TABLE OF CONTENTS

Introduction

The Abbott Architect System is a fully automated random access analyser that utilizes a chemiluminescent microparticle immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemflex®. At first, sample containing either Antigen or Antibody is combined with Antigen or Antibody coated paramagnet particles. Antigen or Antibody present in the sample binds to the Antibody or Antigen coated paramagnet particles. After washing, acridinium-labeled Antigen conjugate or Antibody conjugate is added in the second step. Following another wash cycler, Pre-trigger and Trigger Solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light unit (RLU). A direct relationship exists between the amount of Antigen or Antibody in the sample and the RLUs detected by the Architect System optics.

Assays run in the Architect are as follows:
Anti-HBs, Anti-HBc II, Anti-HBc IgM, Anti-HCV, HIV Ag/Ab Combo, HAVAb-IgG, HAVAb-IgM, HTLV I/II , CMV IgG, CMV IgG Avidity, CMV IgM, EBV VCA IgG, EBV EBNA-1 IgG, Rubella IgG, Syphilis TP, Toxoplasma IgG, HBsAg Qualitaitve II, and HBsAg Qualitative confirmatory.

***Note**: HAVM, HBCM and CMV Avidity are NOT validated on iSR53877 (module 2).*

Specimen Collection and Processing

Specimen collected (5mL for adult and 1mL for neonates) in serum separator tube or potassium EDTA tubes may be tested on Architect. For other specimen type refer to each assay package insert.

Testing of cadaveric blood specimens from patients with plasma dilution due to transfusions of >2000mL of blood or colloids within 48 hours, or >2000mL of crystalloids within 1 hour (or any combination thereof) prior to collection of the specimens have not been validated.

- Follow the tube manufacture's processing instructions for serum and plasma collection tubes. Gravity separation is not sufficient for specimen preparation.
- Previously frozen specimens must be thawed thoroughly.
- Mix thawed specimens by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at ≥10,000 RCF for 10 minutes before testing if:
    - They contain fibrin, red blood cells, or other particulate matter
    - They require repeat testing, or

- They were frozen and thawed

Transfer clarified specimen to a sample cup or secondary tube for testing.

- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.

Proficiency testing specimens must follow the accompanying guidelines for processing and storage.

Collected Specimen Storage prior to testing

The table below indicates the appropriate storage conditions for samples from time of collection for testing to be valid.

Assay	Storage at 2-8 ^{o}C	Storage at ≤ -20 ^{o}C
HBsAg Qualitative II	6 days	>6 days
HBcAb (Total)	Living: 14 days Cadaveric: 7 days	Living: >14 days Cadaveric >7 days
HBc IgM	7 days	>7 days
HBsAb	14 days	>14 days
HBsAg Qualitative Confirmation	6 days	>6 days
HCV Ab	7 days	>7days
HIV 1&2 Ag/Ab Combo	14 days	>14 days
HTLV-I/II Ab	Living: 14 days Cadaveric: 7 days	Living: >14 days Cadaveric >7 days
Syphilis TP	7 days	Living: ≤ 30 days Cadaveric ≤ 11 days
EBV VCA IgG	14 days	>14 days
EBV EBNA-1 IgG	14 days	>14 days
CMV IgG	14 days	>14 days
CMV IgM	14 days	>14 days
CMV Avidity	14 days	>14 days
HAV IgG	14 days	>14 days
HAV IgM	7 days	>7days
Rubella IgG	14 days	>14 days
Toxoplasma IgG	14 days	>14 days

Assay Interference Criteria

Assay	Interference	Concentration	Effect
HBsAg Qualitative II	N/A		
HBcAb (Total)	N/A		
HBc IgM	N/A		
HBsAb	N/A		
HBsAg Qualitative Confirmation	N/A		
HCV Ab	N/A		
HIV 1&2 Ag/Ab Combo	N/A		
HTLV-I/II Ab	N/A		
Syphilis TP	Triglycerides Bilirubin Protein Hemoglobin	3000 mg/dL 20 mg/dL 12 g/dL 500mg/dL	<0.40 S/CO difference on negative specimens <20% S/CO difference on positive samples
EBV VCA IgG	N/A		
EBV EBNA-1 IgG	N/A		
CMV IgG	N/A		
CMV IgM	N/A		
CMV Avidity	N/A		
HAV IgG	N/A		
HAV IgM	N/A		
Rubella IgG	Triglycerides Bilirubin Hemoglobin Red Blood Cells Total Protein	3000mg/dL 20 mg/dL 500mg/dL 3-12 g/dL	$\leq$ 10.0 $\leq$ 10.0 $\leq$ 10.0 $\leq$ 10.0
Toxoplasma IgG	N/A		

Specimen Rejection Criteria

Grossly hemolysed samples

- Visually determine the degree of hemolysis of the sample before loading in Architect. For grossly hemolyzed sample please consult the Seniors or Charge Technologist on how to proceed.

After Hours Shifts:

- Use the prepared hemolysed tubes or colour chart as guide:
  Specimen is considered as Grossly Hemolyzed if it matched with the 5% v/v RBC or 500 mg haemoglobin/dL or Hemolytic Index >200 .

Reporting: result each test as:

"Not Processed" with canned message **@8GRH**
"Specimen was grossly hemolysed, unsuitable for testing"

Inform the ward.

Materials and Reagents

Reagents and bulk solutions

Do not use any material or reagent beyond expiration date.

REAGENT KIT, CONTROL KIT, CALIBRATOR KIT: Instructions must be carefully followed in each assay package insert. Stored at 4 ^{o}C.
- Microparticle bottle requires mixing / inverting prior to first time loaded onto instrument and prior to septum placement.
- Septums must be used on all assay reagents to avoid evaporation and maintain integrity.

CONCENTRATED WASH BUFFER: Must be diluted prior to use. Contains 1.5M phosphate buffered saline with antimicrobial agents. Stored at room temperature.
PRE-TRIGGER SOLUTION: Contains 1.32 %(w/v) hydrogen peroxide. Once opened, placed on board the system no longer than 28 days, then discarded. Stored at 4 ^{o}C.
TRIGGER SOLUTION: Contains 0.35N sodium hydroxide. Once opened, placed on board the systems no longer than 28 days, then discarded. Stored at room temperature.
PROBE CONDITIONING SOLUTION: Contains recalcified human plasma; has infection risk. Preservatives: Antimicrobial Agent and ProClin 300. Stored at 4^{o}C.

Equipment and Materials

- ARCHITECT i System
- ARCHITECT i System Assay CD-ROM
- ARCHITECT i reaction vessels
- ARCHITECT i sample cups
- ARCHITECT i septum
- ARCHITECT i replacement caps

- Pipettes

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operation Manual.

Daily Procedure Overview

1. 'Log on" in Architect

2. **Perform required maintenance:**
   - Daily Maintenance
     - Loading reagents
     - Architect Maintenance
     - LIS QC
   - Weekly Maintenance
     - Data Back-up
     - Architect Maintenance
     - LIS QC

3. **Run Architect Controls**
   - Running Controls
   - Troubleshooting QC Violation Rules
   - Post control results
   - Activating a new lot of controls
     - Activate in LIS
     - Activate in Architect
   - External controls

   Reagent Calibration

4. **Run Specimens**
   - Donor/Recipient Specimen Processing
   - TGLN Specimens
   - Manually add an Order
   - Loading Specimens
   - Replenishing Supplies

5. **Routine Specimen Reflexing and Resulting**
   - Reagent Cut-off Values
   - Reflex Testing and Resulting Table
   - Hepatitis B Qualitative Confirmatory Testing Algorithm
     - HBsAgQ2_Procedure

HBsAgQ2 Calibration
HBsAgQ2 Controls
HBsAgQ2 Confirmation Interpretation
HBsAgQ2 Dilution Procedure

Donor Specimen Reflexing and Resulting

6. Architect Troubleshooting

7. Leave architect in “Running Mode” when unused so that all the solutions will be flushed regularly

Daily Maintenance

Touch '**Log Off**' to log-on with your initials.

Complete daily maintenance as follows:

Loading Reagents

Selecting Reagents to Load

- At snapshot screen: touch SCC (system control center) and RSH (Robotic sample handler) and '**Pause**'. The status will change from '**Running**' to '**Ready**'.
  (The opening of Reagent Carousel lid and turning of the carousel can only be done when Architect is in '**Ready**' mode.)
- Check 'Supplies' to ensure adequate consumables on board. A yellow caution symbol will appear when reagents or reaction cells are less than 20%. This consumable should be loaded immediately or the next time the machine is on pause.
- View Reagent Load List to determine which kits need to be loaded. You may print the Load list if needed.
  (Touch Reagent Icon on Snapshot, '**View All**', Touch '**ASSAY**' to group same reagents together)
- Run Architect Daily Maintenance while preparing reagents to load.

