**PROCEDURE: Coro Molecular Microbiology COBAS 6800 Anaplasma, EHRLICHIA AND Babesia PCR procedure**

1. **PRINCIPLE**
   1. Intended Use
      1. This assay is a nucleic acid amplification test for the detection of *Anaplasma phagocytophilum* and *Ehrlichia* species in human whole blood.
      2. This assay is performed on the Roche cobas® 6800 platform using primers from Fort Worth Diagnostics (ASR).
      3. The results from this assay must be interpreted within the context of all relevant clinical and laboratory findings.
   2. Summary and Background
      1. *Anaplasma phagocytophilum*
         1. *Anaplasma phagocytophilum* is a bacterium that causes human anaplasmosis, which is also known as human granulocytic anaplasmosis (HGA).
         2. The *Ixodes scapularis* tick is the vector for *A. phagocytophilum* in the Northeastern and Midwestern United States, where the incidence is highest. Most anaplasmosis cases occur in the warmer months. Rarely the infection can be transmitted via blood products or solid organ transplantation.
         3. Anaplasmosis is, in most cases, a mild illness, although it can vary in progression and severity depending on factors such as age, immune status, and the presence of comorbidities. Clinical presentation is usually marked by nonspecific symptoms (e.g., fever, chills, and headache); life-threatening illness is less common.
      2. *Ehrlichia* species
         1. *Ehrlichia chaffeensis* is a bacterium that causes most cases of human monocytic ehrlichiosis (HME), which can be associated with severe, life-threatening disease. *E. ewingii* and *E. muris eauclairensis* are less common etiologic species that may cause HME, but these are not known to cause fatal illness.
         2. Most people get ehrlichiosis from the bite of an infected lone star tick. Infections are most prevalent in the Southeastern United States. There have also been rare, reported cases associated with blood product transfusion and organ transplantation.
         3. Signs and symptoms commonly seen in the first few days of illness include fever, chills, rigors, headache, malaise, myalgia, gastrointestinal symptoms (nausea, vomiting, diarrhea, anorexia), and confusion.
         4. Rash develops in up to 60% of children, but less than 30% of adults, and typically begins 5 days after symptom onset. The rash usually spares the face, and rarely may spread to the palms of hands and soles of feet.
         5. If treatment is delayed, the disease may become severe. Severe illness may involve: meningoencephalitis, acute respiratory distress syndrome, toxic shock-like or septic shock-like syndromes, renal failure, coagulopathy and pancytopenia.
      3. Detection of *Anaplasma* and *Ehrlichia* DNA by PCR is most sensitive during the first week of illness; sensitivity may decrease after administration of tetracycline-class antibiotics.
      4. Doxycycline is the recommended treatment for both *Anaplasma* and *Ehrlichia* infections.
      5. *Babesia species*
         1. Babesiosis is a parasitic disease caused by intraerythrocytic protozoa of the *Babesia* genus (*Babesia microti* and other species). *Babesia* are transmitted in nature through the bites of infected ticks but can also be acquired through contaminated blood components from asymptomatic parasitemic donors or, more rarely, transplacentally. The *Ixodes scapularis* tick is the vector for *Babesia* in the United States.
         2. *Babesia* infection can range from subclinical to life-threatening. Clinical manifestations, if any, can include hemolytic anemia and nonspecific influenza-like signs and symptoms (e.g., fever, chills, sweats, headache, myalgia, arthralgia, malaise, fatigue, generalized weakness). Splenomegaly, hepatomegaly, or jaundice may be evident. The clinical presentation is similar to malaria.
         3. In addition to signs of hemolytic anemia, laboratory findings may include thrombocytopenia, and elevated levels of liver enzymes, total and indirect bilirubin, blood urea nitrogen, or creatinine. Risk factors for severe babesiosis include asplenia, advanced age, and other causes of impaired immune function (e.g., HIV, malignancy, corticosteroid therapy). Some immunosuppressive therapies or conditions may mask or modulate the clinical manifestations (e.g., the patient may be afebrile). Severe cases can be associated with marked anemia, disseminated intravascular coagulation, hemodynamic instability, acute respiratory distress, myocardial infarction, renal failure, hepatic failure, altered mental status, and death.
         4. The CDC’s case definition for babesiosis requires confirmation of infection by blood smear or NAAT. NAAT is often the preferred first-line test to diagnose babesiosis because several blood smears may be required for detection. Additionally, blood smears may not differentiate between *Babesia* and Plasmodium.
         5. Treatment of babesiosis typically includes a combination of antimicrobial agents, namely atovaquone and azithromycin.
2. **SAMPLE PREPARATION**
   1. This assay on the cobas® 6800 is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The cobas® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data management is performed by the cobas® 6800/8800 software which assigns test results for all targets as either target detected or not detected. Results can be reviewed directly on the system screen, exported, or printed as a report.
   2. Nucleic acid from patient samples and added lambda DNA-QS molecules are simultaneously extracted. In summary, bacterial nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors are removed with subsequent wash reagent steps and purified nucleic acid is eluted from the glass particles with elution buffer at elevated temperature.
