

STANDARD OPERATING PROCEDURE (SOP) FOR SHIPPING ANALYTES TO DOWNSTREAM CENTERS

I. SCOPE AND PURPOSE

Molecular analytes derived from tumor and normal control samples within a project are provided to Characterization and Sequencing Centers in Matrix Well Plate tubes. These tubes are shipped with a human readable wrap-around label that includes all components of the sample identifier established by the Characterization and Sequencing Centers of the project. The Matrix Well Plate tube also has a unique two dimensional barcode (RVSI Number) on the bottom of the tube. In preparation for dispensing the analytes into the Matrix Well Plate tubes, the barcodes are scanned to identify their respective locations in the plate and then the tubes labeled by a Scinomix robot. After the tubes are labeled, the barcodes are scanned again to ensure proper placement. If applicable the samples are also shipped to Qiagen for Whole Genome Amplification (WGA). The samples for Qiagen are aliquoted in a hard shell 96-well plate.

Whole genome amplification (WGA) is a technique employed to increase the amount of limited DNA samples. This is particularly useful for genetic disease research where DNA quantities are limited but many downstream analyses are required. Qiagen provides a custom WGA service (REPLI-g) that accurately copies the original source DNA, without bias, and produces amplified DNA that can be directly used in a range of genetic analyses.

The BCR submits DNA samples derived from tumor and normal control tissues to Qiagen for WGA. Qiagen employs proprietary internal quality control testing to enable reliable prediction for the success of the targets in downstream applications. If needed, the WGA sample can be shipped to downstream centers.

This procedure is used to establish quality control measures for accurate distribution of analytes derived from the project. This procedure applies to all trained laboratory personnel.

II. PROCEDURE

A. Safety Procedures

1. Use universal safety precautions, including the use of personal protective equipment (PPE).

B. Quality Control

1. Sample barcodes will be verified by two individuals prior to plating and shipping.
2. Two technicians will confirm the configuration and set-up of robots used for labeling or transferring samples.
3. When analytes are transferred between containers, there is a 100% quality control check by a second technologist who observes all sample transfers are made to the proper final tube or plate location.

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- Any deviation from this Standard Operating Procedure will be noted on the Shipping Layout Checklist.

C. Equipment and Materials

- Tube labels(need vendor, and catalog #)
- Empty Matrix Well Plates (Matrix, catalog# 4900, no substitution)
- Matrix Rack with 0.5 mL Screw Tubes with caps (Thermo, catalog# 3744, no substitution)
- Matrix Rack with 0.5 mL Screw Tubes without caps (Thermo, catalog# 3745, no substitution)
- Visionmate96 Scanner (Matrix #3111)
- Visionmate 96 scanner software programs
- Computer with Excel, TechPrinter Software, and Visionmate 96 scanner software programs installed
- Scinomix software and robot
- 8-Multi-Channel Pipetman
- Single-channel pipette
- Cap-It All
- Hard shell skirted 96-well plate (Biorad, catalog # HSP9631)
- Aerosol barrier pipette tips
- 0.1X Tris-EDTA (TE) buffer (1 mM Tris, 0.1 mM EDTA; 100x concentrate, Sigma catalog #T9285)
- Foil adhesive heat seals (Eppendorf, catalog# E0030127854)
- Heat sealer
- Biomek FXp
- Robot Tips P250 Conductive Barrier (VWR, catalog# 394627)
- Greiner UV-Star® 96 well plates (no substitution, Fisher, catalog# NC0532986)
- TempPlateIII, 96-well plates (USA Scientific, #1402-9700, no substitution)
- Personal Protective Equipment
- Cap-it-All(Thermo Scientific)
- Centrifuge
- Repli-g Order Form (available: www1.qiagen.com)
- SOP A005 LabVantage Manual. Specific MGL sections necessary include: Creating shipping layouts, Approving shipping layouts, Creating WGA shipping layouts from Qiagen plates, CDT Shipping Aliquot Boxes to Logistics
- SOP M024: Scinomix Tube Labeler

It is possible to substitute disposable materials and certain equipment from other vendors as long as they are equivalent to the item described above.