Preparing reagents to load

- Take out adequate reagents according to the Reagent Load List**! Invert the microparticle bottle (pink label) 30 times for the first time loading on the ARCHITECT system**
  ! If the microparticles do not resuspend, DO NOT USE. Contact senior/charge technologist
- Replace reagent cap with a clean septum after resuspension of microparticles.
- On the reagent package, write down the **SN#** from the MICROPARTICLE (pink) bottle
- Once Architect Daily Maintenance is complete proceed to load reagent bottles.
- Load the reagent bottles onto architect according to the color of the labels and the colour on the rings.
- **Note that Anti-HCV reagent cannot be loaded on the same module as rHTLV-I/II reagent due to possible interactions when Anti-HCV is tested directly after rHTLV-I/II** if only one module is available please refer to Troubleshooting section
- All Anti-HCV Reagents already on board should be inverted 3 times.

Loading Supplies

Load any other low supplies. See Replenishing Supplies Section

Architect Daily Maintenance

- SCC and RSH should still be in **"Ready"** mode
- Touch '**System**' and '**Maintenance**' Highlight '**6041 Daily Maintenance**' '**Perform**' at the bottom of the screen
- Fill WZ probe maintenance bottle with 25-30 ml of 0.5% Hypochloride (Javex) (2.0 ml of Javex with 400 ml of tap water, is good for one month)
  The maintenance bottle **DOES NOT need a septum.**
- Place a clean septum on probe conditioning solution bottle if a new bottle is opened
- Follow the architect instructions. Maintenance will take approximately 21 minutes.
- When completed, empty 0.5% Hypochloride bottle and rinse it with tap water.

LIS Daily QC

Document Laminar flow hood (MIBCT4) cleaning in 'mic'-go

- 'RESULT'-'Worklist"- Virology Architect.

Weekly Maintenance

Architect MUST be on Ready mode.

Back up weekly

QC and Results must be backed up weekly

1. Back up files to Architect
   - Set architect on the '**Ready**' mode
   - From snapshot screen, touch '**System**', Touch '**Utilities**'
   - Select '**F4-create back up**'
   - Touch '**Done**'

2. Back up test results to CD
   - From the snapshot screen, touch '**Results**'
   - Touch '**Stored Results**', Touch '**Select all**', Touch '**Archive**'
   - **Uncheck** 'delete records after archive before next step'(make sure the ☐ is blank)
   - Touch '**Done**'
   - Follow the onboard instruction
   - Touch '**Done**' when test results back-up is finished
   - Write the back-up date on the CD cover

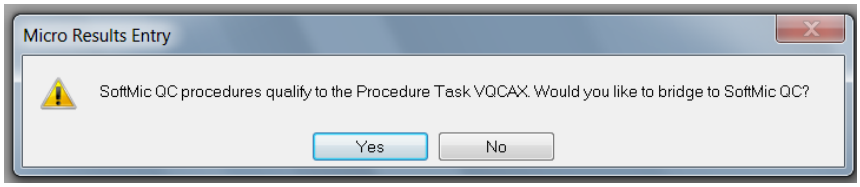
3. Back up QC results to CD
   - From the snapshot screen, touch '**QC-Cal**'
   - Touch '**Stored QC**', Touch '**Select all**', Touch '**Archive**'
   - **Uncheck** 'delete records after archive before next step'(make sure the ☐ is blank)
   - Touch '**Done**'
   - Follow the onboard instruction
   - Touch '**Done**' when results back-up is finished
   - Write the back-up date on the CD cover

Architect Weekly Maintenance

- These procedures appear on the maintenance TO DO list automatically:
  6012 Air Filter Cleaning (Remember to replace & clean the filter **UNDER** the architect)
  6014 Pipettor Probe Cleaning
  6015 WZ Probe cleaning-Manual
- Select each procedure and touch Perform
- Follow onboard instruction to finish each procedure

LIS Weekly QC

- Login to **SoftMic,**
- Click Results**,** click virology Worklist, double click Architect
- Click '**Yes'** in the following window



- Press **F12** key when the QC Result Entry window pops up
- Finish the LIS duties listed

Reagent Controls

Architect positive and negative controls must be run daily (once per 24 hours shift) and with each new reagent **pack.**
Always run the positive control followed by the negative control.

When a new **lot** of controls are opened it must be activated in the LIS and the architect before put into use and the old lot deactivated in the LIS.
In conjunction with the architect controls, for each new lot of reagents, a positive and negative external control must be run.

- Any QC rule violation rules must be addressed before proceeding to process specimens.
- Test is invalid without satisfactory QC results. Do not release reagent for use pending resolution.
- QC must be posted in the LIS.
- Control results are verified by a senior technologist and filed in Architect printout log

CAP, IQMH, and NML provide external proficiency testing

Running Controls

For daily controls, ensure controls are loaded for each reagent on board. A printout of the on-board reagents can be useful to compare to the controls run to the reagents being used.

- Check reagent controls to ensure there is adequate volume in each sample cup to run QC. (If the level reaches the first mark, then it is still good for **one more run)**.
- When volume is too low: change each sample cup and fill up to about 1/3 full. Do **NOT** overfill. Label the top with name of each control; write down lot number, expiration date, and date-in-use on the side.
- If new controls are used, updates in Architect and LIS must be done at the same time. Architect must be paused to change control lots. See Activating a new lot of control section below.
- Once lots are changed continue to Load Controls.

Loading & Ordering Controls

i. Bar-coded controls
   - No ordering necessary on the architect
   - Load bar-coded controls showing barcode directly onto architect

ii. Non bar-coded controls
   To order Controls for specific lot #:
   - Touch '**Order**', '**Control Order**'. Select '**Single Analyte**'
   - Scan in Carrier #, type in position #.
   - Select the assay, e.g. 'HBsAg auto'

- Select the control (P1, P2, Negative)
- Touch '**Add order**'.
- Do this for EACH positive and negative control.

iii. HBsAgQ2 Confirmation Controls

Printing Controls

- Once controls are finished, the '**QC-Cal**' will be flashing.
- Touch '**QC-Cal**', select '**QC result review**'
- Touch '**C/P**' to group same QCs together
- If no flags appear on the QC print-out sheets, print and release QC results and proceed to run patient:
  - Touch '**Select All'**, Touch '**Print**'.
  - For new reagent packs loaded, touch '**details'** on the assay to match SN of QC to reagent pack. Make a note on printout.
  - Once printed, touch '**Release'** to transmit all QC results to LIS
  - For new reagent packs loaded, fill in control results in the Architect Reagent Lot-Cal-QC Chart: T:\microbiology\Virology\architect log sheet\Architect Reagent Lot-Cal-QC chart QPCMI10001a.xls
- If there are QC flags appearing, a pop up will alert on the architect screen. Proceed to QC Rule Violation section for QC troubleshooting.

QC Rule Violations

QC rule violation: a prop up screen will alert us.

- 1-2sd flag: **WARNING flag**
  - Check previous QC result for assay
  - Touch '**QC-Cal**', select '**Levey-Jennings graph**'
  - From **Assay panel**, select the assay which has 2S flag, touch **'Done'**
    - If the 1-2sd flag is the first time, write '1st time' on the QC print-out beside the flag.
    - If the 1-2sd flag is the second time: **REJECT flag**
      - Check control aliquot
      - Repeat QC with new aliquot if aliquot is old
      - If aliquot is new, recalibrate the reagent and repeat the whole set of controls
- If 2 controls are 1-sd: **REJECT flag**
  - Perform calibration on assay and repeat whole set of controls

- 1-3s flag: **REJECT flag**
  - Ensure proper QC sample was run (no mix-up with another QC sample)
  - If the control aliquots are old, change the aliquot and repeat QC
  - If the control aliquots are new, recalibrate the reagent and repeat the whole set of the controls

Posting Control Results in the LIS

QC are designated with an "O" before sequential number. You must go into each QC and post result.

In Soft Lab → Interface Menu

- Choose "Architect"
- 'Open' is highlighted, enter
- Choose result file date you want to post QC for.
- Press "L" for 'Look' – F12
- Post each QC run by pressing "SHIFT" and "+" at the same time. Or, on each test click "Verify all".
- A pop-up will tell you the result was posted.
- Press F5 twice or click to go to next QC result.

Activating a new lot of control

To add NEW control Lot# in LIS:

- Log in to Soft QC
- Select **Maintenance**
  i. Select **"Add new level"**
    - Enter old lot # with N/P/P1/P2 or P3 at the end;
    - Enter New lot # with N/P/P1/P2 or P3 at the end;
    - Press 'F12' 3 times ;
    - Press 'Y'
    - Enter expiration date;
    - Repeat with each level;
    - Once all levels are added, press 'F1' to exit.
  ii. Select **"Deactivate old Lot":**
    - Enter old lot# with N/P/P1/P2/ or P3 at the end;
    - Press 'F12' twice;
    - Press 'Y';
    - Press 'F1' to exit

- Repeat with each level;
- Once all levels are deactivated, press 'F1' to exit

iii. **Activate new lot:**

- Enter new lot# with N/P/P1/P2 or P3 at the end;
- Press 'F12' twice;
- Press 'Y';
- Press 'F1' to exit
- Repeat with each level;
- Once all levels are activated, press 'F1' to exit.