   3. Selective Amplification
      1. Selective amplification of target nucleic acid from the sample is achieved by the use of target bacterial-specific primers (msp2 gene for Anaplasma, 16s gene for Ehrlichia and 18s for Babesia). Selective amplification of DNA-QS is achieved by the use of sequence-specific forward and reverse primers which are selected to have no homology with the Anaplasma, Ehrlichia or Babesia genome. A thermostable DNA polymerase enzyme is used for amplification. The target and DNA-QS sequences are amplified simultaneously utilizing a universal PCR amplification profile with predefined temperature steps and number of cycles. The master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythimidine triphosphate (dTTP), which is incorporated into the newly synthesized DNA (amplicon). Any contaminating amplicon from previous PCR runs is eliminated by the AmpErase enzyme, which is included in the PCR mix, when heated in the first thermal cycling step. Newly formed amplicons are not eliminated since the AmpErase enzyme is inactivated once exposed to temperatures above 55°C.
      2. The assay master mix contains one detection probe specific for each target (Anaplasma, Ehrlichia and Babesia) sequences and one for the DNA-QS. The probes are labeled with target-specific fluorescent reporter dyes allowing simultaneous detection of the bacterial target and DNA-QS in three different target channels. The fluorescent signal of the intact probes is suppressed by the quencher dye. During the PCR amplification step, hybridization of the probe to the specific single-stranded DNA templates results in cleavage by the 5'-to-3' nuclease activity of the DNA polymerase resulting in separation of the reporter and quencher dyes and the generation of a fluorescent signal. With each PCR cycle, increasing amounts of cleaved probes are generated and the cumulative signal of the reporter dye is concomitantly increased. Real-time detection and discrimination of PCR products is accomplished by measuring the fluorescence of the released reporter dyes for the viral targets and DNA-QS.
3. **AVAILABILITY**
   1. Specimens may be submitted 7 days a week/ 24 hour a day.
4. **TEST CODE**
   1. AEPCR-Anaplasma and Ehrlichia
   2. BABES- Babesia
5. **SPECIMEN REQUIREMENTS**
   1. Specimen Collection
      1. Handle all specimens as if they are capable of transmitting infectious agents.
      2. Whole blood should be collected in sterile tubes using EDTA as the anticoagulant. Follow the sample collection tube manufacturer instructions.
   2. Specimen Transport
      1. Whole blood collected in sterile tubes using EDTA as the anticoagulant may be stored and/or transported at 2°C to 8°C prior to testing.
   3. Specimen Storage
      1. EDTA plasma samples may be stored for up to 6 days at 2°C to 8°C.
6. **MATERIALS AND REAGENTS**
   1. Reagents
      1. cobas® Omni channel kit includes the following components that are stored at 2-8°C:
         1. Proteinase Solution
         2. DNA Quantitation Standard
         3. Elution Buffer
      2. Reagents not included in the kit and stored at 2-8°C unless stated otherwise:
         1. MGP Reagent
         2. Specimen Diluent
         3. Lysis Reagent
         4. Wash Reagent, store at 15-30°C
      3. Fort Worth Diagnostics Primer Sets stored at -20°C
         1. Anaplasma phagocytophilum
         2. Ehrlichia species
         3. Babesia species
   2. Materials
      1. cobas omni Processing Plate
      2. cobas omni Amplification Plate
      3. cobas omni Pipette Tips
      4. cobas omni Liquid Waste Container
      5. Solid Waste Container and Bag
   3. Reagent Precautions
      1. Handle all reagents, controls, and samples according to good laboratory practice in order to prevent carryover of reagents or controls.
      2. Before use, visually inspect each reagent cassette, diluent, lysis reagent, and wash reagent to ensure that there are no signs of leakage. If there is any evidence of leakage, do not use that material for testing.
      3. cobas omni Lysis Reagent contains guanidine thiocyanate, a potentially hazardous chemical. Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, burns can occur.
      4. Do not allow cobas omni Lysis Reagent, which contains guanidine thiocyanate, to contact sodium hypochlorite (bleach) solution. This mixture can produce a highly toxic gas.
      5. cobas omni MGP Reagent, and cobas omni Specimen Diluent contain sodium azide as a preservative. Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, burns can occur. If these reagents are spilled, dilute with water before wiping dry.
      6. cobas® cobas®NHP Negative Control Kit contain plasma derived from human blood. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents.
      7. Dispose of all materials that have come in contact with samples and reagents in accordance with country, state, and local regulations.
   4. Reagent Storage and Handling
      1. Controls are stored in the -20°C freezer.
      2. Reagents are stored in the 2-8°C refrigerator.
      3. Reagents loaded onto the **cobas®** 6800 System are stored at appropriate temperatures and their expiration is monitored by the system. The **cobas®** 6800 Systems allow reagents to be used only if all of the conditions shown in the following table are met. The system automatically prevents use of expired reagents. The following table allows the user to understand the reagent handling conditions enforced by the **cobas®** 6800 System.

