**Quality Management Program**

1. **PRINCIPLE**
   1. A quality management procedure is used to specify the process the laboratory follows to ensure high quality testing and reporting.
      1. This procedure includes pre-analytic instructions including specimen collection, transport, and processing.
      2. It also includes analytical variables including standard laboratory practice and quality control processes.
      3. Post-analytic instructions include reporting processes, report review, error corrections, and specimen retention.
2. **PRE-ANALYTIC PROCESSES**
   1. **Molecular Laboratory Standard Practices**
      1. **Laboratory access is restricted to authorized individuals.**
      2. Universal Precautions are employed with all patient material.
      3. Clean gloves must always be worn and should be changed whenever potentially contaminated. Separate lab coats must be used for pre- and post- PCR work areas, as well as the PCR set-up room.
      4. Use gloves, disposable lab coat, and UV camera shield when cutting out gel electrophoresis bands on the BioRad Gel Digital Camera.
      5. Use gloves, disposable lab coat, and hood when pipetting phenol, chloroform, xylene, or 2-mercaptoethanol; pouring acrylamide/bis; and when working with any other chemical in which the safety data sheet (SDS) recommends adequate ventilation.
      6. Xylene monitoring was performed and will be repeated if there is a change in production, equipment, process, personnel, or control measures likely to increase exposure levels.
      7. Waste disposal: follow SDS disposal recommendations.
         1. Appropriate waste containers must be used for phenol/chloroform disposal.

Some plastics are not suitable for this type of waste.

* + - 1. Leftover acrylamide/bis must be polymerized and disposed of in the trash.
      2. Empty acrylamide/bis containers must be disposed of with the hazardous waste.
    1. A dedicated set of pipettors must be used for each different type of procedure: a set for work with cloned or amplified DNA and loading gels, a set for DNA extraction, a set for RNA extraction, and a set for PCR set-up.
    2. Because of the enormous amplification possible with PCR, even small levels of DNA contamination, especially from previous PCR reactions, can result in false positive results. For this reason, stringent hygiene is required in the laboratory, including the segregation of PCR products from the assembly site of PCR reactions.
    3. All supplies such as pipette tips, microcentrifuge tubes, etc. shall be sterile, disposable, and used only once.
    4. All PCR reactions are assembled in the PCR set-up room in a hood that is treated with high intensity UV light after each use.
    5. Barrier pipette tips are used for all repetitive pipetting and great care is taken to prevent contamination of reactions.
    6. For most assays, a ‘No Template’ control reaction which omits target nucleic acid is performed to test for possible contamination.
       1. ‘Master Mixes’, which contain all of the components of the PCR reaction except the target nucleic acid, are assembled in the hood designated for this purpose. These mixes are aliquoted to the individual reaction tubes prior to the addition of DNA. In this manner, any contamination of reaction components will yield an inappropriately positive reaction in the negative/no template control tube lacking added target DNA. Assay runs should be appropriately evaluated by the Director/Pathologist and appropriate steps should be taken.
    7. Loading of samples and controls:
       1. For most single tube assays, patient nucleic acid samples are added first, followed by controls. The direction of adding components should be from right to left. These steps help to reduce the risk of contamination of clinical samples.
       2. For most plate assays, the order of loading is dependent on how the plate is setup (i.e., A1 through H1 or A1 through A12).
       3. See separate procedures for exceptions. For example, in the Actionable Mutation Panel and Solid Tumor Fusion Panel, controls are pre-set and loaded in the specific order indicated on the worksheets.
    8. Enzymatic reactions are performed with sterile plastic-ware and solutions, whenever possible.
    9. Plastic-ware and racks are cleaned with 10% bleach followed by two distilled water rinses.
    10. All electrophoresis devices are equipped with safety lids to minimize the risk of electric shock. Power supplies are turned off when gels are manipulated.