To enter NEW Control Lot# onto Architect:

A. Change control lot number for the **single analyte**

- Log on as '**ADMIN**', pass word' **ADM**'
- Architect must be in **pause mode.**
- Touch '**System**', '**Configuration**', '**QC Cal Setting**'
- In the QC-categories panel, '**QC single analyte**' is highlighted as default.
- In the Assays panel, choose the assay needs to be updated e.g. HBsAg.
- Select '**Configure**'.
- A new screen will come up showing lot #, touch box with bar: 
- Select '**New lot-copy data**' from the drop down menu
- Highlight lot #, enter new lot #, Highlight exp date, enter new exp date.
- Check 'Default', then 'Done'.

B. Change control lot number for the multiconstituent controls: CMV avidity & HBsAgQ2+(HBsAg confirmatory)

- Log on as '**ADMIN**', pass word' **ADM**'
- Architect must be in **pause mode.**
- Touch '**System**', '**Configuration**', '**QC Cal Setting**'
- In the **QC-categories panel** , select **QC-Multiconstituents**
- In the Assays panel, choose the assay needs to be updated: CMV Avidity or HBsAgQ2+.
- Select '**Configure**'.
- Press Ctrl+Alt+Print Scrn, configuration summary sheet will be printed
- Touch box with bar  beside **Level**, select and print out each level configuration summary sheet by pressing Ctrl+Alt+Print Scrn
- Touch box with bar  beside **lot number** .
- Select '**New Lot**' from the drop down menu
- Type now lot# and expiration date
- Highlight the 1st test in the assay panel

- Touch '**Define data**'
- Type the data in the proper place according to the configuration summary sheet for each level. Touch **"Add Level".** Then proceed to enter Level 2.
- Touch '**Done**'
- Repeat from **xiii** to **xvi** for all the assays
- Review the screen against the print out summary to make sure everything is correct
- Check '**Default**'.
- Touch '**Done**'.

External Controls

- External controls are run with each new lot or shipment of reagent after calibration is performed
- External controls should be run on a reagent after any re-calibration.
- Run external control Virotrol for HBsAg after any service.
- External Controls are entered in Architect External QC.xls. All QC controls are verified by a senior technologist.
- If any external control result is out of range, withhold test results. Repeat with a new aliquot and consult with Charge/senior technologists for review

For external control selection see Serology External Control Selection Criteria

Reagent Calibration

Calibration is performed on each new reagent **LOT** or when QC fails as per QC Rule Violations.

Ordering Calibration

- Touch '**Order**' from snapshot screen, select '**Calibration**'.
- Scan in Carrier #, type in position #.
- Select the assay, e.g. 'HBsAg auto'
- Touch '**Assay option…**' to check the in-use calibrator lot number
  i. If the in-use calibrator has **new lot number**
    - Highlight lot#
    - Enter new calibrator lot#
    - Enter new calibrator expiration date
    - Touch '**Done**' button; Touch '**Add Order**'

  ii. If the in-use calibrator has **same lot number**
    - Touch 'Cancel' button, Touch 'Add Order'

See HBsAg Qualitative Confirmation Reagent Calibration

External controls should be run on a reagent after any re-calibration. See external control section

Running Specimens

Specimens are constantly loaded in priority sequence:

i. TGLN specimens
ii. STAT specimens
iii. Donor specimens
iv. Routine specimens

Manually add an Order in Architect

- Touch '**Order**', select '**Patient Order**'.
- Scan in Carrier #. type in position #.
- Touch ID field, scan in order#
- Select all the tests required in **Assay panel**.
- Touch '**Sample details**'.

- Type in '**Last name**' and '**First name**'.
- Touch '**Done**', Touch '**Add Order**'

Loading specimens

- Ensure each label has a "96" extension.
- A sample cup can be placed inside the blood tube if serum/plasma level is low or sample comes aliquoted.
- Once samples are loaded, the Orange light will light up.
- Stat samples can be loaded in individual carrier's slots at any time.
- Carriers can be unloaded if there is solid green lights or flashing green/yellow lights.
    - Carriers can NOT be unloaded if there is solid yellow lights.

STAT specimens

!!!Turn Around Time for STAT Testing is **2 hours**

Needle stick incident

- Source Blood: 8HAGX, 8HCA, 8TSC should always be ordered – tested in house
- Staff Blood: 8HAB, 8HCA should always be tested - tested in house
  Staff HIV Ag/Ab is sent out to PHL for testing.
  Note: For needlestick "immune status" orders, any other tests requested other than those above should NOT be done. Forward requisition to senior/helper.
- In order entry, make sure in the '**Reported to** ' is the respective occupational health department:
    - OHS -MSH occupational health
- All results must be informed to occupational health department by phone or email
    - MSH needle stick results: email results to Occ Health & Safety- MSH (MSH) ohsmsh@sinaihealthsystem.ca
- For any positive results:
    - For **cadaveric** source needlesticks, centrifuge the same aliquot and repeat in duplicate as in the donor reporting section; do not send any samples to PHOL. Phone results as per requisition.
    - For **living** patient source needlesticks, follow the Reflex Testing and Resulting Table regarding any positive results.
        - For regular hours (Monday to Friday from 7:45 to 16:00), contact occupational health department to find out patient's history regarding any reactive results.
        - For after hours (Monday to Friday from 16:00 to7:00), **email microbiologist-on-call** with positive result value, patient's information, and name of attending physician.
- All sera are stored in 10 years storage boxes.

Case room prenatal serology

Specimen is collected from case room patients with NO previous prenatal test results.

Case Room Laboratory Contact Information

- Do all the tests in house. If HIV requested, also order 9HIV and send out unopened specimen or minimum 0.5ml serum to PHL for HIV confirmation testing.
- All results must be phoned to the ward.
- Follow the Architect SOPs regarding any reactive result.
    - Microbiologist on-call must be informed with all reactive syphilis S/CO values.
    - For after hours (Monday to Friday from 16:00 to 7:00), any reactive HIV screening result must be emailed to microbiologist-on-call with result value, patient's information and name of attending physician.
- All sera are stored in 10 years storage boxes

Rapid HIV testing for UHN Emergency only:

- Order 8HIVR (HIV Rapid (for ER only))
- Test HIV in-house
- If positive, report in LIS as positive, confirmation to follow from PHL (send to PHL)
- Call positive result to Emergency
- If negative, report as negative. No need to send to PHL
- Freeze an aliquot of both negative and positive sera

Replenishing Supplies

While running samples, supplies may get low.

Log any buffer, trigger and pre-trigger bottles opened onto **Architect consumable log**

A yellow caution symbol ⚠ will appear when reagents or reaction cells are less than 20% under the appropriate module.

Wash buffer:

- 2 bulk boxes of 10L concentrated wash buffer are on board ALL THE TIME

- Working buffer will automatically be filled by ARM system.
- Can check volume on the wash buffer system screen

Trigger/Pre-trigger solution:

- If less than 20% at the beginning of your shift, change the solution immediately.
- Architect must be in pause mode to replace solution.
- If the caution symbol appears midway through testing, change the solution the next time the architect is paused.

Reaction cells:

- Monitor the supplies caution symbol, however, ensure there are enough RVs in the hopper so the red sensor light is always on.
    1. At snapshot screen, touch '**Supplies'**
    2. Touch '**Supply status'**
    3. Select **'module 1'** or **'module 2'**
    4. Touch '**update supplies'**
    5. Select '**RVs added 500/1000' or** enter estimated number (1 bag has 500 RVs)
    6. Touch '**Done**' and '**Exit**' to go back snapshot screen
       ! Do NOT overfill RVs to prevent RV jam

Liquid waste is drained directly from Architect into the floor drain.

Specimen Pending List

1. Log on 'Lab'.
2. Enter 'ID' &'Password'.
3. Go to "Results", "Result Worklist"
4. Select tests by 'Template'
5. Enter '8SERO' under 'Template', 'Status- pend +nonver'.
6. From order (enter last month's lab #) to' leave it blank'.'F12'.
7. 'F9' to print. Choose a printer to print.
8. Look up each record, and find out why the results are still pending.

Routine Specimen Reflex and Resulting

Printing Results
Once all tests are finished, the 'Result' field will be flashing.

- Touch '**Result**', Select '**Result review**',
- Highlight the results to be printed.
- Touch '**Print**', Select '**Result LIS Report**' and once printed, release highlighted results.
    - For **HBsAg confirmatory** result, select '**Sample Report**')

Result reporting includes auto verification by LIS and manually verification by operator.

- For auto verification process, refer to auto verification process.
- For manually verification, refer to Reflex testing and resulting table
    - Underline any Positive result or anything requiring reflex testing including:
        - Positive: HBsAg Qualitative, HCA, HBcAb, HBcAb IgM, HIV, VD, Low positive CMS, HAVM,
        - Negative and low Positive Rubella
    - Follow Reflex testing and resulting table to report each result.
        - Initial anything you have verified manually
        - Indicate where reflex testing is being done
        - Highlight and mark all NEW Hep B Ag or Hep C Ab results

- Leave completed testing printouts on the senior bench for revision.

