**Coro Molecular Microbiology 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. This procedure includes pre-analytic instructions including specimen collection, transport, and processing. It also includes analytical variables including standard laboratory practice and quality control processes. Post-analytic instructions include reporting processes, report review, error corrections and specimen retention.
2. **PRE-ANALYTIC**
   1. Molecular Laboratory Standard Practices
      1. **Laboratory access is restricted to authorized individuals.**
      2. Universal Precautions with appropriate PPE are employed when handling all patient material, during instrument maintenance, troubleshooting, cleaning and when disposing of biohazardous waste or cleaning up spills.
      3. Clean gloves must always be worn and should be changed whenever potentially contaminated. Separate lab coats and gloves must be used for pre and post PCR work areas.
      4. A dedicated set of pipettes must be used for each different type of procedure.
      5. 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.
      6. Environmental wipe tests are performed monthly for each assay/ instrumentation area to monitor for contamination.
      7. Barrier pipet tips are used for all repetitive pipetting and great care is taken to prevent contamination of reactions.
      8. Smoking, eating, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting are prohibited in the laboratory.
      9. All supplies such as pipette tips, microcentrifuge tubes, etc. shall be sterile, disposable, and used only once.
      10. The use of serological pipets and graduated cylinders are limited to the preparation of bleach solution and Extran solution for decontamination and instrument maintenance.
      11. 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.
   2. 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 – for those specimen types that are difficult to recollect, have the person responsible for correctly identifying the specimen fill out **Patient Identification Sheet** and give it to the manager. 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 physician is notified.
      4. Plasma for HCV viral load testing and genotyping can be drawn in an EDTA or PPT tube. Plasma for HBV or HIV viral load testing can only be drawn in an EDTA tube. A dedicated tube is required for molecular testing. The tubes are spun at 3000 rpm for 20 minutes within 6 hours of collection (PPT tube is stable spun for 48 hours refrigerated) and the plasma is transferred to an aliquot tube. The aliquot tube is frozen at -70°C before transport to the laboratory.
      5. Specimens for Gonorrhea, Chlamydia, and Trichomonas are collected with the appropriate collection kit.
      6. HPV specimens are collected in Thin Prep vials. The laboratory will aliquot some of that fluid into the appropriate collection container for testing prior to Cytology processing.
      7. No aliquot will be returned to the original container.
   3. Specimen Transport
      1. Samples are transferred between hospitals and the laboratory by couriers using properly labelled coolers.
      2. Each sample arrives with a downtime slip, or a Soft tracking list.
      3. The person receiving the samples follows the Coro Molecular Microbiology Soft Procedures to receive the samples.
      4. All Soft tracking lists will state the temperature that the specimens are to be transported in. The person receiving the specimens is to ensure that they are received at the correct temperature. They then sign the packing list, ensuring that the list is complete and the samples were shipped at the correct temperature.
   4. Sample Processing and Storage
      1. Samples for GC, CT, Trich and HPV are held at room temperature.
      2. Samples for Viral load and Genotyping are stored in the freezer at -70°C.
      3. Cytology samples for HPV are aliquoted by the Tomcat instrument. The original containers are packaged and sent back to Cytology by courier.
3. **ANALYTIC**
   1. Quality Control
      1. All QC documentation is monitored bi-weekly by the Quality Control Designee.
      2. All QC results are recorded on QC forms. All out of control results are reported to the Lead/Senior Tech or manager, and the corrective action taken is recorded on the Invalid Assay Form.
      3. Daily, working surfaces and pipetters are cleaned before and after each use with 10% or 50% bleach or other appropriate disinfecting solution followed by distilled water and/or 70% alcohol, depending on the assay, and is documented on the **Decontamination Form.**
      4. Pipetting devices are inspected before each use. Pipettors are checked for calibration accuracy every 6 months by an outside vendor. Broken pipettors are returned to the manufacturer or calibration vendor for repair and calibration.
      5. Humidity is monitored automatically by probes in the laboratory. Refer to Aeroscout Procedure.
      6. 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.
   2. Reagents and Supplies
      1. All reagents are labelled with:
         1. Content and quantity, concentration or titer
         2. Storage requirements
         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.)
      2. Containers for prepared reagents must list the content, concentration, preparation, quantity, expiration date, storage conditions, and hazardous pictogram. All bottles must be dated when opened. Chemicals are not returned to the original container after weighing, and excess chemicals are discarded.
      3. 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.
      4. Outdated material and reagents and those that fail performance standard are discarded.
      5. Upon receipt, kits to be QC’d are placed in a designated area and labelled ‘QC Needed’ with the received date marked on the boxes.
      6. Each new batch, lot number and/or shipment is tested.
      7. Manufacturer’s recommendations are used for QC testing.
      8. Once QC is completed, the document sheet is stored in the Kit QC section of the appropriate QC book. A green sticker stating, “QC Performed On” with the date added is placed on each kit. The kit is then placed into use.
      9. QC of molecular assays is addressed in each individual test procedure and documented in QC sheets in the QC binder.
   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. This is done by performing controls and/or verification panels to ensure proper function.
      2. For Quantitative Viral load assays a linearity panel is run at least every 6 months and with a change of kit lot number for verification of the analytical measurement range. Records are kept in the QC binder. Previously tested patient specimens which include 3 levels of quantitation that test the linear range are acceptable when purchased material is not available. An unacceptable result would be an R² value <0.9900 or 2 panel members with a >0.5 Log difference and would warrant an investigation and repeat.
      3. Preventative Maintenance records are kept in the ‘Maintenance Log Book’ along with all the other maintenance records for the life of the instrument.
      4. Refrigerators and Freezers: Temperatures are monitored automatically by probes in each unit. Refer to Aeroscout 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: Centrifuges are checked yearly for RPM’s and the records are kept by the Biomedical Department. Preventative maintenance and service records are kept by the Biomedical Department.
      6. 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 70% alcohol.
      7. There are individual procedures for each testing instrument that address QC and maintenance that needs to be done. Refer to individual procedures for detail.
      8. Individual wells (or a representative sample) of thermocyclers are checked for temperature accuracy before being placed into service and at least annually thereafter.
      9. Interface Autoverification is validated yearly and with any major instrument or LIS change.
      10. Validation of Calculations for Cobas Analyzer is performed yearly and with any major instrument or LIS change.