    11. Proper pipetting technique must always be used.
        1. Pre-wet the pipette tip by aspirating and expelling the liquid.
        2. Reagents should be at room temperature unless they are prone to degradation at ambient temperature.
        3. Make sure there are no air bubbles in the tip or droplets on the outside of the tip.
        4. Use standard mode pipetting unless pipetting extremely viscous liquids. Standard mode pipetting is performed as follows:
           1. depress the plunger to the first stop
           2. immerse the tip into an appropriate amount of the liquid
           3. pre-wet the pipette tip
           4. aspirate the liquid
           5. expel the liquid by depressing the plunger to the second stop or the ‘blow out’ mode.
        5. Reverse mode pipetting will result in over-delivery of liquid unless you are working with extremely viscous or volatile liquids.
           1. Reverse mode pipetting is performed by depressing the plunger to the second stop, aspirating the viscous liquid, and expelling it to the first stop.
        6. Pause 1 second after pipetting to allow the full amount of liquid to flow into the pipette tip.
        7. The pipette tip should be put into the liquid vertically and pulled out vertically.
        8. Immerse the tip to the proper depth. Large volume pipettors should have the tip immersed 5-6 mm, small volume pipettors should have the tip immersed 2-3 mm. Do not touch the sides or bottom of the tube while aspirating the liquid.
        9. Use the correct pipette tip and pipettor. Always check the pipettor’s range and use the appropriate tip for the volume needed.
        10. Use consistent plunger pressure and speed.
    12. The use of serological pipets is acceptable for the TNA cytology extraction, TNA manual extraction, reconstitution of reagents, and instrument maintenance.
    13. Smoking, vaping, eating, gum chewing, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting are prohibited in the laboratory.
    14. When making a correction to a laboratory record (QC data, temperature logs, etc. NOT PATIENT RESULTS) the original data must be visible. The initials of the person changing the data and the date of the change needs to be noted on the document.
  1. **Specimen Collection**
     1. Primary specimens (unprocessed) are labeled with patient name and another identifier, such as date of birth or medical record number. Additionally, the individual who collected the sample should initial each sample container collected.
     2. Mislabeled specimens:
        1. For those specimen types that are difficult to recollect, have the person responsible correctly identifying the specimen. Fill out **Patient Identification Sheet** and give it to the manager.
        2. Any issues relating to the quality and labeling of specimens should be addressed with the nurse or physician caring for the patient.
     3. For any specimen that is deemed unacceptable, the nurse or physician caring for that patient is notified and the information is documented in the test final report. The specimens will be kept in the refrigerator for one week after the provider is notified.
     4. Secondary specimens (processed), such as formalin-fixed, paraffin-embedded (FFPE) blocks or slides prepared from blocks, must be labeled with the patients’ name or associated identification number, such as surgical number or medical record number.
     5. Peripheral blood and bone marrow aspirates must be collected in EDTA- or Citrate-containing tubes.
     6. CSF and other body fluids must be collected in a sterile container and should not be spun prior to transporting.
     7. Fresh tissue: Tissue can be sent in absolute ethanol, on ice, or embedded in OCT. Any fresh tissue received should be processed immediately or stored at -80°C.
     8. Samples for DNA testing may be stored at room temperature or in the refrigerator prior to delivery.
     9. Samples for RNA testing must be stored at 4°C for no longer than 72 hours after collection.
     10. FFPE blocks are stored at room temperature. The Histology lab is responsible for pulling blocks and either sending the entire block or preparing unstained slides from block sections.
     11. Slides prepared from FFPE can be stored at room temperature.
     12. All samples should be collected appropriately to maintain DNase and RNase free conditions.
     13. Because we often receive specimens that have been shared with another department, all results are interpreted accordingly.
  2. **Specimen Transport**
     1. Samples are transferred between hospitals and the laboratory by couriers using properly labelled coolers.
     2. Each sample arrives with a requisition form, as well as either a CoPath tracking list or a Softlab tracking list.
     3. The person receiving the samples follows the MGP Specimen Accessioning Procedure to receive the samples.
     4. All tracking lists will state the temperature in which the specimens should be transported.
        1. The person receiving the specimens should ensure that they are received at the correct temperature.
        2. S/he then signs the packing list, ensuring that the list is complete, and the samples were shipped at the correct temperature.