- Architect must be on 'running' mode overnight, so that all the solutions will be flushed regularly

Cut-off Values

Assay	LIS code	Neg	Pos	Equivocal/ Gray Zone	Reflex Range
HBsAg (Qualitative)	8HAGX	<1.00 S/CO	≥ 1.00 S/CO		Refer to reflex testing details
HBsAb	8HAB	<10.00 S/CO	≥ 10.00 S/CO		
HbcAbII	8HBC	<1.00 S/CO	≥ 1.00 S/CO		1.00-5.00 S/CO
HbcII IgM	8HBCM	<1.00 S/CO	≥ 1.00 S/CO		
HCV Ab	8HCA	<1.00 S/CO	≥1.00 S/CO		Refer to reflex testing details
HIV 1&2	8TSC	<1.00 S/CO	≥1.00 S/CO*		
HAV IgM	8HAV	<0.8 S/CO	>1.20 S/CO	0.80-1.20 S/CO (Gray Zone)	Refer to reflex testing details
HAV IgG	8HAVG	<1.00 S/CO	≥1.00 S/CO		
EBV VCA IgG	8EBVG	<0.75 S/CO	> or = 1.00 S/CO	0.75-1.00 S/CO (Equivocal)	
EBV EBNA-1 IgG	8EBNA	<0.5 S/CO	> or = 1.00 S/CO	0.5-1.00 S/CO (Equivocal)	
Rubella IgG	8RUB	0.00-4.9 IU/mL	≥10.00 IU/mL 10.0-15.0 IU/mL (Low Level)	5.00-9.9 IU/mL (Gray Zone)	0.00-9.9 IU/mL
CMV IgG R	8CMS	<6.0 AU/mL	≥6.0 AU/mL		
CMV IgM	10CMM	<0.85 Index	≥1.00 Index	0.85-0.99 index	Refer to reflex testing

Assay	**LIS code**	**Neg**	**Pos**	**Equivocal/ Gray Zone**	**Reflex Range**
					details
CMV Avidity	10CMA	<50%(Low avidity)	>50%(High Avidity)		
SyphilisTP Ab	8VD	<1.00 S/CO	≥1.00 S/CO		
HTLV I/II	8HTLA	<1.00 S/CO	≥1.00 S/CO		
Toxoplasma IgG	8TOXG	<1.6 IU/mL	≥3.0 IU/mL	1.6-2.9 IU/mL	
HBsAg Confirmatory	8CON	<50% (Not confirmed)	>50% (Confirmed)		

Reflex Testing and Resulting Table

8HAGX (HBsAg Qualitative)

8HAGX	Patient History	8CHK	Repeat in Duplicates	8CON		Comment
POSITIVE (≥1.00 S/O)	New Positive (≥1.00S/CO)	Enter "New Positive" and verify	Both positive (≥1.00 S/CO)	Yes	Confirmed ≥50% (see confirmation section)	1) 8HAGX: POSITIVE@x1, **verify and call to ward** 2) Order 8CON. 3) Result as "**.Conf"** (ensure there is a dot before) and verify 4) Order 8COM and document repeat results. 5) Highlight 8HAGX new positive on print out and give to Senior for CD
			one Positive (≥1.00 S/CO) one Negative (<1.00S/CO)	Yes	Not Confirmed <50% (see confirmation section)	1) 8HAGX: Indeterminate@x1, **verify** 2) Order 8CON. 3) Result as "**.NotConf"** (ensure there is a dot before) and verify 4) Order 8COM and document repeat results. 5) Consult with Senior or Charge tech.
			Both Negative (<1.00S/CO)	No	N/A	1) 8HAGX:Negative@x1 Auto-verified 2) Order 8COM and document repeat results.
	Previous Positive	Enter "Previous +ve" and verify	N/A	N/A		1) Verify Positive 8HAGX result in LIS 2) Report 8HBC as "Not done Hag+" and verify 3) Delete HBcII in pending list on Architect

8HBC ordered only or HBsAg is 'Negative'

8HBC	8HBC2	Comment
Positive (>5.0 S/CO)	Result 'Not Need' and verify	1) Report 8HBC as "Positive" and verify
Positive 1.0 ≤HBC≤5.0 S/CO	both positive (≥1.0 S/CO)	1) There are 2 8HBC reflexes in the pending list on Architect 2) Do not release HBC result before both 8HBC2 complete 3) Print all 3 8HBC results 4) Release all 3 positive results 5) Take off keypad and report 8HBC2 as "Positive" in LIS and verify 6) Report 8HBC as "Positive" and verify
	one Positive (≥1.0 S/CO) one Negative (<1.0S/CO)	1) There are 2 8HBC reflexes in the pending list on Architect 2) Do not release HBC result before both 8HBC2 complete 3) Print all 3 8HBC results 4) Release both two positive results 5) Take off keypad and report 8HBC2 as "Positive" in LIS and verify 6) Report 8HBC as "Positive" and verify 7) Release negative 8HBC2 from Architect
	Both Negative (<1.0S/CO)	1) There are 2 8HBC reflexes in the pending list on Architect 2) Do not release HBC result before both 8HBC2 complete 3) Print all 3 8HBC results 4) Release both negative results FIRST, 8HBC will be reported as negative and auto verified 5) Then release positive result 6) Take off keypad and report 8HBC2 as "Negative" in LIS and verify

8HCA

8HCA	Patient History	8HCA2	Comment
Positive (≥10.00 S/CO)	New Positive	≥10.00 S/CO	1) Result reflex 8HCA2 as "Positive" and verify 2) Result 8HCA as "Positive"--- **verify and call to ward** 3) Highlight new positive HCA on print out and give to senior for CD
		<10.00 S/CO	1) Repeat one more 8HCA 2) If 2 results out of 3 are >10.00S/CO: i) Result reflex 8HCA2 as "Positive" and verify ii) Result 8HCA as "Positive"--- **verify and call to ward** iii) Highlight new positive HCA on print out and give to senior for CD 3) If 2 results out of 3 are < 10.00S/CO: i) Result reflex 8HCA2 as "Positive" and verify ii) Result 8HCA as "To PHL@MOH+" and verify iii) Order 9HCA and print out send-out form using "RLRF5, RR13" iv) Send specimen to PHL for confirmation
	Previous Positive	N/A	1) Result 8HCA as "Positive" and verify 2) Result reflex 8HCA2 as "Prev. conf" and verify 3) Delete reflex order from pending list on Architect
Positive 1.0 ≤HCA<10.00 S/CO	New Positive	<10.00 S/CO	1) Result reflex 8HCA2 as "Positive" and verify 2) Result 8HCA as " To PHL@MOH+" and verify 3) Order 9HCA and print out send-out form using "RLRF5, RR13" 4) Send specimen to PHL for confirmation
		≥10.00 S/CO	1) Repeat one more 8HCA 2) If 2 results out of 3 are >10.00S/CO: i) Result reflex 8HCA2 as "Positive" and verify ii) Result 8HCA as "Positive"--- **verify and call to ward** iii) Highlight new positive HCA on print out and give to senior for CD 3) If 2 results out of 3 are < 10.00S/CO: i) Result reflex 8HCA2 as "Positive" and verify ii) Result 8HCA as "To PHL@MOH+" and verify iii) Order 9HCA and print out send-out form using "RLRF5, RR13" iv) Send specimen to PHL for confirmation
	Previous Positive	N/A	1) Result 8HCA as "Positive" and verify 2) Result reflex 8HCA2 as "Prev. conf" and verify 3) Delete reflex order from pending list on Architect

8RUB

8RUB	8RUB2	Comment
Negative 0.0-4.9IU/mL	Negative 0.0-4.9 IU/mL Or Gray zone 5.00-9.9IU/mL	1) Result 8RUB2 as "Negative" and verify 2) Result 8RUB as "Negative" and verify
Gray zone 5.00-9.9IU/mL	Negative 0.0-4.9 IU/mL Or Gray zone 5.00-9.9IU/mL	1) Result 8RUB2 as "Negative" and verify 2) Result 8RUB as "Negative" and verify
	Low Positive 10-15IU/mL	1) Repeat one more reflex 2) If 2/3 results are negative or grayzone i) Result 8RUB2 as "Negative" and verify ii) Result 8RUB as "Negative" and verify 3) If 2/3 results are low positive i) Result 8RUB2 as "Low Positive" and verify ii) Result 8RUB as "Low Positive" and verify
Low Positive 10-15 IU/mL	N/A	1) 8RUB will be auto verified 2) Manually change 8RUB result to "Positive@low level" and verify

8TSC

8TSC / 8HIVR	Comment
≥1.00S/CO *Note: for result < **2.00 S/CO** spin & repeat x2.* *If 2/3 positive, continue with reflexes. Document values in comment.*	1) Result 8TSC as "To PHL@MOH+" and verify 2) Result 8HIVR (refer to Architect STAT section) as positive confirmation to follow from PHL. Call result 3) Order 9TSC and print send -out form using "RL10H, RR10" 4) Send specimen to PHL

8HTLA

8HTLA	Comment
≥1.00S/CO *Note: for result < **2.00 S/CO** spin & repeat x2.* *If 2/3 positive, continue with reflexes. Document values in comment.*	1) Result 8HTLA as "To PHL@MOH+" and verify 2) Order 9HTL and print send -out form using "RL10H, RR10" 3) Send specimen to PHL

8VD

8VD	Comment

≥1.00S/CO.	1) Result 8VD as "To PHL@MOH+" and verify 2) Order **9VD** and print send -out form using "RLRF5, RR13" 3) Send specimen to PHL