Refer to Appendix A: Cobas Analyzer Calculation QC

* + 1. Comparability of Results QC is performed twice per year on the Panther Systems.
  1. 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. Quantitative tests require three controls daily, including a negative, low positive, and high positive.
     3. Qualitative tests require a positive and negative control daily.
     4. The results for controls are reviewed for acceptability before reporting of results.
     5. Controls that exceed acceptability are logged into a problem log. The Senior Tech and Directors are responsible for following up on those instances and developing appropriate action.
     6. For each quantitative assay QC statistics are calculated and reviewed monthly to define analytic imprecision and monitor trends over time. Refer to Viral Load Monitoring in the QC book and folder on M drive.

1. **POST-ANALYTIC**
   1. Reporting of Results**:**
      1. When testing is completed, the technologist makes sure the controls are adequate. No results should be reported for an assay if QC has failed.
      2. All results that are entered manually must be checked for accuracy.
      3. Manually entered results will be reviewed by the Senior/Lead Technologist or Manager.
      4. If there is a discrepancy found in the reporting of a result, the physician is immediately notified, the result is updated with the correct information as well as the original incorrect information and the event is reported in the Safety Net System.
      5. Test results are only released to the ordering physician or another physician in charge of the patients’ care.
   2. Statistics

Note: Any drastic fluctuation is brought to the attention of the lab manager and director.

* + 1. Daily
       1. The percent positive for GC, CT, Trich and HPV are recorded daily on QC sheets.

1. Repeat testing of positive and equivocal samples is necessary when the positivity rate is above the established threshold.
   * 1. Monthly
2. HIV, HBV, HCV Viral Load totals
3. HCV Genotype totals
4. HPV, HPV Genotypes, GC, CT and Trich Totals and Positivity rate
   1. Record Retention
      1. Requisition Slips: These are scanned into the EMR.
      2. Instrument Maintenance: These are kept in the lab if 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 until 2 years after the test is discontinued.
      5. Patient test records: These are kept within the SoftLab LIS system indefinitely.
   2. Specimen Retention
      1. Plasma samples are saved at -70C for 6 weeks after completion.
      2. GC/CT/Trich samples are saved at room temperature for 1 week after completion. Positive Child Safe Clinic patients and patients under the age of 14 are saved at -70C indefinitely.
      3. HPV
         1. Negative samples are saved at room temperature for 1 week after completion.

b. Positive samples are saved at room temperature for 6 weeks after completion.

* + 1. HPV Genotype samples are saved for 1 week after completion.
    2. Aliquoted Thin Prep samples are saved for 8 weeks after receipt.
  1. Turn Around Time
     1. Two to five days after receipt in the lab for all assays performed.
     2. Any potential delay in turnaround time is communicated to the outreach laboratory supervisor and the Medical Director.
  2. Taxonomy Changes
     1. Taxonomic nomenclature is reviewed annually to ensure accuracy of reporting patient and proficiency testing results.
     2. Nomenclature changes will be verified in IJSEM before changes are made.
     3. All nomenclature changes are made in collaboration with prescribers, antimicrobial stewardship teams, and infection control committee, as appropriate. Any changes will be documented.
     4. Evidence of review and records of review can be found on the shared M drive\ CAP\CAP Documentation\ Nomenclature changes.

1. **Attachments**
   1. Coro QM Procedure Appendix A: Cobas Analyzer Calculation QC
2. **REVISIONS**
3. 1/21/2020

1. Deleted footer and updated signage page.

2. Updates regarding monitoring QC statistics for quantitative assays, checking the

AMR at changes of lot numbers for quantitative assays, and acceptance criteria for

verification of AMR

3. Added Taxonomy information