|  |  |  |  |
| --- | --- | --- | --- |
| **Reagent** | **Open-kit stability** | **Number of runs for which this kit can be used** | **On-board stability** |
| **cobas®** NHP Negative Control Kit | N/A | N/A | Max 10 hours |
| **cobas omni** Lysis Reagent | 30 days from loading\* | N/A | N/A |
| **cobas omni** MGP Reagent | 30 days from loading\* | N/A | N/A |
| **cobas omni** Specimen Diluent | 30 days from loading\* | N/A | N/A |
| **cobas omni** Wash Reagent | 30 days from loading\* | N/A | N/A |

*\*Time is measured from the first time that reagent is loaded onto the* ***cobas®*** *6800 Systems.*

* + 1. Do not use reagents after their expiration dates.
    2. Do not pool reagents.
    3. Gloves must be worn and must be changed between handling specimens and cobas® 6800 reagents to prevent contamination.
    4. Dispose of unused reagents and waste in accordance with country, federal, state and local regulations.
    5. Handle all reagents with caution and avoid contact with skin, eyes, or mouth. Refer to the package insert for any known toxicity.
       1. Wear eye protection, laboratory coats and disposable gloves when handling any reagent. Avoid contact of these materials with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water. Burns can occur if left untreated. If spills of these reagents occur, dilute with water before wiping dry.
       2. If spills occur on the cobas® 6800 System, follow the instructions in the appropriate cobas® 6800 System – System Manual to clean.

1. **QUALITY CONTROL**
   1. Quality Control Information
      1. One Negative Control
         1. The negative control used for this assay can be found in the 2-8° refrigerator. Both the Anaplasma/Ehrlichia combo and the Babesia assay use the Cobas Buffer Negative Control kit.
      2. One Positive Control for each target
         1. Positive controls are located in the -20°C freezer.
            1. The positive control should be thawed to room temperature prior to use. Be sure to vortex the controls and change gloves in between the setup of each control.
            2. Each positive control needs to be set up in a sterile plasma tube.

To set up the control, take a Fort Worth Diagnostic 975uL Specimen Diluent plasma tube and add 25uL of control to the plasma tube containing the 975uL of Specimen Diluent. Each control requires its own specimen tube for testing. For **Babesia,** add **100uL** of positive control to the 975ul Specimen diluent tube by Fort Worth Diagnostics.

To program, a test patient label has been created that can be placed on the buffer tube containing the positive control. Each control will have its own test patient label that will be located at the Roche benchtop. The label is placed on the buffer tube containing the appropriate positive control needed for testing. After the control is added to the buffer tube and vortexed for 5 seconds, load the buffer tube into the appropriate labeled specimen racks for testing. These patient labels will eliminate the need to manually enter the name of each control performed on your runs.