8HAV

8HAV	Comment
>1.20S/CO	1) Result 8HAV as "POSITIVE" and verify 2) Call ward regarding positive HAV IgM result 3) Check report and fax the report (RL15, RL10) to MOH :416-392-0047 on regular hours(8:30-16:30) 4) phone MOH on after-hours(416-392-CITY (2489) Check the link of Reportable Diseases to the Medical Officer of Health **5) Send to PHOL for Hep A Genotyping**

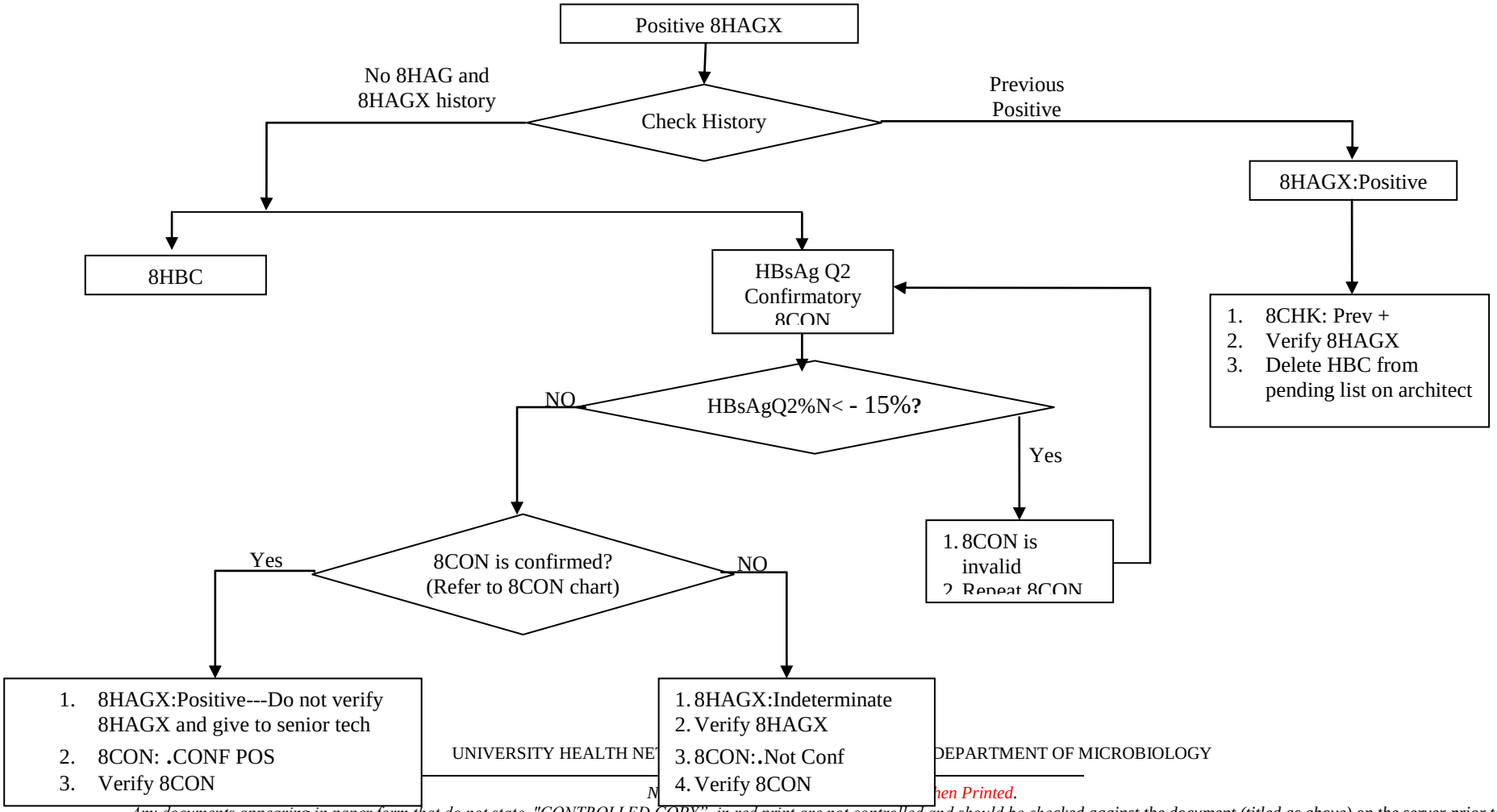
8HBCM

8HBCM	Comment
≥1.00S/CO	1) Verify 8HBCM result in LIS 2) No reflex needed

10CMM

10CMM	Comment
Positive ≥1.00 index Negative <0.85	Appended on all CMV IgM interpretation on the report: It is recommended to confirm clinical relevance of results >=0.85 index by testing for CMV IgG Avidity. <u>The following only applies to **pre-natal** CMV IgM testing:</u> 1) Send all pre-natal CMV IgM >= 0.85 index to PHL for CMV avidity. Place sample and requisition in a biohazard bag and then in a brown bag labelled CMV avidity. Ship with daily shipment in PHL blue bag. 2) Order 9CMAX 3) Give a copy of PHL requisition to the senior technologist to fax to PHL at 416-235-6188

HBsAgQ2 Confirmatory Testing - Routine Patient HBsAgQ2 Auto Testing Algorithm



HBsAgQ2 Procedure

DO NOT order 8CON in LIS until **AFTER** the confirmatory results are completed and released

Set Architect in **Ready** Mode, and load the HBsAg confirmatory reagents.

If reagent has not been calibrated:

1. Order HBsAg Qulitative Confirmatory Calibration:
   - At snapshot screen, touch '**Order**', Select '**Calibration order**'.
   - Scan in Carrier #, type in position #.
   - In assays panel, select '**HBsAg Q2 C2**'.
   - Touch '**Assay option…**' to check the calibrator lot number
     If the in-use calibrator has new lot number
     - Highlight lot#
     - Enter new calibrator lot#
     - Enter new calibrator expiration date
     - Touch '**Done**' button;
     - Touch '**Add Order**'

     If the in-use calibrator has same lot number
     - Touch '**Cancel**' button
     - Touch '**Add Order**'
     - Load a carrier with 2 sample cups
     - Add Cal1 to position 1 & add Cal 2 to position 2.

1. Order HBsAg Qualitative confirmatory Control:

   ALWAYS RUN CONFIRMATORY CONTROL BEFORE SPECIMEN
   Only a positive control (HAGX HBsAg Qualitative II **Positive** Control) needs to be run

   - At snapshot screen, touch '**Order**', Touch '**Control Order**', Select '**Multiconstiuent**'
   - Touch box with bars ☰ beside **'Control:'**, highlight **HBsAgQ2+**
   - In the '**Panel:**' highlight **HBsAgQ2Pa**
   - Touch '**Assay options…**' to check the lot number of control

- If control lot number changes, follow instruction of Change control lot number for the multiconstituent controls
- Scan Rack and enter position number of control
- Touch '**Add Order**'
- Load HAGX POS control into the architect in pre-determined spot ensuring barcode DOES NOT show.

2. Order HBsAg Qualitative Confirmatory test for patient
   - At snapshot screen, touch '**Order**', Touch '**Patient Order**'.
   - Scan in Carrier #., Type in position #
   - At SID, Scan in specimen SID#
   - In '**Panel**', highlight '**HBsAgQ2Pa**'- HBsAg Q2% N, HBsAg Q2 C1 and HBsAg Q2 C2 will be highlighted.
   - Touch '**Sample Details**' and type in patient's last name and first name,
   - Touch '**Done**'. Touch '**Add order**'.

3. To Print HBsAg Qualitative Confirmatory test
   - Highlight all three assays:**HBsAgQ2C1, HBsAgQ2C2, HBsAgQ2%N**
   - Touch '**Print**'
   - Select '**Sample Report**'
   - Touch '**Done**'

4. HBsAgQ Interpretation of Results

***If the % neutralization is <-15%, then the results should be considered invalid and specimen should be retested.**

Dilution	S/CO HBsAgQ Cf2	% Neutralization	Final Interpretation	LIS result
Neat (Undiluted)	<0.70	Not applicable	Not confirmed	• 8CON: **.Not Conf** • 8HAGX:**Indeterminate** • Verify 8CON and 8HAGX
	<10.00	<50%	Not confirmed	• 8CON: **.Not Conf** • 8HAGX:**Indeterminate** • Verify 8CON and 8HAGX
	≥0.70	≥50%	Confirmed Positive	• 8CON: .**CONF POS** • 8HAGX:**Positive** • Verify 8CON & 8HAGX
	≥10.00	<50%	Repeat test using a 1:500 dilution	N/A
1:500	<0.70	Not applicable	Not confirmed	• 8CON: **.Not Conf** • 8HAGX:**Indeterminate** • Verify 8CON and 8HAGX
	≥0.70	≥50%	Confirmed Positive	• 8CON: .**CONF POS** • 8HAGX:**Positive** • Verify 8CON & 8HAGX
	≥0.70	<50%	Repeat test using a 1:20000 dilution	N/A
1:20000	<0.70	Not applicable	Not confirmed	• 8CON: **.Not Conf** • 8HAGX:**Indeterminate** • Verify 8CON and 8HAGX
	≥0.70	≥50%	Confirmed Positive	• 8CON: .**CONF POS** • 8HAGX:**Positive** • Verify 8CON & 8HAGX
	≥0.70	<50%	Not confirmed	• 8CON: **.Not Conf** • 8HAGX:**Indeterminate** • Verify 8CON and 8HAGX