  3. **Sample Processing/Storage**
     1. Each sample is accessioned following the MGP Specimen Accessioning Procedure.
     2. Any deviations from standard procedures should be appropriately indicated in Soft Molecular using the Internal Note option.
     3. Fresh tissue must be processed immediately or stored at -80°C.
     4. Blood for DNA extraction may be stored for up to 48 hours at room temperature.
     5. Blood for RNA extraction must be stored at 4°C and processed within 72 hours of collection.
     6. Blocks and slides can be stored at room temperature.
     7. If an aliquot of a specimen is performed, good laboratory practice must be performed (as described above) to prevent cross-contamination of specimens. No aliquot should ever be returned to the original container.

1. **ANALYTIC PROCESSES**
   1. **Quality Control**
      1. All QC documentation is monitored weekly by the Quality Control Designee.
      2. All surfaces and equipment are cleaned with 10% bleach or other appropriate disinfecting solution once per week. This is recorded on the **QC Checklist.**
      3. Daily, working surfaces and pipettors are cleaned before each use with 10% bleach or other appropriate disinfecting solution, followed by water. This is documented on the **Decontamination Form.**
      4. Glassware is cleaned with a low phosphate detergent (<1%) and rinsed with distilled water.
      5. To make sure all detergent is removed from glassware, a pH indicator is placed on the clean glassware while still wet. The pH should be 6.0. If outside of range, rinse again in distilled water and check pH again. Record results on **Glassware Cleaning Form**.
      6. Pipetting devices are inspected before each use.
         1. Pipettors are checked for calibration accuracy every 6 months by an outside vendor.
         2. Broken pipettors are returned to the manufacturer or calibration vendor for repair and calibration.
      7. Soft Total QC is integrated with SoftMolecular LIS. SoftMolecular documents all steps performed in the assay. Total QC documents all the QC performed as well as all the reagent preparation, reagent batch numbers, and kit lot numbers. Refer to the Total QC Procedures for more details.
      8. Formulas for all SoftMolecular assay worksheets/tasklists are checked once per year.
      9. The Cepheid GeneXpert IQCP is reviewed yearly and documented using the **Cepheid IQCP Yearly Review Checklist**.
         1. QC is performed every 30 days or with every new lot or shipment of kits, whichever comes first. The controls used are included below.
            1. Xpert FII & FV NOR/MUT Control, MMQCI Cat# G11601.
            2. Xpert FII & FV HET, MMQCI Cat# G108-2H.
            3. Environmental control: performed monthly.
            4. Please see *Cepheid GeneXpert Instrument Procedure* for additional information.
      10. Humidity is monitored automatically by probes in both the pre- and post-PCR areas. Refer to the Aeroscout Mobile View Temperature Recording Procedure.
   2. **Reagents and Supplies**
      1. Manufacturer specification and Certificate of Analysis sheets for purchased enzymes, substrates, nucleotides, and chemicals are dated upon receipt and filed in the Assay Sheets binder.
      2. Lot numbers of all reagents must be entered in Soft Total QC following the Total QC Receiving Inventory Procedure or the Total QC Preparing Batches or Reconstituting Procedure.
      3. Reagents need to be labeled with:
         1. Content and quantity, concentration, or titer
         2. Storage requirements
            1. If this is not noted on the reagent label, the information can be found in Soft Total Quality Control.
         3. Received, prepared, or reconstituted date
         4. Opened date
         5. Expiration date (if not supplied, the expiration date will be decided after consultation with the manufacturer.)
      4. Containers for prepared reagents must list the content, concentration, preparation, quantity, expiration date, and storage conditions.
         1. If storage condition is not noted on the reagent label, the information can be found in Soft Total Quality Control.
         2. All bottles must be dated when opened.
         3. Chemicals are not returned to the original container after weighing. Excess chemicals are discarded.
      5. New lots are QC’d and documented in Total QC. Refer to the Total QC Result Entry Procedure
      6. If there are multiple components of a reagent kit, use the components of reagent kits only within the kit lot, unless specified otherwise by the manufacturer.