III. PROCEDURE-STEPWISE

A. Creating a Shipping List/ QC Shipping List

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1. Open Excel and click on the Data Tab. Click on “From Other Sources.” Click on “From SQL Server.”
2. Under Server Name type: **resbcrdb**. Click on the drop down and select “BCR.”
3. Double click on “vwQCSampleSummaryMGL” and click “Finish.” Click “Yes.”
4. View the data as a table and click “OK.”
5. Filter the data by Batch and select the pseudobatches being shipped. Copy this information into a new Excel File. Save the file to \\rex\BPC\TCGA-BCR\Shared Documents\Molecular Projects\Shipping layout checklist under a folder labeled with the date of the shipment. Name the Shipping Layout Checklist file with the date and “shipment.” This is the MGL Shipping Review File.
6. The Clinical Outreach Shipping Review File must be created from the MGL Shipping Review File. Save only the following columns from the MGL file:

BatchID	tcgaBarcode	sampleID	studyname	studysubtypeName	organ site	NormalAnatomicSiteOfCase	tssSubjectID	ocStudySubjectID	tssID
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7. Save the file to \\rex\BPC\TCGA-BCR\Clinical Outreach\Pre-shipment Review.
8. Email Clinical Outreach to begin their QC of each case (SOP C032 “Quality Control of Case Qualification Metrics for BCR Analyte Shipments”).
9. Email BCR Informatics for a request of Batch Numbers. Give them the name of the studies that will be shipped.
10. While Clinical Outreach QC’s the samples, Molecular will QC simultaneously using the MGL Shipping Review File created in step 5. Sort this file accordingly to examine yields and RIN’s for samples in the Pseudobatches.
11. After Molecular and Clinical outreach review to confirm all analytes meet metrics for distribution per specific project requirements (project specific metrics are found on the BCR SharePoint under the Project and QMS folder), the Pseudobatch can be renamed with the Batch Number as assigned by Informatics.
12. Open the MGL Shipping Review File and copy all Sample IDs into a new tab. Save the tab as a CSV file to be imported into LabVantage.
13. Log into LabVantage.
14. Under Sample Management, click on “Lab Operations Samples.”
15. Click on the “Import List” button. Click on “browse” and select the CSV file. Click on “Open.”
16. Refresh the page and the list will appear in a new folder. Click on the folder.
17. Sort the folder by Study. Select one study at a time to change the batch number.

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18. Click on “Update Batch Number.” Type in the new Batch Number for that specific study given by Informatics. Click “OK.”

B. Setting up Matrix Plates

1. Export the imported list from LabVantage by selecting all the samples and clicking “Export to Excel” on the left. Sort the Excel file to have all DNA on one tab and all RNA on another tab. Arrange the samples by study and characterization center.
2. Retrieve DNA/RNA from their storage locations; arrange the RNA in an empty Matrix Rack and the DNA in another Matrix rack.
 - a. For smaller shipments, DNA tumors are arranged in columns 1-6 in groups by study/sequencing center and normals are arranged in columns 7-12 that correspond to the tumor.
 - b. For larger shipments, normals are placed on one plate and all tumors on another plate with corresponding positions.
 - c. If possible keep row H empty so the same shipping layout may be used to create the Qiagen plate (if applicable).
 - d. Note any discrepancies in storage location, tube condition, or other abnormalities on the shipping checklist. Discrepancies must be reconciled prior to distribution. If a specimen is missing, LabVantage must be updated to reflect that the specimen cannot be located.
3. Confirm there is enough volume to send each analyte to the recipients as required by the project metrics (located on the BCR SharePoint in the Project and QMS folder). Make sure the quantity (volume) of each sample is sufficient for shipping to all required centers. Document gross discrepancies between volumes recorded in LabVantage and the physical tube on the shipping checklist.
4. Once all DNA/RNA samples are arranged in Matrix Plates, begin the shipping process in LabVantage.
5. Go to the BCR Home Page in SharePoint. Click on Shared Document on the left. Click on document labeled “NCH BCR Sequencing and Characterization Center Plating Checklist-v3.”
6. Click “OK.” Document should open in Word. Print document and close.
7. Create shipping layouts for the shipment by referencing the LabVantage Manual in the section “Creating shipping layouts.”
8. If applicable create shipping layouts for WGA samples that will be shipped to downstream centers by referencing the LabVantage Manual in the section “Creating WGA shipping layouts from Qiagen plates.”
9. Email the senior laboratory technologist (“QC Person”) who will be verifying and approving the shipment with notification that the shipping layout is ready for review. Specify the shipping layout number. The QC Person may approve the layouts by referencing the LabVantage Manual in the section “Approving shipping layouts.”