* + 1. Negative controls are stored at 2-8°C.
    2. Positive controls are stored at -20°C.
    3. Controls are stable until the expiration date indicated.
    4. Record QC results on the sheets provided. Include date of testing, kit lot #, control lot #s, expiration dates, and results.
    5. Batch validity is checked within the cobas 6800 software (monitor) and is printed with the run report.
    6. The batch is valid if no flags appear for the negative control and if your Positive control results as Positive for the desired target.
    7. Validation of patient results is performed automatically by the cobas® 6800 software based on negative and positive control results.
    8. New lot numbers/shipment of primers are QC’d using control kits that have passed QC.
    9. New lot numbers/ shipments of Positive and Negative Control kits are run using assay kits that have passed QC.
    10. Environmental testing is performed monthly
        1. The hood, instruments, and bench space are swabbed and placed in an aliquot of plasma dilution matrix and placed on the run of patient samples.
        2. For any positive result, clean all areas and retest.
  1. Acceptable Limits
     1. For any run, valid results must be obtained for both the Positive and Negative Controls for the cobas® 6800 Software to display the reportable assay results from that run.
     2. QC statistics are reviewed monthly to monitor trends over time.
  2. Corrective Actions
     1. The assay will require repeating if either positive or negative controls are not valid.
     2. If the control results are consistently invalid, contact your local Roche Support Network Customer Support Center for technical assistance.

1. **SETTING UP OMNI CHANNEL KITS**
   1. Omni Channel Kits are located in the 2-8° refrigerator.
   2. The Omni Channel Kit **must** be set up in the Master Mix Hood located in Molecular Genomics Laboratory PCR set up room. This is a hood that is never exposed to any extracted nucleic acids.
   3. Supplies needed
      1. 1 mL Pipette
      2. Sterile container
      3. Reynolds wrap
      4. Pipette tips- same tips used for COVID testing.
      5. Primer Pair located in -20° freezer.
      6. Nuclease free water
      7. Non-filtered pipette tip for venting.
      8. Plastic cup for trash.
      9. New clean lab coat.
   4. Steps for Omni Channel Set up:
      1. Sterile container needs to be light protected. Place Reynolds wrap around the sterile container.
      2. Take the Master Mix out of the Omni Channel Kit and invert 2-20 times. Each kit contains two bottles of Master Mix. Only 10mL is needed. The remaining Master Mix/sterile container can be discarded.
      3. Let Primer Pair thaw to room temperature.
      4. Pipette 10mL of Master Mix into the sterile container, 1 mL at a time.
      5. Pipette primers/nuclease free water into the sterile container (total volume of this step adds up to 600uL). There will be two different cassettes to set up:
         1. **Babesia Omni Cassette**: 150uL of target primer and 450uL of nuclease free water is added to the sterile container.
         2. **Anaplasma/Ehrlichia Omni Cassette:** 150uL of each target primer and 200uL of nuclease free water is added to the sterile container.
         3. Recap the sterile container and invert 20 times to insure proper mixing of reagents.
      6. Place the Omni Channel Cassette inside of the Master Mix hood. Place the back of the cassette on a pipette box to achieve a 45° angle. The rounded notch on the Omni Channel cassette should be in the right-hand corner as pictured below in picture 1:

Picture 1

A grey rectangular object with black and red dots

Description automatically generated

* + 1. Place a nonfiltered tip (acts as a release valve) in the top spot located in the second row from the right of the cassette (indicated by the top arrow seen in Picture 1). If fluid is seen in the venting pipette during pipetting, gently lift the nonfiltered tip to allow the fluid to work its way back into the cassette. Before pipetting, make sure nonfiltered tip is pushed back into the cassette.
    2. Pipette a total of 9.7mL from the sterile container into the bottom spot of row 2 (indicated by the bottom arrow seen in picture 1). Only dispense a maximum amount of 1mL at a time. The last step should only require 700uL of the mix made in the sterile container. Discard sterile container when done.
    3. Discard the venting needle and all pipette tips into the plastic cup used for trash.
    4. After all reagents have been added and all pipette tips have been discarded, gently rock the cassette 20 times.
  1. Programming an Omni Channel Cassette
     1. Program the Omni Cassette using the computer to the right of the P480 instrument. The login information is located on the modem.
        1. Username: Lab1
        2. Password: Lifespan1
     2. Click the icon on the desktop labeled: Cobas Omni Utility Channel tool
     3. Next, click “Open published UC analysis package to write on reagent cassette RFID tag.”
     4. Under desktop, click either:
        1. AP\_U\_Tickborn\_01.00 for the Anaplasma/Ehrlichia assay.
        2. AP\_U\_Babesia\_01.00 for the Babesia assay.
     5. Type in the cassette lot number located on the Omni Cassette box.
     6. Click “Write Data on RDIF Tag”.
     7. Place RDIF tag (black square with target circle in center which is plugged into the modem by USB) against white sticker on cassette to program.
     8. The software will let you know when the program has been uploaded.
     9. Place the cassette onto the Roche instrument. It is now ready for testing.