      7. Outdated material and reagents and those that fail performance standard are discarded.
      8. Sensitivity controls are low-positive controls that have been diluted to achieve results near the limit of detection for the assay.
         1. For example, for an assay detecting mutations in tumor samples, a sensitivity control would have a variant allele fraction near the limit of detection.
         2. Sensitivity controls can be used for qualitative tests that use a cut-off value to distinguish positive from negative results and to verify that the cut-off is appropriate.
         3. See individual assay procedures for the specific sensitivity controls used (for most assays, this is performed with every run).
      9. Sensitivity, Tonsil, and Placenta Controls: These are diluted and aliquoted according to the Quality Management Program Appendix A: Sensitivity, Tonsil and Placenta Control Dilutions. They are then tested on the next run along with the current controls, with each new lot/delivery or at least every 6 months.
      10. Purchased Master Mixes: These are tested with current sensitivity controls. Controls should react as expected.
      11. Gels: New agarose gel lots are checked for clarity when photographed.
          1. The person that pours the Gel will choose the oldest Gel by looking at “Date Made” on the bottle. If it needs to be QC’d, a QC order label will be on it.
          2. The person that takes the gel pictures will put the QC result into TQC using the Total QC Result Entry procedure. They will place the lot label on the bottle and write “QC’d” on the bottle.
      12. Batches of prepared acrylamide will be made and used in the same day. QC is documented by the acceptance of results by the Director or Pathologist.
      13. DNA Extraction kits: These are QC’d by observing the DNA ladder for good quality.
      14. EZ Methylation: This is compared against previously run cell lines or positive patient samples.
      15. FISH:
          1. New lots of 1p19q probes are tested with a previously tested patient sample upon initial use. Assay must perform as expected.
      16. *BCR*-*ABL1* qualitative RT-PCR:
          1. RT kits are tested with the HC and ISCAL controls from the *BCR-ABL1* ISMMR kit and should perform as expected.
          2. ISMMR and mbcr kits have standard controls supplied in each kit, which are tested during each run. The standard curve must meet the criteria listed in the *BCR-ABL1* procedure.
          3. An external low positive control is run with each new lot of BCR-ABL1. RNA is extracted from the controls and the concentration is determined by spectrophotometry. This is diluted with water to 100ng/ul and aliquoted into single use tubes. These are stored at -80°C until ready to use.
   3. **Instruments**
      1. The performance of all instruments and equipment is verified prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations.
      2. Microscopes are cleaned and inspected yearly by an outside vendor.
      3. Water Baths and Incubators:
         1. If not monitored automatically by Aeroscout (See the Aeroscout Mobile View Temperature Recording Procedure), displayed or preprogrammed temperatures of all water baths and incubators must be verified daily or before each use using thermometers which have been previously checked against a certified NIST thermometer. Temperature checks are documented on the **Temperature Form**.
         2. Water baths are cleaned monthly and after contamination and are documented on the **Yearly QC Form**.
      4. Refrigerators and Freezers: Temperatures are monitored automatically by probes in each unit. Refer to the Aeroscout Mobile View Temperature Recording Procedure.
         1. If storage temperatures exceed the tolerance limit for an extended period of time and the reagents integrity is questioned, items in that refrigerator or freezer will be QC’d again before being put onto clinical use.
      5. Centrifuges: High speed centrifuges are checked yearly for RPM’s and are under service contracts through the Biomedical Department. Preventative maintenance and service records are kept by the Biomedical Department. Centrifuges are wiped down with ethanol daily. If contaminated, clean with 10% bleach followed by distilled water.
      6. Microcentrifuge: These are cleaned weekly with 10% bleach.
      7. Flow and Fume Hoods: Hoods are monitored and calibrated by an outside vendor hired by the hospital. They are cleaned prior to use with 10% bleach followed by distilled water or with a DNAse Away product. Clear plastic surfaces are cleaned with an ammonia-based glass cleaner.
      8. Gel Boxes: These are washed in double distilled water and detergent weekly. Combs are cleaned with 10% bleach and washed two times with distilled water.
