1.0 QUALITY CONTROL FOR CHEMISTRY (INTEGRA 400 PLUS)

1. Controls for Chemistry utilizes PCC1 (normal control) and PCC2 (pathological control).
2. Always check the Lot number of the control used. (If new lot number is to be used, change the allowed normal limits into the machine by following the designated normal values inserted in the box of each control). Also, check the expiration date.
3. Prior to running of QC, make sure all the reagent cassettes are already inserted inside the machine.

1.1 QUALITY CONTROL PROCEDURE FOR INTEGRA 400 PLUS

1. Control samples for Chemistry are reconstituted with distilled water. (Each bottle: PCC1 and PCC2 requires 5 ml of distilled water).
    1.1 Proper pipetting of distilled water should be followed in order to have accurate QC results.
2. Let the control sample be mixed in a rotator for at least 30 mins.
3. Prepare an aliquot sample for PCC1 (normal control), PCC2 (pathological control) and put it in a sample cup. At least 500 ul is needed during QC running.
    3.1 There should be no bubbles in the aliquoted sample during running of QC.
4. Put the aliquoted samples in control rack and run all the necessary tests for PCC1 and PCC2.
    4.1 There are 15 analytes to be tested:
        a. Glucose
        b. BUN
        c. CREA

CONTROLLED

d. BUA
e. CHOLESTEROL
f. TG
g. HDL
h. TP
i. ALBUMIN
j. TBIL
k. DBIL
l. ALT
m. AST
n. ALP
o. GGT

5. Once QC results are calculated in the machine, check and evaluate if the results are within the allowable limits.

5.1 The ideal results should be that both normal and pathological controls are within the expected range (+/-2SD).

6. If there are no outliers in the QC, print the control values.

1.2 PROCEDURE FOR OUT OF THE LIMIT RESULTS FOR INTEGRA 400 PLUS

1. Run the analyte for calibration.
2. If there is no flaggings in the calibration, re-run the control and check if it's within the required limit.
3. If in case, the control is still out of the limit, check the possible reasons why it is out of the range:

3.1 Check the reagent if it is still stable and good to use. If not, change the reagent to a new one.

3.2 Check if the error is within the analyst itself. Double check if there is any incorrect pipetting during the reconstitution of the controls.

3.2.1 Do parallel testing with another analyst to correct the error. (Run the control up to two times only and then correlate each other's result.)

3.3 Check if its machine error. If so, contact the specialist for further checking.

2.0 QUALITY CONTROL FOR IMMUNOLOGY (COBAS E411)

1. Controls for immunology utilizes PC1 (normal control) and PC2 (pathological control).

1.1 Some of the controls for immunology requires reconstitution. Just follow and add the desired volume of distilled water written in their box. Some controls are already reconstituted upon order.

2. Always check the lot number of controls to be processed. If not yet installed into the machine, let the barcode of the control be scanned and installed. Also, check the expiration date.

3. Prior to running of QC, make sure all the reagents are already loaded inside the machine.

2.1 QUALITY CONTROL PROCEDURE FOR COBAS E411

1. Arrange the controls accordingly. They go in pairs during running (PC1 first, followed by PC2).

1.1 Check the volume of each control sample if it is sufficient for QC running.

1.2 There are 13 tests to be processed:

1. Anti-HIV
2. HBsAg
3. HAV-G
4. HAV-M
5. Anti-HCV
6. HBeAg
7. Anti-HBs
8. PSA
9. FT3
10. FT4
11. TSH
12. AFP
13. CEA

2. Once QC results are calculated in the machine, check and evaluate if the results are within the allowable limits.

    2.1 The ideal results should be that both normal and pathological controls are within the expected range (+/-2SD).

3. If there are no outliers in the QC, print the control values.

2.2 PROCEDURE FOR OUT OF THE LIMIT RESULTS FOR COBAS E411

1. Run the analyte for calibration.
2. If there is no flaggings in the calibration, re-run the control and check if it's within the required limit.
3. If in case, the control is still out of the limit, check the possible reasons why it is out of the range:

    3.1 Check the reagent if it is still stable and good to use. If not, change the reagent to a new one.

3.2 Check if the error is within the analyst itself. Double check if there is any incorrect pipetting during the reconstitution of the controls.

3.2.1 Do parallel testing with another analyst to correct the error. (Run the control up to two times only, and then correlate each other's result.)

3.3 Check if its machine error. If so, contact the specialist for further checking.

3.0 QUALITY CONTROL FOR IMMUNOLOGY (EVOLIS PREMIUM)

1. Controls for EVOLIS are packed in each kit upon order.
2. Controls for Evolis utilizes negative control, PCAntibody, and PCAntigen (positive control).

2.1 No need for control reconstitution because they are ready to use.

3. Always check the lot number of controls to be processed. If new lot number is to be used, change and set the lot number into a new one. Also, check the expiration date.