1. **TEST PROCEDURE**
   1. Clean bench tops with 10% bleach followed by 70% alcohol pre and post running the assay.
   2. Remove samples from refrigerator and allow to come to room temperature.
   3. Required sample volume is 500ul.
   4. Go to the 6800 **Monitor Tab** and check the taskbar and messages at the top left on the monitor screen.
      1. Address any issues or maintenance due.
   5. Refill reagents and consumables as prompted by the system:
      1. Load wash reagent, lysis reagent and diluent.
      2. Load tip racks, processing plates and amplification plates.
      3. Load Magnetic Glass Particles.
      4. Load test specific reagents.
      5. Load control cassettes.
      6. Replace rack for clotted tips.
   6. Set the system to “Ready”.
      1. In the task overview, ensure that there is no maintenance overdue.
      2. On the **Monitoring** tab, Choose the **Start** button.
         1. The system changes to **Preparing** status.
      3. Wait for the system to change to **Ready** status before you start loading. This may take 15 minutes.
   7. Organize the runs for the day and make Tasklists.
   8. Load sample racks onto rack trays.
      1. Cobas 6800 has LIS Order Download
      2. For any samples without LIS barcode use Rack Based Ordering, i.e. environmental samples.
         1. Designated Anaplasma/Ehrlichia racks have Pink labels on them with the letters A&E.
         2. Designated Babesia racks have Red labels on them with the letter B.
         3. Sample ID must be entered in Manual Barcode Entry tab
   9. Bring racks and samples to hood for loading racks with samples.
      1. Anaplasma/Ehrlichia and Babesia can be performed at the same time on the same processing plates.
      2. Dilute samples in the hood.
         1. Using the 975ul Specimen Diluent tube by Fort Worth Diagnostics, place a specimen label on the specimen diluent tube.
         2. Take the patients’ specimen and invert 5-10 times.
         3. Uncap the specimen diluent tube with a gauze. Save cap.
         4. Pipette 25uL of patient specimen into the labeled tube containing the 975uL of diluent.
         5. Recap using the same cap and vortex for 5 seconds.

f. Discard cap and add diluted sample tube to sample racks.

* 1. Load trays with sample racks onto the Sample Supply module and go to the “Batches” tab.
     1. Monitor the “error lane” for any problems.
     2. After the sample barcodes are read it will make the “batch” and list the number of samples in the batch.
        1. **Make sure that number matches the expected number of tests**.
        2. Resolve any discrepancies.
  2. Hit the “**Start Manually**” button to begin processing.
     1. At this point you may go to the Routine Tab> Test Order Status to see the finish time.
  3. Monitor the instrument during processing in the Transfer Module.
     1. Address any errors or issues.

**Note: Do not walk away from instrument until samples are moved to the Processing module.**

* 1. Unload racks and samples when finished pipetting.
     1. Recap tubes in the hood with new caps and discard.
     2. Original Whole Blood specimen is stored in racks in our 2-8°C refrigerator. Specimens are saved for **ONE WEEK** before being discarded.
  2. Unload consumables at the end of processing:
     1. Remove amplification plates from the analytic module.
     2. Unload empty control cassettes.
     3. Empty solid waste.
     4. Empty liquid waste.