      9. Gel Power Packs: The voltage should be tested by the Biomedical Department if electrophoresis times appear to deviate from the normal times. At 20 watts per acrylamide gel, run time is 50±5 minutes. For agarose gels 8X8 cm at 80 volts, gel run time is 60±10 minutes.
      10. Spectrophotometer: This will be checked for linearity every 6 months with a solution of Hind III DNA and the results are documented on the Spectrophotometer QC Spreadsheet. This is saved on the RICMBLAB$ shared drive, within the QC Folder. A set of serial dilutions of DNA of known concentration should be read at 260 nm and 280 nm. Ratios of A260/A280 and A260/A230 should be recorded. See Spectrophotometer Worksheet for instructions. Significant deviation from linearity requires a service call. The calibration curves should be repeated if the machine is serviced, or a lamp is changed.
      11. Thermometers: Non-certified thermometers are checked against a NIST-certified thermometer before initial use and annually after that. All temperatures are recorded on the **Annual Aeroscout Probe and Thermometer Form** and must be within the range specified on the sheet.
      12. Balance: This is checked annually by an outside vendor and the results documented. Any deviation above 10% requires a service call.
      13. PCR Machines: These are calibrated before they are put into use and monthly thereafter. The monthly calibration is documented on the **Thermal cycler QC Form – Monthly**. Service is done through the Biomedical Department. The machine blocks are cleaned monthly with ethanol. The wells of the PCR blocks are tested using the *TP53* primer QC reaction on an every-other-month schedule. 16 or 24 wells are checked each time on a rotating basis so that each well is checked once per year. This is documented on the **Thermal cycler QC Form – Bi-monthly.**
          1. Primers for QC: Add equal volume of each *TP53* primer to create a primer mix to add to the PCR master mix.
          2. p53 exon 7 sense primer, 100 uM in water 5 ’TCC TAG GTT GGC TCT GAC T
          3. p53 exon 7 antisense primer, 100 uM in water 5’ CAA GTG GCT CCT GAC CTG
      14. FISH Hybridizer: Temperatures are checked with a thermocouple and recorded each day of use on the **Hybridizer Temperature QC Form**. Each slide position is checked at least once per year by moving the probe to a new slot position each month.
      15. ABI 3500 Sequencer: Monthly maintenance notifications are on the home screen. Once performed, they are documented on the **ABI 3500 Maintenance Form** in the 3500 Instrument Binder. Yearly maintenance is performed by the company under a service contract.
      16. Promega Maxwell: The Maxwell instruments are cleaned before each extraction with a 70% ethanol wipe-down. After each run, A UV light is turned on. If contaminated, cleaning is performed with 10% bleach followed by a distilled water rinse.
      17. Real-Time PCR Instruments: All required maintenance is documented on the individual Instrument Maintenance Forms. Service is performed by the appropriate company under a service contract.
      18. QIAcube: All required maintenance is documented on the **QIAcube Maintenance Form.**
      19. MiSeqDx: All required maintenance is documented on the **MiSeq Maintenance Form**.
      20. NextSeq: All required maintenance is documented on the **NextSeq Maintenance Form.**
      21. Bio-Rad Camera: All required maintenance is documented on the **Bio-Rad Gel Doc Maintenance Form.**
      22. Cepheid GeneXpert: All required maintenance is documented on the **Cepheid GeneXpert Instrument Maintenance Form**. Yearly maintenance is performed by the appropriate company under a service contract.
      23. BioView: Maintenance and service is performed under a service contract. Fluorescent bulb in-use time is tracked automatically by the power supply. The bulb is changed at 2000 hours, according to the manufacturer’s recommendation.
      24. Tolerance Limits
          1. 37°C Waterbath: 37°C ± 3°C
          2. Heat blocks: 70°C ± 2°C and 55°C ± 2°C
          3. 55°C Waterbath: 55°C ± 5°C
          4. 65°C Waterbath: 65°C ± 5°C
          5. Refrigerators: 5°C ± 3°C
          6. -20°C Freezers: -20°C ± 5°C
          7. -80° Freezers: -80°C ± 10°C
          8. Balance: ± 10% of weight
          9. FISH Waterbaths: ± 1°C of set temperatures inside Coplin jars
      25. Water Quality: Megohms are documented daily on the **Water Filtration System Check Form**. Bacterial cultures are performed at least quarterly. If either of these is out of range, American Aqua is called. American Aqua inspects the main water feed yearly.