C. Creating Shipping Aliquots

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1. Once the shipping layout is approved in LabVantage, reference the section in the LabVantage Manual “Creating Shipping Aliquots” or “Creating WGA shipping layouts from Qiagen plates”, whichever is applicable.
2. Set up the empty matrix rack with the tubes in the appropriate locations based on the Aliquot Box created from the Shipping Layout.
3. Label the matrix rack with “NCH Plate ID XXXX, Batch XXX”
4. Create a folder in N:\Molecular Genetics\BCR\Matrix Tube Barcode Scans labeled with the batch numbers. (i.e. Batch 1).
5. Open up the Visionmate 96 software. Make sure it is in “rack mode.” Go to the excel tab and change the directory to your batch folder created above.
6. Scan the matrix plate. A pop up will appear asking how to name the file. Use the plate ID written on the rack (i.e. A235). Open the excel file that is created with the RVSI barcode positions and select “text tab delimited” file extension and save on the Import drive on ‘reslabvantage.’
7. After Matrix racks have been scanned and saved in the Labvantage Import folder, RVSI numbers are added to the Aliquot boxes:
 - a. Log on to LabVantage. Under Storage, click on the “Boxes” page. Find your Aliquot Box, check the box, and click on the “Add RVSI Alias” button. This will link the unique RVSI barcode to a specific aliquot of a sample being shipped.
 - b. Find the .txt tab delimited file corresponding to the Aliquot Box. Click “Open.”
 - c. If import was unsuccessful double check that your tubes are in the correct orientation. Repeat steps 6/7 if necessary.
 - d. Select the Aliquot Box. Click on “Update TCGA Number.” This will complete the process of attaching the PlateID at the end of the CCG BCR ID. This can only be done one Aliquot Box at a time. *NOTE: Only click this once! If you click more than once the TCGA number will be updated that many times.*
8. Repeat for all remaining aliquot boxes.

D. Printing Labels on Aliquot Matrix Tubes

1. See Scinomix Tube Labeler SOP (M024: Scinomix Tube Labeler) for details on labeling the tubes.
2. Once the tubes are labeled, the labels are QC’s by visually verifying that each of the tube labels are clearly printed.
 - a. If a tube label is not printed completely, reprint the label per SOP M024.
3. Once the visual QC step is complete and labels are re-printed if necessary, scan the rack with the Visionmate software (as stated in step 6 under the Creating Shipping Aliquots in LabVantage section).
4. Open the excel file. Copy the barcodes from the second tab and paste it in column E of the first tab of the initial scan. In column F enter the formula “= E=C”. Drag this formula down and make sure it covers all of the barcodes. All of the values for this column should be TRUE. If any value displays FALSE, check for swapped matrix tubes and rescanning the matrix rack to resolve.