1. **RESULTS INTERPRETATION**
   1. Results
      1. From the **Routine Tab > Control Batch**
      2. Choose the control batch for your run.
      3. From the drop-down list choose Print from both right and left side of screen.
         1. The printout from the left has lot #s of reagents and controls
         2. The printout from the right has the actual results of controls.
         3. View results
   2. Reporting Results- Refer to Appendix A for LIS resulting instructions.
      1. For a valid batch, check each individual sample for flags in the cobas® 6800 software and/or report.
      2. Results are reported as: DETECTED or Not Detected
      3. Release Results
         1. Select all test results to be released
         2. Choose the **Release button**
            1. It is possible to release an Invalid result so use caution when releasing.
         3. Test results are sent to the SOFT Instrument Menu for posting.
   3. Invalid Patient Results
      1. An Invalid sample will be retested on the next run. If it repeats as Invalid report as Indeterminate- Suggest repeat collection.
      2. If a sample has an error code of P131H, it means that the concentration is too high. Please repeat the specimen using the following dilutions:
         1. 1:10 (100uL whole blood + 900uL TE buffer)
         2. 1:100 (10uL whole blood + 990uL TE buffer)
         3. 1:1000 (1uL whole blood + 999uL TE buffer)
2. **LIMITATIONS**
   1. Reliable results depend on proper sample collection, storage, and handling procedures.
   2. This test has been validated only for use with EDTA whole blood. Testing of other sample types may result in inaccurate results.
   3. Detection of target DNA may be affected by sample collection methods, patient factors (i.e., age, presence of symptoms), and/or stage of infection.
   4. Results should be interpreted by qualified healthcare professionals in conjunction with clinical signs and symptoms and all other laboratory findings.
   5. Mutations within the highly-conserved regions of the genes covered by the Fort Worth Primers, may affect primers and/or probe binding resulting in the failure to detect the presence of bacterial DNA.
   6. Negative test results do not preclude Anaplasma, Ehrlichia, or Babesia infection, and test results should therefore not be the sole basis for patient management decisions.
   7. Assay sensitivity may decrease after administration of tetracycline-class antibiotics.
3. **INTERFERENCES**
   1. Haemoglobin
      1. Known to decrease amplification efficiency.
      2. Ten positive hemolyzed samples were tested and resulted with no inhibition.
4. **TECHNICAL ASSISTANCE**
   1. Roche Support Network Customer Support Center at 1-800-526-1247.
5. **REFERENCES**
   1. Roche Cobas 6800 Operators Manual
   2. Centers for Disease Control and Prevention. Tickborne diseases of the United States: a reference manual for healthcare providers. 6th edition, 2022. Last reviewed Aug 2022; accessed Jun 2023.
   3. Centers for Disease Control and Prevention. Diagnosis and management of tickborne rickettsial diseases: Rocky Mountain spotted fever and other spotted fever group rickettsioses, ehrlichiosis, and anaplasmosis - United States: a practical guide for health care and public health professionals. Morbidity and Mortality Weekly Report. Last reviewed Jun 2017; accessed May 2023.Centers for Disease Control and Prevention. Clinical testing and diagnosis for ehrlichiosis. Last reviewed May 2024; accessed Jun 2024.

**Appendix A**

**Anaplasma/Ehrlichia/Babesia SCC Soft Resulting**

Test ID: **AEPCR=Anaplasma/Ehrlichia BABES=Babesia**

Template: AERPCR and BABES

Workstation: **RMOLM**

1. Print a “Resulting Worklist” by Template: AEPCR or BABES
   1. Status= Pending and Nonverified
   2. Start date= go back 1 month
   3. End date= current date
   4. Received box- unchecked
   5. Check list for any old outstanding orders- investigate and resolve any issues.
   6. List will be in Order sequence number from low to high. Except:
      1. STATs will go to top of list
      2. Add ons or any order that has been changed will stay at the bottom
      3. Print list:
         1. Click Printer icon
         2. Choose Worklist- Layout Horizontal or Vertical
         3. Print to Local Printer J73
   7. Use this list to check against specimens in the freezer
2. Create a Tasklist
   1. Follow procedure for “Creating a Tasklist” in Soft Manual under TASKLIST
      1. Template= AEPCR or BABES
   2. Number the specimens according to the tasklist beginning with #1 and ending with #94
   3. Print the worklist and check it against the samples to verify both are in the same order.
3. Posting Results using LIS Interface
   1. View and Review results from the cobas 6800
   2. Click on all results to be released and click the **RELEASE** button
   3. Results will transfer to the Soft Instrument Menu
   4. From SoftLab, go to “Interfaces”, and “Instrument Menu”
   5. Select Cobas 6800 from the Instrument Menu
   6. Select “Loadlist and Today’s Results”, “Not Posted”, “By Sequence”
   7. Each order will be highlighted individually. Verify the result against the instrument printout. Click “Post All” for each order to be verified.
   8. If any Result Comments, i.e. phone reports need to be added:
      1. Do not Post result
      2. Go to “Lab Result” tab.
      3. Open “Comment” box for line ANAP1, EHRL1, or BAPCR and add comment, i.e. @CALT, to the box. OK and Save
      4. Go back to “Instrument” tab and “Post” result.
   9. Check Results
      1. Go to “Resulting Worklist” by Tasklist
      2. Choose Tasklist
      3. Enter Tasklist ID
      4. Review Worklist to verify that all results have posted. They should all have “\*” next to them.
      5. Print a new pending worklist and check on any outstanding orders.
4. Positive results will automatically print an instant repot from Soft.
5. Use the instant reports for disclosing.