      26. Comparability of Instruments and Methods: Twice per year, we will compare results of our single gene assays to our NGS assays. We will also compare assays performed on our two QuantStudio instruments. Results will be documented on the **Comparability of Instruments and Methods Form**. Results must match to be acceptable.
   4. **Controls**
      1. Controls are run with each assay and are specified in each assay procedure. They are tested in the same manner and by the same personnel as patient samples.
      2. The results for controls are reviewed for acceptability before reporting of results.
      3. Controls that exceed acceptability are documented in Total QC using the Corrective Action option. The Senior Tech and Directors/Pathologists are responsible for following-up on those instances and developing appropriate action.
      4. Numerical controls are recorded and reviewed at least quarterly to monitor trends over time. Variation within a lot of 2 standard deviations will be brought to the director for review.
      5. Pass /Fail results for non-numerical controls are recorded and reviewed monthly. Two control failures within a lot will be brought to the director for review.
2. **POST-ANALYTIC PROCESSES**
   1. **Reporting of Results:**
      1. When testing is completed, the technologist, Director, or Pathologist makes sure that the control results are adequate. No results should be reported for an assay if QC has failed unless with Director approval.
      2. The Pathologist or Director will score the results of tests and confirm the specimen adequacy by checking the QC reaction.
      3. Results will be reviewed by the Lab Director or Pathologist and signed out in SoftMolecular by the Pathologist or Director.
         1. However, results are often reviewed by multiple laboratory personnel prior to final sign-out, including some combination of technologist, bioinformatician, lab director, and pathologist (depending on the test; see individual assay procedures for workflows).
         2. Some tests results are reviewed through Soft Molecular by the Senior Technologist or Director approved designee for typographical/clerical errors.
         3. This system ensures multiple checks on result entry to ensure accuracy of the results prior to sign-out.
         4. In addition, the system also ensures competency of users, in terms of usage of the Soft Molecular LIS, scientific performance and medical interpretation.
            1. Occasionally, samples that were previously tested are re-tested for clinical purposes. For example, the clonality assays may include testing of prior specimens in comparison to current specimens to identify clonal relationships between specimens. This system results in re-review of prior interpretations made by the Lab Director or Pathologists and ensures accuracy, consistency, and competency.
            2. For assays that have interpretative comments, statements made in prior reports are occasionally reviewed by the Pathologists and this system ensures accuracy, consistency, and competency of clinical interpretation.
      4. If appropriate: for results entered into the SoftMolecular LIS, a Daily Result Log can be generated and reviewed to confirm the result was entered correctly.
      5. If there is a discrepancy found in the reporting of a result, the result is updated with the correct information in the LIS. If appropriate, the physician is immediately notified (for example, if there is a change to Final Diagnosis) and the event is reported in the Safety Net System.
      6. Turnaround times are monitored. A goal of 5-7 working days turnaround for most PCR assays is in place. The turnaround times for Actionable Mutation Panel are monitored. If a trend toward increased turnaround time is identified, appropriate corrective action will be instituted. If there is a known delay in turnaround time for an assay, the physician will be notified directly.
         1. The target turn-around-time (TAT) for the Actionable Mutation Panel is 90% of samples within 10 business days, with a threshold of 80% at within 10 business days. Individual samples are added to a log maintained by the Manager, along with TAT in business days (from the day that processing starts until the day of sign-out).
      7. Test results are compared with those of other laboratories when appropriate. Because of the specialized nature of testing in this laboratory, direct correlation of results with other assays is usually not possible or appropriate. Corrective action is taken when necessary.
      8. Test results are only released to the ordering physician or another physician in charge of the patient’s care.
   2. **Record Retention**
      1. Requisition Slips: These are scanned into the EMR.
      2. Instrument Maintenance: These are kept in the lab while the instrument is in use.
      3. Quality Control, Proficiency Testing, Quality Management, and Training/Competency Records are held for at least 5 years.