E. Print Paperwork for Downstream Centers

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1. Samples need to be created as aliquots in LabVantage one day before paperwork can be printed.
2. Go to BCR SharePoint.
3. Go to Reports, Click on “shippingforms.”
4. Type in the PlateID. Click on the Calendar and select the date of shipment.
5. Click the Apply button.
6. Click on the “Actions” drop-down. Highlight over Export and click on “Excel.”
7. Click on Sheet 5.
8. Print on 11x17 paper to a colored printer.
9. Create a folder in \\rex\BPC\TCGA-BCR\Shared Documents\Molecular Projects\Shipping Forms labeled with the Batch Numbers. Save the EXCEL file as “Location (shipping destination) and Batch Number.”
10. Return to the webpage that has the shipping form.
11. Click on the “Actions” drop-down. Highlight over Export and click on “PDF.”
12. Print the pages containing the Audit Checklists, QC Checklists, and the Matrix Well Plate Form. If there are no problems with the Audit, these pages will appear on Page 1, 5, 9, 13, 17.
13. Save the PDF file as “Location (shipping destination) and Batch Number” in the folder created in \\rex\BPC\TCGA-BCR\Shared Documents\Molecular Projects\Shipping Forms.
14. QC Shipping forms using the Shipping Layout Checklist printed from the PDF. Date and initial the checklist if correct. The Shipping Layout Checklist defines all items specifically reviewed prior to shipping.
15. Give the checklist and shipping forms to Quality Management.
16. Quality Management will review and give the checklist and shipping forms to Informatics.
17. Once all shipping documents have been approved, the paperwork is returned to Molecular for release with final signature.

F. Print Paperwork for Qiagen – if applicable

1. Open the file “Template for Creating Qiagen Shipping Form.xlsx” which can be found at \\rex\BPC\TCGA-BCR\Shared Documents\Molecular Projects\Repli-G_Qiagen
2. Log-in to LabVantage.
3. Use the Shipping Layout Checklist to retrieve the Aliquot Box number for the Qiagen plates.
4. Under LabOperations, search for bxSorted.
5. Type in the Aliquot Box number. Click OK. All the samples will appear.
6. Select all the samples. On the left, click on “Export to Excel.”
7. Delete all the columns between TCGA ID and Location.
8. Copy the columns TCGA ID and Location. Paste this into columns A and B (respectively) on the Template for Creating Qiagen Shipping Form opened in step 1.
9. Paste Column A into Column C.

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10. Update the Box Number in Column F.
11. All the samples will appear in the correct location in Column J.
12. Open the “Repli_g_Orderform0907_template.xls” found on \\rex\BPC\TCGA-BCR\Shared Documents\Molecular Projects\Repli-G_Qiagen.
13. Click on the tab titled “PartII Samples.”
14. Enter the appropriate information under the “A. 96-well Plate Information.”
 - a. The Plate ID and number of sample will always be different.
 - b. Sample Type – Genomic DNA
 - c. Sample Amount – enter appropriate volume
 - d. Sample Source – human
 - e. REPLI-g service request – select appropriate request
 - f. Last column is always left blank

Order Form to QIAGEN Whole Genome Amplification Services: Part II - sample information

Orderform V

A. 96-well plate information: Please fill out all fields for each 96-well plate (please see ordering guidelines part 3A for further details on how to easily fill out this table).

Plate no.	Plate ID	No. of samples	Sample Type	Sample Amount	Sample Source	REPLI-g service request	If you have selected the custom service, 805990, please briefly specify the description of the services
EXAMPLE	84	84	Genomic DNA	50 µl	human	805990 - Other (please specify)	40 µg reaction scale
1	NCHQ87	81	Genomic DNA	20ul	human	805923 - 100 ug (plates < 84 sz)	
2	NCHQ88	11	Genomic DNA	20ul	human	805923 - 100 ug (plates < 84 sz)	
3							

15. Copy Column J from the “Template for Creating Qiagen Shipping Form.xlsx” file into the Sample Names column for that specific plate on “Repli_g_Orderform0907_template.xls” file.
16. The number of samples for each Plate can be found in LabVantage when you selected the samples.
17. Save file as “Repli_g_Orderform0907_BatchXXX,XXX.xls”
18. Click on tab Part I. Add the Purchase Order number provided by Program Office. Print this page.
19. Click on tab PartII. Print page 1-3 if you only have one Qiagen plate. Print pages 1-5 if you have two Qiagen plates (and so on).
20. Submit the excel form to a senior technologist for QC and form approval. Inform logistics you are ready to QC the shipment.

G. Aliquot the Stock DNA/RNA into Aliquot Matrix Racks

If aliquots are needed for shipping Stock DNA to Qiagen (described in H below) the Qiagen plates can be made simultaneously when aliquoting DNA/RNA into Matrix Racks.