3.1 QUALITY CONTROL PROCEDURE FOR EVOLIS PREMIUM

1. Prepare all the necessary reagents to be used during running, so with the controls.

1.1 Running of QC is processed at the same time with blood samples.

1.2 Check the volume of each control sample if it is sufficient for QC running.

2. Arrange the sample controls into their control rack accordingly.

2.1 There are 4 tests to be processed:

CONTROLLED

1. HIV
2. HBsAg
3. HCV
4. TREP

3. Put all the reagents, control samples and the blood samples into the machine and proceed with running.

3.1 It takes 4 hours for the running.

4. Once running is finished, control results and the sample results are automatically printed.

5. Check and evaluate the control results.

6. If there are no outliers in the QC, validate results.

3.2 PROCEDURE FOR OUT OF THE LIMIT RESULTS FOR EVOLIS PREMIUM

1. Run the analyte for calibration.

2. If there is no flaggings in the calibration, re-run the control and check if it's within the required limit.

3. If in case, the control is still out of the limit, check the possible reasons why it is out of the range:

3.1 Check the reagent if it is still stable and good to use. If not, change the reagent to a new one.

3.2 Check if the error is within the analyst itself. Double check if there is any incorrect pipetting during the reconstitution of the controls. * Do parallel testing with another analyst to correct the error. (Run the control up to two times only, and then correlate each other's result.)

3.3 Check if its machine error. If so, contact the specialist for further checking.

4.0 QUALITY CONTROL FOR HEMATOLOGY (PHOENIX NCC 3300)

1. Hematology utilizes all 3 levels of controls such as LOW, NORMAL and HIGH controls.
    1.1 No need for control reconstitution because they are ready to use.
2. Always check the lot number of controls to be processed. If new lot number is to be used, change and set the lot number into a new one. Also, check the expiration date.

4.1 QUALITY CONTROL PROCEDURE FOR PHOENIX NCC 3300

1. Stand the control samples to be in room temperature for at least 15 minutes.
2. Mix the control samples by proper inversion (20x inversion).
    2.1 Be careful during inversion to avoid hemolysis.
    2.2 Wipe any blood clots seen in the entry point of the tube to avoid clogging inside the tubings of the machine.
3. Run QC by feeding the control samples one at a time into the machine. (Low control, Normal control, and High Control)
    3.1 The parameters to be tested are:
        1. Hemoglobin,
        2. Hematocrit,
        3. RBC count,
        4. WBC count,
        5. DIFF count and
        6. Platelet count.
4. Once QC results are calculated in the machine, check and evaluate if the results are within the allowable limits.
    4.1 The ideal results should be within the expected range (+/-2SD).
5. If there are no outliers in the QC, validate results.

4.2 PROCEDURE FOR OUT OF THE LIMIT RESULTS FOR PHOENIX NCC 3300

1. Run the analyte for calibration.
2. If there is no flaggings in the calibration, re-run the control and check if it's within the required limit.
3. If in case, the control is still out of the limit, check the possible reasons why it is out of the range:
    3.1 Check the reagent if it is still stable and good to use. If not, change the reagent to a new one.
    3.2 Check if the error is within the analyst itself. Double check if there is any incorrect pipetting during the reconstitution of the controls. * Do parallel testing with another analyst to correct the error. (Run the control up to two times only, and then correlate each other's result.)
    3.3 Check if its machine error. If so, contact the specialist for further checking.

5.0 QUALITY CONTROL FOR CLINICAL MICROSCOPY (COBAS U411)

1. Controls for Clinical Microscopy utilizes Liquicheck1 (normal control) and Liquicheck2 (pathological control)
2. No need for control reconstitution because they are ready to use.
3. Always check the lot number of controls to be processed. If new lot number is to be used, change and set the lot number into a new one. Also, check the expiration date.

5.1 QUALITY CONTROL PROCEDURE FOR COBAS U411

1. Stand the control samples at room temperature for at least 10 minutes.

2. Get an aliquot sample for each control using a medicine dropper and let it flow into Combur strips.
3. Feed the strips one at a time. LQ1 as the first one followed by LQ2.
4. Once QC results are calculated in the machine, check and evaluate if the results are within the allowable limits.
    4.1 The ideal results should be that both normal and pathological controls are within the expected range (+/-2SD).
5. If there are no outliers in the QC, print the control values.

5.2 PROCEDURE FOR OUT OF THE LIMIT RESULTS FOR COBAS U411

1. Run the analyte for calibration.
2. If there is no flaggings in the calibration, re-run the control and check if it's within the required limit.
3. If in case, the control is still out of the limit, check the possible reasons why it is out of the range:
    3.1 Check the reagent if it is still stable and good to use. If not, change the reagent to a new one.
    3.2 Check if the error is within the analyst itself. Double check if there is any incorrect pipetting during the reconstitution of the controls. * Do parallel testing with another analyst to correct the error. (Run the control up to two times only, and then correlate each other's result.)
    3.3 Check if its machine error. If so, contact the specialist for further checking.