5. Specimen Dilution Procedure for HBsAg Qualitative II Confirmatory Assay

- The suggested dilution for the ARCHITECT HBsAg Qualitative II Confirmatory assay is 1:500
    - Add **25µL** of patient specimen to **475µL** of ARCHITECT HBsAg Qualitative II Confirmatory Manual Diluent for a 1:20 dilution
    - Add **20µL** of the 1:20 dilution to **480µL** of ARCHITECT HBsAg Qualitative II Confirmatory Manual Diluent for a 1:500 dilution
- Additional specimen dilutions may be performed if the 1:500 dilution result is still reactive but not neutralized
    - For a 1:20000 dilution, add **25µL** 1:20 dilution to **975µL** of ARCHITECT HBsAg Qualitative II Confirmatory Manual Diluent for a 1:20000 dilution

!Record How Many Tests Left on the Reagent Bottle

Transplant Donor/Recipient Serology Testing

STAT serology testing may include the following tests:

Test Name	LIS code	Testing Assay
Hep B Surface Antigen (Donor Screening Only)	8HAGX	Architect HBsAg Qualitative II, Device#2G22, Abbott Diagnostics
HBsAg Confirmatory Assay	8CON	HBsAg Qualitative II Confirmatory, Device#2G23, Abbott Diagnostics
Hep B surface Antibody	8HAB	Architect Anti-HBs Device#7C18, Abbott Diagnostics
Hep B Core Antibody	8HBC	Architect Anti-HBC II, Device#8L44, Abbott Diagnostics
Hep C Antibody	8HCA	Architect Anti-HCV, Device#6C37, Abbott Diagnostics
HIV 1&2 Antibody/p24 Antigen	8TSC	Architect HIV Ag/Ab, Device#4J27, Abbott Diagnostics
HTLV 1&2 Antibody	8HTLA	Architect rHTLV-I/II, Device#6L61, Abbott Diagnostics
CMV Total Antibody	8CMSE	CAPTURE-CMV Kit, Device Identifiers 66206, 66238, 66239 Immucor Inc.
Syphilis Screening	8VD	Architect Syphilis TP Assay [donor screen and cadaveric], Device Identifier 8D06, Abbott Diagnostics
EBV VCA IgG	8EBVG	Architect EBV VCA IgG assay, Device#3P65, Abbott Diagnostics

Donor/Recipient Specimens Processing

1. Testing of cadaveric blood specimens:
    - After initial centrifugation, transfer the supernatant to a centrifuge tube and centrifuge at ≥10,000RCF for 10 minutes prior to testing.

- Document the degree of hemolysis if present in test "8hem".

2. NON-STAT test requests e.g. Toxoplasma IgG, VZV IgG, aliquot separate tubes of serum.

3. Only HIV and HTLV initial reactive samples **require** be centrifuged at 10,000 rcf for 10 minutes before repeating in duplicate.

Donor/Recipient Serology Reporting:

Test	Initial Result	Retest In Duplicate	LIS Report	Confirmation	Comment
8HAGX (S/CO)	<1.00 (Nonreactive)	N/A	8HAGX:Negative @x1	N/A	• Auto-verified
	≥1.00 (Reactive)	Both results <1.00 (Nonreactive)	8HAGX:Negative @x1	N/A	• Verify 8HAGX • Order 8COM, recorder all values in the comment under 8COM , verify 8COM
		One or both results ≥1.00 (Reactive)	**Living or Cadaveric Donor** 8HAGX:Positive @x1	Not Confirmed <50% (see confirmation section)	• 8HAGX: Indeterminate@xi • Order 8CON, verify as "**.NotConf**" • Order 8COM, record all HAGX values in the comment under 8COM , verify 8COM
				Confirmed ≥50% (see confirmation section)	• 8HAGX: POSITIVE@x3 • Order 8CON, verify as "**.Conf**" • Order 8COM, record all HAGX values in the comment under 8COM , verify 8COM
8HBC (S/CO)	<1.00 (Nonreactive)	N/A	8HBC:Negative@c1		• Auto-verified
	≥1.00 (Reactive)	Both results <1.0	8HBC:Negative@c1 8HBC2:Negative		• Verify 8HBC &8HBC2 • Record all values in the comment under 8HBC2
		One or Both results ≥1.00 (Reactive)	8HBC:Positive@c1 8HBC2:Positive		• Type 'Repeatedly Reactive' in the comment under 8HBC and verify 8HBC • Record all values in the comment under 8HBC2
8CMSE	Negative	N/A	8CMSE:Negative@cm1		• Manually verify
	Indeterminate	N/A	8CMSE: Indeterminate@cm1		• Manually verify • **For sick kids ONLY** Run CMV IgG (8CMS) and CMV IgM (10CMM) on Architect

Test	Initial Result	Retest In Duplicate	LIS Report	Confirmation	Comment
	Positive	N/A	8CMSE:Positive@cm1		• Manually verify • Positive 8CMSE result for Sick Kids needs to run CMV IgG (8CMS) and CMV IgM (10CMM) on Architect
8EBVG S/CO	<0.75 (Nonreactive)	N/A Add 8EBNA	8EBVG: Negative@a1 8EBNA:Based on EBNA result		• Both results are auto-verified
	≥0.75 to <1.00 (Grayzone)	N/A Add 8EBNA	8EBVG:Equivoca@a1 8EBNA:Based on EBNA result		• Both results are auto-verified
	≥1.00 (Reactive)	N/A	8EBV: Positive		• Auto-verified
8HCA (S/CO)	<1.00 (Nonreactive)	N/A	8HCA:Negative@y1		• Auto-verified
	≥1.00 (Reactive)	Both results<1.00 (Nonreactive)	8HCA:Negative@y1 8HCA2:Negative		• Verify 8HCA&8HCA2 • Record all values in the comment under 8HCA2
		One or Both results≥1.00 (Reactive)	**Living Donor** 8HCA:Posiitve@y1 8HCA2:Positive		• Type 'Repeatedly Reactive' in the comment under 8HCA and verify 8HCA • Record all values in the comment under 8HCA2 & verify 8HCA2 • **FOR ONTARIO LIVING DONOR ONLY**, order HCA send out using keypad and send specimen to PHL for further testing.
			Cadaveric Donor 8HCA:Positive@y1 8HCA2: Positive		• Type 'Repeatedly Reactive' in the comment under 8HCA and verify 8HCA • Verify 8HCA2 • Record all values in the comment under 8HCA2
8TSC (S/CO)	<1.00 (Nonreactive)	N/A	8TSC:Negative @z1		• Auto-verified
	≥1.00 (Reactive)	Both results<1.00 (Nonreactive)	8TSC:Negative @z1		• Order 8COM, record all values in the comment under 8COM
		One or both results≥1.00 (Reactive)	**Living Donor** 8TSC:Positive @z1		• Verify 8TSC. Result as: "Repeatedly reactive" • Order 8COM, recorder all values in the comment under 8COM , verify 8COM • **FOR ONTARIO LIVING DONOR ONLY**, Order send out TSC test using keypad and send specimen to PHL for further testing.

Test	Initial Result	Retest In Duplicate	LIS Report	Confirmation	Comment
			Cadaveric Donor 8TSC:Positive @z1		• Type 'Repeated Reactive' in the comment under 8TSC and verify 8TSC • Order 8COM, record all values in the comment under 8COM , verify 8COM
8HTLA (S/CO)	<1.00 (Nonreactive)	N/A	8HTLA:Negative@i1		• Auto-verified
	≥1.00 (Reactive)	Both results<1.00 (Nonreactive)	8HTLA:Negative@i1		• Order 8COM, record all values in the comment under 8COM, verify 8COM
		One or bother results≥1.00 (Reactive)	**Living Donor** 8HTLA:Positive@i1		• Type 'Repeated Reactive' in the comment under 8HTLA and verify 8HTLA • Order 8COM, record all values in the comment under 8COM, verify 8COM • **FOR ONTARIO LIVING DONOR ONLY**, Order 8HTLA, send out test using order entry keypad and send specimen to PHL for further testing.
			Cadaveric Donor 8HTLA:Positive@i1		• Type 'Repeatedly Reactive' in the comment under 8HTLA and verify 8HTLA • Order 8COM, record all values in the comment under 8COM , verify 8COM
8VD (S/CO)	<1.00 (Nonreactive)	N/A	8VD:Negative @V3		• Auto-verified
	≥1.00 (Reactive)	N/A	**Living Donor** 8VD:Positive @V3		• Report as "Positive@V3" and verify 8VD • Order 8COM, record positive value in the comment under 8COM , verify 8COM • **FOR ONTARIO LIVING DONOR ONLY**, Order VD send out using order entry keypad and send specimen to PHL for further testing.
			Cadaveric Donor 8VD:Positive @V3		• Report as "Positive@V3" verify 8VD. • Order 8COM, record positive value in the comment under 8COM , verify 8COM

- Leave completed testing printouts on the senior bench for revision.