1. Remove the Matrix rack containing the stock shipping samples from the liquid nitrogen or -80°C freezer. Keep RNA on wet ice to thaw; immediately transfer the RNA to dry ice when aliquoting is finished. DNA samples can be thawed at room temperature.
2. When the samples are completely thawed, centrifuge the stock shipping samples briefly to collect all the liquid at the bottom of the tube.

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3. Use the Cap-it-All to de-cap the Matrix rack containing the empty aliquot tubes. Recap the caps from the aliquot tubes onto a clean, empty Matrix tube rack for storage while aliquoting is being performed.
4. Use the Cap-It-All to remove the caps of the tubes in the Matrix rack containing the stock shipping samples. All samples will be kept uncapped long enough to aliquot the samples. These caps are kept on the Cap-it-All until aliquoting is complete and the stock tubes can be recapped.
5. Transfer the stock samples to the appropriate wells of the aliquot Matrix rack. One technologist transfers the analytes using a multichannel pipet, one column at a time, while the second one observes. The second quality control technologist will confirm that the height of the volume aspirated is the same in all of the multichannel tips and that all liquid has been dispensed from each tip into the appropriate well.
6. If applicable – continue to step H “Aliquot the stock DNA for Qiagen.”
7. Use the Cap-It-All to recap the stock sample Matrix rack, confirming correct matrix plate orientation before recapping.
8. Use the Cap-It-All to de-cap the caps from the empty Matrix tube rack. Recap these caps onto the aliquot Matrix rack.
9. In the event that there is insufficient sample to meet the requested volume, the actual volume provided will be entered in LabVantage.
10. Spin down the aliquot Matrix rack before freezing in a -80°C freezer, where the aliquot Matrix rack will be stored until the entire shipment is ready.
11. Return RNA and DNA stock tubes to appropriate storage location.

H. Aliquot the Stock DNA for Qiagen – if applicable

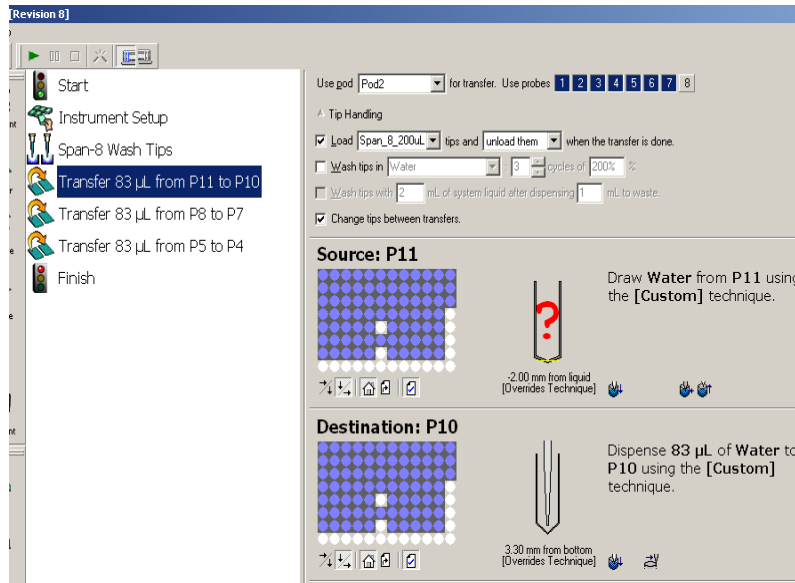
1. Label a skirted 96-well plate with the NCHQXXX identifier.
2. Transfer the stock samples to the appropriate wells of the skirted 96-well plate. One technologist transfers the analytes, one column at a time, while the second one observes. The second quality control technologist will confirm that the height of the volume aspirated is the same in all of the multichannel tips and that all liquid has been dispensed from each tip into the appropriate well. Note: Unless requested otherwise by the Project Sponsor, 2uL of DNA at 160ng/uL ± 15ng/uL plus 18uL of distilled H₂O will be shipped to Qiagen. Qiagen suggests sending 250ng at 5ng/uL but will accept anything from 1ng/uL to 100ng/uL.
3. Use the Cap-It-All to recap the stock sample Matrix rack.
4. Cover the Qiagen plate with a foil adhesive and heat seal. NOTE: Samples shipped under liquid nitrogen vapor require heat-sealable foil adhesives.
5. Spin down the skirted 96-well plate before freezing in a -80°C freezer, where the plate will be stored until the entire shipment is ready.