      4. Validation/Verification Summaries: These are held in the Manager’s office until 2 years after the test is discontinued.
      5. Patient test records: These are kept within the SoftMolecular LIS system indefinitely.
   3. **Specimen Retention**
      1. Blood and Bone Marrow Aspirates are kept in the refrigerator for two weeks.
      2. Body fluids are kept in the refrigerator for one week.
      3. CSF is kept in the refrigerator for one month.
      4. FFPE blocks are returned to Histology after testing is completed.
   4. **DNA and RNA Retention**
      1. DNA isolated for genetic or oncology testing is kept indefinitely and stored at -20°C.
      2. RNA isolated for genetic or oncology testing is kept indefinitely and stored at -80°C.
   5. **FISH Retention**
      1. FISH slides that have been hybridized will be retained for 1 month due to fluorescence decay over time.
      2. Images of FISH assays are retained a minimum of 20 years.
      3. For each sample, each reviewer/technologist should take two representative images of representative cells (total of at least 4 cells per case).
3. **DATA MANAGEMENT**
   1. General laboratory data management policies and procedures can be seen under the Next-Generation Sequencing Infrastructure Policies document.
   2. Transfer of data should be in compliance with Lifespan IS Policy HSP-97. Specific examples of transfer methods include:
      1. Data transfer events are documented in the DataTransferLog.xlsx file located at \\lsfile03\ RICMBLAB$\Problem log\DataManagement
   3. Long-term storage of data
      1. Certain data is stored in external hard drive of network drives for the long-term. The addition of this data (or deleting, based on lab policies) is recorded in the DataLongStorage.xlsx file located at \\lsfile03\ RICMBLAB$\Problem log\DataManagement
4. **GENETIC TESTING**
   1. Reporting of Incidental or Secondary Findings
      1. Genetic findings unrelated to the clinical purpose for testing are reported if appropriate and as applicable to the specific assay.
      2. Actionable Mutation Panel:
         1. This assay is designed to detect somatic mutations in cancer specimens and cannot definitively identify germline mutations. However, criteria are used to interpret variants as benign and likely benign and, if appropriate, this is reported using Tier IV of the clinical report.
         2. In most cases, synonymous and intronic variants are not reported; however, if clinically relevant, these variants may be reported by the Director/Pathologist with appropriate comment.
      3. Solid Tumor Fusion Panel:
         1. This assay is designed to detect somatic mutations in cancer specimens and cannot definitively identify germline mutations. However, criteria are used to interpret variants as benign and likely benign and, if appropriate, this is reported using Tier IV of the clinical report.
5. **DOCUMENTATION OF LABORATORY ISSUES**
   1. An electronic problem log is retained for issues within the lab, located at \\lsfile03\ RICMBLAB$\Problem log.
   2. Within this folder, there are subfolders dedicated to different assays and processes within the lab. Some folders contain Excel/Word documents summarizing issues, and these files are periodically reviewed by the Lab Director(s).
   3. In addition, since the implementation of Soft Molecular, issues can also be documented within the LIS in a variety of ways, including (but not limited to):
      1. Internal notes
      2. Notes on worksheet headers
      3. Notes within tasklists
      4. Comments on the test report
6. **REVISIONS:**
   1. 3/14/2018: Inclusion of low positive external controls for BCR-ABL kit QC, updated retention information on FISH slides, and comparability of instruments.
   2. 1/3/2019: Clarification on the order of loading samples and controls in PCR set up, FISH control slides, FISH hybridizer QC and Comparability of instruments. Updates made to the entering of results and storage of RNA and DNA.
   3. 1/19/2020: Incorporation of SoftMolecular and Total QC information, and updated footer to reflect new laboratory name.
   4. 10/5/2020: Clarification on the way samples are loaded, incidental findings for the Fusion Panel and the addition of the NextSeq maintenance.
   5. 11/18/2022: Updated to include Cepheid and changes to data storage/transfer and Lab Problem log