Donor Specimen Storage:

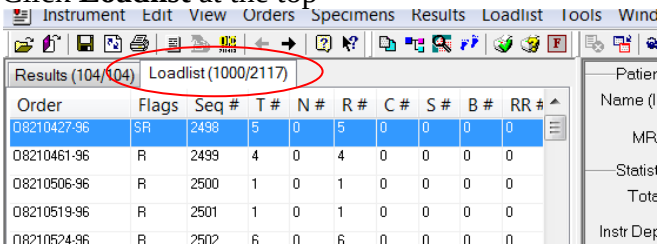
- Freeze all serum and plasma donor specimens to DONOR storage box.
- For specimen storage information, refer to Specimen Retention Times manual.
- For specimen storage location refer to and and.

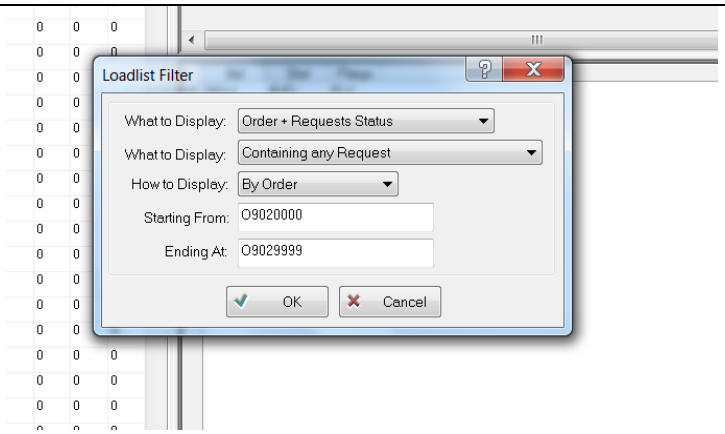
Trillium Gift of Life Network Procedure

Refer to Study Manual:

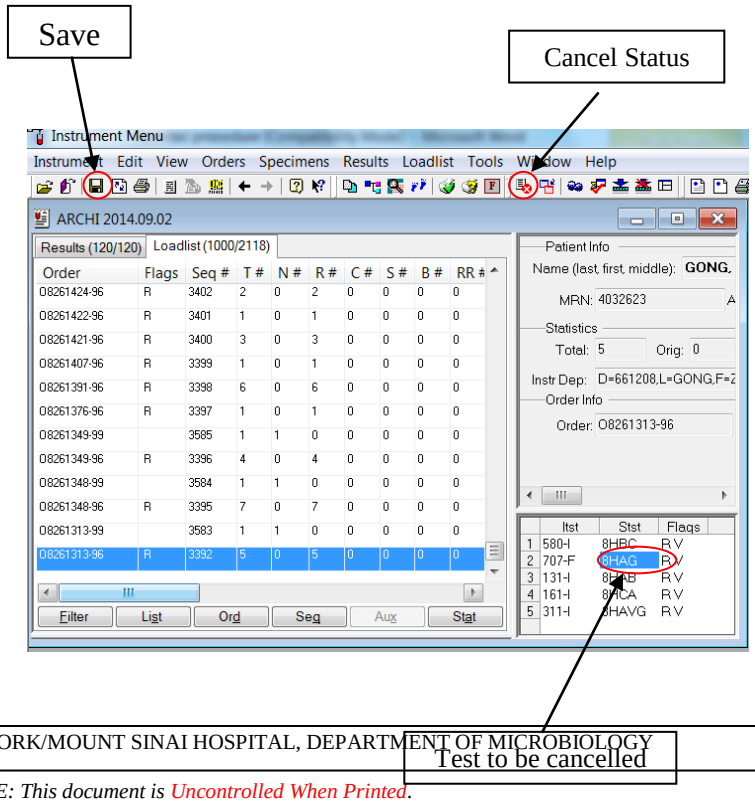
Architect Troubleshooting

Error	Action
LIS is not responding	1) At snapshot screen, touch 'System' 2) Select 'Configuration' 3) Select 'Host release Mode' 4) Configure- click on' ON with Query' under 'Bidirectional Host' 5) LIS Icon should appear on Snap Shot Screen. 6) If problem persists, contact Ed Cudek.
1005/Result cannot be calculated, final RLU read is outside the specification of the lowest calibrator.	1) Spin sample at 10,000g(rcf) for 10 minutes and repeat the test; 2) If the same error code persist, enter "PHL@MOH+" in the LIS result. 3) Order send out test(e.g. 9VD) and send the specimen to PHL for testing
Both SCC (system control center) and RSH (Robotic sample handler) are 'Offline'	i. Check connection of Dlink modem (little white box) ii. Check connection between instrument and LIS (purple plug) iii. Turn off and restart the whole system in proper sequence. **i. To turn off the system:** a. Turn off computer first by touching 'F3 shutdown' b. Follow instruction till monitor screen goes black c. Press computer power switch d. Turn off the architect **ii. To turn on the system** a. Press computer power switch b. Wait the computer starting up until the snapshot screen comes up c. Turn on the architect instrument 4) If problem persists, call architect hotline
Negative query received for Sample ID (######)	1) Check if the tests are done in LIS 2) If the tests are not done: • Order manually on Architect • Download test through LIS

	1) Log into Softlab 2) Click **interfaces** 3) Double click **instruments** 4) Double click **#6 ARCHI** 5) Click **loadlist** on the top menu bar 6) Select '**Build….**' 7) Click '**More>>**' 8) Type the order twice at '**Range of orders**' 9) Click'**OK**' 10) Instrument Menu window pops up saying '# orders and # tests were added or updated in the loadlist'
Cancel architect order from LIS	1. Click **Interfaces** 2. Double click **Instrument Menu** 3. Double click **ARCHI** 4. Click **Loadlist** at the top  5. Click **Filter** at the bottom  6. Change **How to Display to: '**By Order' 7. Type the order# at **Starting From** field only



8. Click **OK**
9. The specific order will appear at the very bottom of the list
10. Highlight the order, all tests belong to this order appear on the right panel
11. Click the test to be cancelled (e.g. 8HAG)
12. Click the Toggle Cancel Status
13. Click Save symbol to save the cancellation



Instrument failure	1. Write down error code(s) in Architect Analyser History Log book, call Abbott Technical Help Line@ 1-877-422-2688 for instruction to solve the problem(s).Instrument serial # is iSR06299. 2. If problem cannot be solved by the operator(s), Abbott will send technical service specialist on site(Except weekends and holidays). 3. If technical service specialist comes and replaces parts, all Abbott controls have to be re-run before testing patient samples. 4. Also run external control Virotrol for HBsAg.
Only 1 module available for Anti-HCV and rHTLV-I/II testing.	1. Deactivate Anti-HCV reagent; 2. Run all rHTLV tests; 3. Perform daily maintenance procedure again on the instrument prior to batching anti-HCV samples; 4. Activate Anti-HCV reagent; 5. Run the controls for Anti-HCV reagent; 6. Run all the pending Anti-HCV tests for the patients

Reference

Abbott Operation Manual (201837-106).
Assay Packages inserts.
For Health Canada approved donor test licence numbers for non-TGLN donors

Appendix I: Architect Autoverification Process

Introduction

To document the autoverification process.

Autoverification is the process by which the computer performs the initial verification of test results. Any value, that falls outside of the defined criteria, must be assessed by a technologist before release of results.

Procedure

1. The laboratory has a policy signedby the laboratory director approving the autoverification procedure.
2. The results ofautoverification is thoroughly tested, appropriately documented and signed by the section head/designee before implementation.
3. If changes are made to the autoverification rules initially chosen and documented, the process is reverified as to its accuracy.
4. The autoverification processis checked yearly.