I. Aliquot the WGA DNA into Aliquot Matrix Racks – if applicable

1. Open the Biomek Software.
2. Open the File "WGA Transfer 1 Plate Span 8."

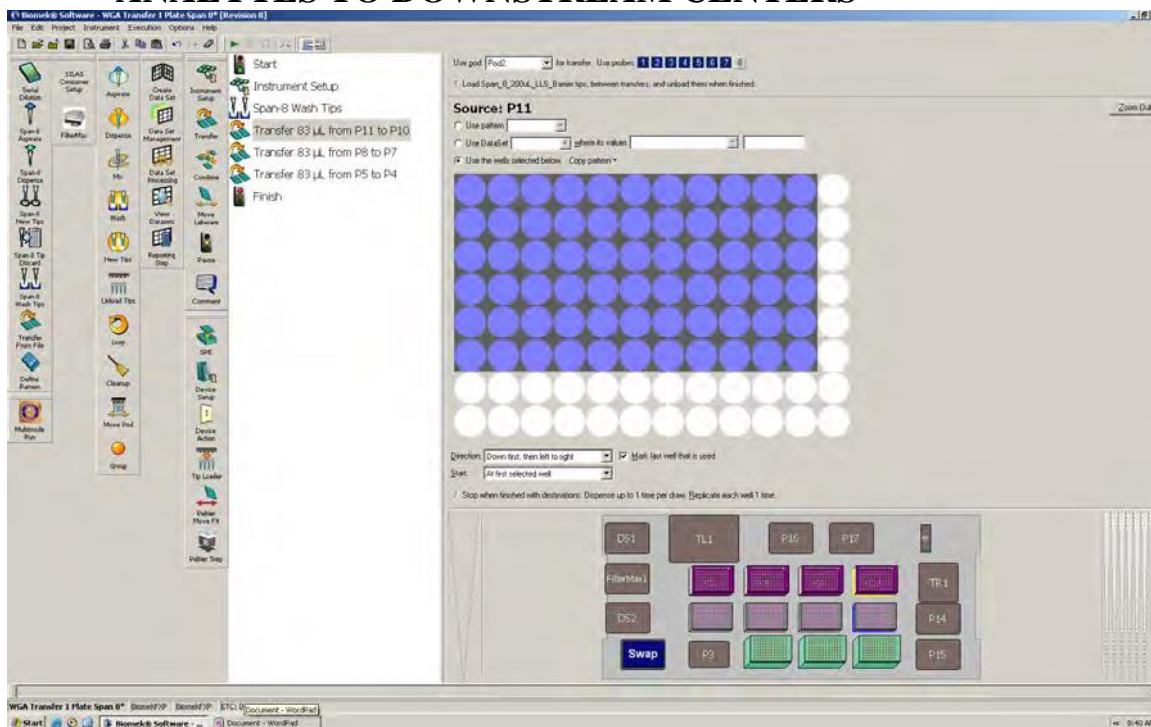
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- Only three WGA plates may be aliquoted at one time. Disable the step "Transfer 83 μ L from P5 to P4" if there are only 2 WGA plates to aliquot. Also, disable "Transfer 83 μ L from P8 to P7" as well if there is only 1 WGA plate to aliquot.
- Click on "Transfer 83 μ L from P11 to P10."



