  |
| **1** |   |   |   |   |   |   |   |
| **2** |   |   |   |   |   |   |   |
| **3** |   |   |   |   |   |   |   |
| **4** |   |   |   |   |   |   |   |
| **5** |   |   |   |   |   |   |   |
| **6** |   |   |   |   |   |   |   |
| **7** |   |   |   |   |   |   |   |
| **8** |   |   |   |   |   |   |   |
| **9** |   |   |   |   |   |   |   |
| **10** |   |   |   |   |   |   |   |
| **11** |   |   |   |   |   |   |   |
| **12** |   |   |   |   |   |   |   |
|  | **female control** | x |   |  |  |  |  |
|  | **male control** | x |   |  |  |  |  |

**Cytogenetics Laboratory**

**University of Washington Medical Center**

**Seattle, Washington**

**Appendix E: aCGH Patient Hybridization Sheet** (Nimblegen 3-plex array template)

Date:\_\_\_\_\_\_\_\_\_\_\_ Tech:\_\_\_\_\_\_ Hyb in\_\_\_\_\_\_\_\_\_\_\_ Hyb out\_\_\_\_\_\_\_\_\_\_\_\_

**Bay1.** **Barcode:\_\_\_\_\_\_\_\_\_\_\_**

A01: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A02: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A03: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

**Bay2.** **Barcode:\_\_\_\_\_\_\_\_\_\_\_**

A01: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A02: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A03: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

**Bay3.** **Barcode:\_\_\_\_\_\_\_\_\_\_\_**

A01: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A02: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A03: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

**Bay4.** **Barcode:\_\_\_\_\_\_\_\_\_\_\_**

A01: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A02: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

A03: case#\_\_\_\_\_\_\_\_\_\_Patient ID\_\_\_\_\_\_\_\_ Gender\_\_\_\_Control\_\_\_\_\_\_Tracking#\_\_\_\_

Written By: Director Approval:

(Signature and Date) (Signature and Date)

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

 Cytogenetic Supervisor

**UW Medicine - Pathology**

 **Cytogenetics - UWMC**

**SIGNATURE PAGE FOR POLICIES AND PROCEDURES**

Procedure / Policy Title: Reporting Array Results Procedure

Procedure / Policy Number: 400-11-01-06

|  |  |  |
| --- | --- | --- |
| **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 |  |  |