AUTOVERIFICATION FOR THE ARCHITECT INSTRUMENT

Autoverification will occur for results performed on the architect instrument for assays in the table below as follows:

TEST NAME	SOFT TEST CODE	RESULT	TRANSLATION	ACTION	REFLEX TESTS
Hep B Surface Ag	8HAGX (Qualitative)	Nonreactive	Negative@x1	Autoposted Autoverified	
Hep B Surface Ag	8HAGX (Qualitative)	Reactive	Check	Autoposted Not Autoverified	8HBC
Hep B Surface Ab	8HAB	0.00 - >1000.0	###.#	Autoposted Autoverified	
Hep B Core Ab	8HBC	Reactive	POSITIVE@c1	Autoposted Not Autoverified	8HBC2
Hep B Core Ab	8HBC	Nonreactive	Negative@c1	Autoposted Autoverified	
Hep B Core Ab (RPT)	8HBC2	Reactive	POSITIVE	Autoposted Autoverified	
Hep B Core IgM Ab	8HBCM	Reactive	POSITIVE	Autoposted Not Autoverified	8HBC2
Hep B Core IgM Ab	8HBCM	Nonreactive	Negative	Autoposted Autoverified	
Hep A IgG Antibody	8HAVG	Nonreactive	Negative	Autoposted Autoverified	
Hep A IgG Antibody	8HAVG	Reactive	POSITIVE	Autoposted Autoverified	
Hep A IgM Ab	8HAV	Reactive	RE-CHECK	Autoposted Not Autoverified	
Hep A IgM Ab	8HAV	Nonreactive	Negative	Autoposted Autoverified	
Hep A IgM Ab	8HAV	GZ-Reactive	Grayzone@V2	Autoposted Autoverified	
Rubella	8RUB	Nonreactive	Check	Autoposted Not Autoverified	8RUB2

TEST NAME	SOFT TEST CODE	RESULT	TRANSLATION	ACTION	REFLEX TESTS
Rubella	8RUB	Grayzone	Check	Autoposted Not Autoverified	8RUB2
Rubella	8RUB	Reactive	POSITIVE	Auto posted Autoverified	
HIV 1&2 Antibody Screen	8TSC	Nonreactive	Negative@z1	Autoposted Autoverified	
HIV 1&2 Antibody Screen	8TSC	Reactive	TO PHL	Autoposted Not Autoverified	9TSC
Hep C Antibody	8HCA	Reactive	Check #	Autoposted Not Autoverified	8HCA2
Hep C Antibody	8HCA	Nonreactive	Negative@y1	Autoposted Autoverified	
Syphillis Screen	8VD	Nonreactive	Negative by CMIA	Autoposted Autoverified	
Syphillis Screen	8VD	Reactive	Check	Autoposted Not Autoverified	
HTLV 1&2 Antibody	8HTLA	Nonreactive	Negative@i1	Autoposted Autoverified	
HTLV 1&2 Antibody	8HTLA	Reactive	Check	Autoposted Not Autoverified	
CMV IgG R Antibody	8CMS	Nonreactive	Negative	Autoposted Autoverified	
CMV IgG R Antibody	8CMS	Reactive	POSITIVE	Autoposted Autoverified	
CMV IgG R Antibody	10CMG	Nonreactive	Negative	Autoposted Autoverified	
CMV IgG R Antibody	10CMG	Reactive	POSITIVE	Autoposted Autoverified	10CMA when both 10CMM & 10CMG are POSITIVE
CMV IgM Antibody	10CMM	Nonreactive	Negative	Autoposted Autoverified	

TEST NAME	SOFT TEST CODE	RESULT	TRANSLATION	ACTION	REFLEX TESTS
CMV IgM Antibody	10CMM	Reactive	POSITIVE	Autoposted Autoverified	10CMA when both 10CMM & 10CMG are POSITIVE
CMV IgM Antibody	10CMM	Grayzone	Negative	Autoposted Autoverified	
CMV IgG Avidity	10CMA	Value (% AVI)		Autoposted Autoverified	
EBV EBNA IgG	8EBNA	Reactive	POSITIVE@b1	Autoposted Autoverified	
EBV EBNA IgG	8EBNA	Nonreactive	Negative@b1	Autoposted Autoverified	
EBV EBNA IgG	8EBNA	GZ-Reactive	Equivocal@b1	Autoposted Autoverified	
EBV VCA IgG	8EBVG	Reactive	POSITIVE@a1	Autoposted Autoverified	
EBV VCA IgG	8EBVG	Nonreactive	Negative@a1	Autoposted Autoverified	
Toxoplasma IgG	8TOXG	Reactive	Positive	Autoposted Autoverified	
Toxoplasma IgG	8TOXG	Nonreactive	Negative	Autoposted Autoverified	
Toxoplasma IgG	8TOXG	Greyzone	Equivocal	Autoposted Autoverified	

Related Documents

Serology Specimen Management Manual	
Architect Cal _ Control Inventory	T:\microbiology\Virology\architect log sheet
Architect Consumable Log	
Architect Reagent Lot-Cal-QC chart	
Architect Done Storage	

Serology Manual for George Washington	

Record of Edited Revisions

Manual Section Name: Architect Manual

Page Number / Item	Date of Revision	Signature of Approval
Transferred from Serology Manual, Policy # MI/SER/v51	2016.05.17	Dr. T. Mazzulli
Specimen Collection and Processing section: modified stored specimens days per assay at 2-8C and stored at ≤ -20C (changed from < -10C)	June 13, 2016	Dr. T. Mazzulli
Addition of specimen rejection section with criteria for grossly hemolysed samples.	July 24, 2016	Dr. T. Mazzulli
Updated Occ health MSH email: • All results must be informed to occupational health department by phone or email MSH needle stick results: email results to Occ Health & Safety- MSH (MSH) ohsmsh@sinaihealthsystem.ca	August 23, 2016	Dr. T. Mazzulli
External control section added reminder: • External controls are run with each new lot or shipment of reagent after calibration is performed • External controls should be run on a reagent after any re-calibration. • Run external control Virotrol for HBsAg after any service. Calibration section reminder: External controls should be run on a reagent after any re-calibration. See external control section	August 29, 2016	Dr. T. Mazzulli
External Control section - removed chart, added link to document "External control selection criteria"	February 16th, 2017	Dr. T. Mazzulli
Annual Review Updated all 9 send out codes to choose from order entry keypad. For Patient results HAGX, HIV, HTLV, VD if positive <2.00 spin and repeat x2 first. If 2/3 positive, then continue with positive workup, or call negative. HAGX test for patients and donors, updated procedure for testing with confirmation. Modified resulting phrases.	March 8, 2017	Dr. T. Mazzulli
For STAT needlestick specimens:	August 14, 2017	Dr. T. Mazzulli

Page Number / Item	Date of Revision	Signature of Approval
Added note "for immune status needlestick samples with any other tests requested other than those above should NOT be done. Forward requisition to senior/helper".		
Removed inventory task to be performed every Friday. (Replaced by IMS) For Hep A IgM positive, send to PHOL for Genotyping added to reflex table reporting.	February 19, 2018	Dr. T. Mazzulli
In specimen collection section, Include dilution caveat on provided requisitions / test order. Addition of senior review following Donor/Recipient Serology Reporting section Clarify in Architect manual "Loading Reagents" microparticle resuspension while preparing reagents should be done prior to septum placement on bottle Incorporate values of other interferences within specimen processing instructions in the Architect Manual section "Specimen Collection and Processing". Created interference table. Addition of documentation of hemolysis status for Donors Testing in test 8hem.	May 10, 2018	Dr. T. Mazzulli
Corrected HTLV donor device number from 2G22 to 6L61.	September 14, 2018	Dr. T. Mazzulli
The following sections were updated for HBsAb: Cut-off Values LIS translation	November 12, 2018	Dr. T. Mazzulli
Annual Review Addition of Toxo IgG to assays list, reflex ranges, autoposting table and reporting tables.	April 20th, 2018	Dr. T. Mazzulli
Modified Syphilis procedure for donors removing repeating positive results in duplicates to report as per package insert.	May 1st, 2018	Dr. T. Mazzulli
Addition of cadaveric needlestick instructions.	July 31st, 2018	Dr. T. Mazzulli
Removed low level report from CMV IgG interpretations Removed CMV IgG from result reflex & resulting tables Updated wording of auto verification section introduction	January 11, 2019	Dr. T. Mazzulli
Minor typographical errors corrected. Reworded for 8EBVG: 0.75< 8EBV <100 to ≥0.75 to	March 19, 2019	Dr. T. Mazzulli

Page Number / Item	Date of Revision	Signature of Approval
<1.00 (Grayzone); No change to procedure.		
Corrected cut-off values for HBsAb	May 3, 2019	Dr. T. Mazzulli
pg 37 5. correction: • For a 1:20000 dilution, add 25µL 1:20 dilution to 975µL of ARCHITECT HBsAg Qualitative II Confirmatory Manual Diluent for a 1:500 dilution - change to 1:20000 dilution	Sep 12, 2019	Dr. T. Mazzulli
p.31 for clinical patients removed repeating syphilis in duplicates.	December 5, 2019	Dr. T. Mazzulli
Specimen collection section updated with Syphilis storage requirement: ≤ -20C storage updated from ≥7days to ≤ 30days for living and ≤ 11 days for cadaveric samples	February 7, 2020	Dr. T. Mazzulli
Annual review Minor grammatical changes Added note: Anti-HCV and rHTLV-I/II not to be run on the same module Added troubleshooting section for running Anti-HCV and rHTLV-I/II if only one module is available	October 27, 2020	Dr. T. Mazzulli
HAV IgM- <0.80 Nonreactive >0.80-1.20 Equivocal/Gray Zone >1.20 Reactive	October 29, 2020	Dr. T. Mazzulli

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by
Minor formatting update	April 12, 2021	Jessica Bourke
Updated rapid HIV UHN ER only	April 22, 2021	Wayne Chiu
Added greyzone for CMV IgM	June 9, 2021	Wayne Chiu
Added test comment for CMV IgM	June 18, 2021	Oliver Li
Added reflex detail for CMV IgM Noted this only applies to pre-natal samples	July 14, 2021 July 17, 2021	Wayne Chiu Oliver Li
Updated reflex table for 8HAGX and 8HCA – verify if confirmed Updates above reviewed and confirmed	Sep 1, 2021 Sep 22, 2021	Wayne Chiu Oliver Li