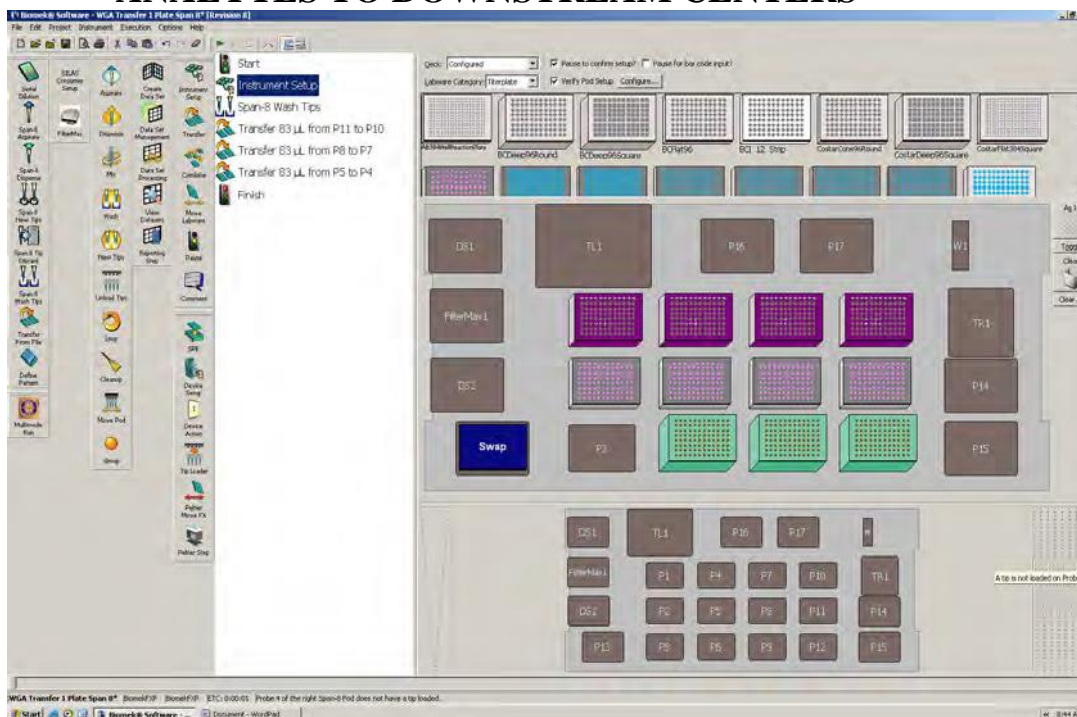
- Double-click on the Source: P11 Plate. This will allow you to select the wells intended for aliquoting. Use the Qiagen Form printout to determine which wells to select. Drag and hold to select. If you hold the Shift Key, you can select other wells. If hold the Ctrl Key, you can deselect the wells.
- Click on Zoom Out.

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7. Double-click on the Destination: P10 Plate. Use the Qiagen Form printout to determine which wells to select. The same wells should be selected as on the Source: P11 plate.
8. Click on Zoom Out.
9. Repeat Steps 5-8 as needed for additional plates (Transfer 83 µL from P8 to P7 and Transfer 83 µL from P5 to P4).
10. Centrifuge stock WGA plates. Use the Cap-It-All to decap the matrix rack (and recap these tops onto an empty matrix rack).
11. Open the WGA plate carefully, without splashing.
12. Set up the deck to reflect the layout below.
 - i. Dark purple plate – Represents the Matrix Aliquot plate
 - ii. Light purple/gray plate – Represents the WGA plate nestled into a UV-Star 96 well plate and held into place with tape
 - iii. Green tip box – Represents the Conductive Barrier P250 tips

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13. Once the deck is set up to reflect the number of plates being aliquoted, a senior technologist will QC the Well Layouts for each transfer step.
14. After the deck has been QC'd by a second technician, click on Instrument > Home All Axes. Follow the prompts and make sure there are no bubbles present in the tubing connected to the Span 8 head.
15. Click on the "Play" button at the top of the screen to initiate transfer program.
16. When the program has finished, re-seal the WGA plate and recap the matrix tubes.
17. The aliquot matrix rack is labeled with a Tech label and includes NCH PlateID XXXX and Batch XXX. The WGA plate seal is initialed and dated by both the plating and QC technicians.
18. Aliquoting can also be performed by hand while observed by a second QC technologist.

J. CDT Shipping Aliquot Boxes to Logistics

1. Reference the LabVantage Manual section "CDT Shipping Aliquot Boxes to Logistics."

K. Communication with Sites Receiving Samples

1. GCC/GSC Sites
 - a. Prior to shipping samples, the GCC/GSC coordinators will be contacted to confirm their facility is available to accept delivery.
 - b. On the day of shipment, the GCC/GSC coordinators will be contacted to notify them that samples are being shipped. This notification will include relevant package

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tracking information and a shipping manifest to document the contents of the shipment and the unique identifiers on each sample. This includes the human readable CCG BCR ID printed on the sample tube label (side) as well as the RVSI barcode (bottom). The RVSI is a unique identifier that links to a specific tube (aliquot) shipped to a center on a specific date.

- c. To maintain a feedback loop from investigators regarding the QC/QA of specimens produced and stored at the BCR, the following language will be included in the shipping notification email:
“Please let us know if you have any questions or feedback on the samples after they arrive.”
 - d. When feedback is received from recipients, the GCC/GSC coordinators will forward the information to the BCR Quality Manager and, if appropriate, initiate a full investigation into the matter.
 - e. Receiving institutions are required to confirm receipt by faxing the BCR a copy of the signed Matrix Well Form.
2. Qiagen – If applicable
- a. On the day of shipment, the CCG BCR shipping coordinator will contact Qiagen to notify them that samples are being shipped. This notification will include relevant package tracking information and a shipping manifest to document the contents of the shipment and the unique identifiers on each sample.
 - b. Qiagen will return the cryoport empty and ship the WGA samples to the BCR on dry ice or via a cryoport according to their standard protocol.
 - c. Qiagen will provide a “Whole Genome Amplification Service Report” indicating that the samples passed their internal quality control criteria. This report will be used in BCR SOP M0006 “Normalization of Whole Genome Amplification Samples”
 - d. The Project Sponsors will be notified via email if WGA is deemed “unusable” or “synthesis failures” by Qiagen standards for any samples. In this event the BCR will send a replacement sample to Qiagen in the next shipment.
 - e. If Qiagen deviates from their SOP in the whole genome amplification or in the receipt, handling, and/or shipping of the samples, then they will provide a deviation report detailing the deviation and the number of samples affected will be noted.
 - f. After normalization (using SOP M006 “Normalization of Whole Genome Amplification Samples”), SNP analysis is performed (refer to SOP M010 “Tissue Matching by SNP Analysis”), and passing WGA samples are shipped to the centers of interest.

IV. REFERENCES

- A. BCR SOP M024 “Scinomix Tube Labeler”
- B. BCR SOP C032 “Quality Control of Case Qualification Metrics for BCR Analyte Shipments”

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- C. BCR SOP “LabVantage Manual”
- D. BCR SOP M0006 “Normalization of Whole Genome Amplification Samples”
- E. BCR SOP M006 “Normalization of Whole Genome Amplification Samples”
- F. BCR SOP M010 “Tissue Matching by SNP Analysis”

V. COMPREHENSIVE REVISION HISTORY

- A. Changes made in Version 2, Effective Date 1/7/2015
 - 1. Updated formatting
 - 2. Updated disclaimer
 - 3. Added SOP M009 (Whole Genome Amplification) to this procedure
 - 4. Added SOP M007 (Quality Control Plating) to this procedure
 - 5. Removed any reference to TCGA
 - 6. Minor word changes
 - 7. Updated LabVantage images
 - 8. Updated locations of files used throughout the procedure
 - 9. Add the section “Aliquot the WGA DNA into Aliquot Matrix Racks – if applicable”
 - 10. Removed LabVantage steps where applicable and placed them in the LabVantage Manual SOP A005.
 - 11. Added to the Materials section to include the SOP’s that go along with this SOP
 - 12. Included language of where to find project specific metrics
- B. Version 1, Effective Date 9/14/2012 - New

Effective Date: 1/7/2015

Biospecimen Core Resource



M018
Version 2

**STANDARD OPERATING PROCEDURE (SOP) FOR SHIPPING
ANALYTES TO DOWNSTREAM CENTERS**

Signatures

Approved By: Signature on file
Julie Gastier-Foster, PhD, FACMG
Principal Investigator

Date: Date on file