I. INTRODUCTION

QUALITY ASSURANCE SYSTEM refers to the systematic actions necessary to provide adequate confidence that laboratory services will satisfy given medical needs for patient's care Ospital ng Parañaque 1, Laboratory Section is committed to providing the best possible service to its patients and is dedicated to constant improvement in terms of technology.

The following complementary components comprise the quality assurance program of the laboratory: Internal Quality Assurance, External Quality Assurance, and Quality Improvement.

II. INTERNAL QUALITY ASSURANCE

A. Pre-analytical

1. All requests received in the laboratory should be properly filled out. It should contain all pertinent data. It should also contain any precautions that the laboratory must be aware of. Should any correction or alteration be done in the request, the person who made the correction should sign his initial beside the information that was altered.
2. The laboratory phlebotomist should strictly follow the standard protocol as provided in the general SOP.
3. Specimens sent to the laboratory are to be examined at the reception area if the said material is fit for analysis. In case the specimen is unfit for testing, the ward should be immediately informed of the reason for rejection.

B. Analytical

1. Reagents

a. All reagents should be properly stored in an area that has the appropriate temperature as specified by the manufacturer to ensure optimal quality.
b. The date when the reagent has been opened should be noted on the box/bottle of the reagent.
c. The Medical Technology staff should check the expiration date of the reagents before using them.

2**. Methodologies and Procedures**

a. Appropriate standards and controls (2 or 3 levels) are analyzed together with the patient's specimen during each shift. Controls are tested in the same manner as that of the patient's specimen following the assay procedure of each test. This is done to assess the quality of the reagent as well as to detect any problem with the performance of the machine that is used. It also helps to check any human random technical error if the test uses manual procedure. The control should fall within the proper range (+/-2SD) for it to be considered within the control limit. Results can only be reported once control values are within acceptable limits.
b. Quality control results should be recorded in the appropriate logbook for each section. For Clinical Chemistry, QC results are plotted in a quality control chart and regularly viewed.
c. Any problem related-pattern in the QC chart should be examined and corrected before any result is released. For specific guidelines in troubleshooting when the control is out of range, kindly refer to the individual section's SOP.
d. For every new lot of reagents, the laboratory shall establish its own set of control ranges for each assay in accordance with standard statistical procedure.
e. Appearance of the specimen must be noted as this may affect the result. Results that fall outside of the linearity range should be diluted with NSS or distilled water. The diluted sample is tested again and the necessary adjustment in the computation is done.

f. Abnormally high or abnormally low samples should be rechecked. After the recheck has been performed, a second sample can be requested by the MT staff on duty to confirm the validity of abnormally high or abnormally low results.
g. The patient's result must be checked against his previous result (up to 2 weeks) of the same examination. Any sudden change or deviation in the result should be correlated with the clinical picture or medical procedure that the patient may undergo. Should there be an incompatibility, a recheck should be done or a new specimen may be extracted if the senior technologist deems it proper.
h. Any suggestion to change the assay procedure must be justified in writing. The request is to be addressed to the Pathologist thru the Chief Medical Technologist. Any change in an assay procedure willonly be implemented once it is reviewed by the Head MT recommended, then approved by the Pathologist.

3. Machines

a. The daily temperature of laboratory equipment like refrigerators and freezers shall be recorded. The record shall be filed by the section responsible for the machine.
b. Daily, weekly and periodic maintenance will be performed on the laboratory instruments and machines. A centralized file of Maintenance Records for the various Laboratory Equipment shall be maintained.
c. Only authorized personnel shall perform preventive maintenance that requires special technical procedures. The preventive maintenance program for each machine shall be attached to the PM folder of the equipment.

4. **Review of Records**

The Medical Technologist staff together with the Chief Medical Technologist shall perform a monthly review of the section's Quality Control records.

C. Post Analytical

1. Results can only be released if the quality control results are within acceptable limits.
2. Before releasing, the result should be properly checked and countersigned by Registered Medical Technology staff (fresh signature for the analyzer and verifier).
3. Each section must maintain an entry logbook for patients with test requests and a logbook containing the results of patients' tests.
4. Panic values for specific tests are found in the SOP logbook of each section and are posted in appropriate places for each section. If the result falls within this range, it should be immediately reported to the attending physician. Relaying the panic values should be in accordance with the guidelines stated in the section "Relaying of Results".
5. Results that may have social and legal implications can be relayed verbally, but in person, to **AUTHORIZED PERSONNEL ONLY.** These include the attending physician who made the request and if the disease may affect the public's health in general. The official result should only be released to the appropriate person. **POSITIVE** results of these examinations SHOULD NOT be relayed by phone. Reporting of examinations with positive results should follow the protocol stated in the SOP of the section involved
6. Confidentiality of the laboratory results should be strictly implemented.
7. Once an official result has been released and a correction on the name of the patient has to be made, an official request for correction of the name has to be submitted. All results bearing the erroneous name of the patient should be returned to the Laboratory and a new set of results shall be released to the patient.

III.EXTERNAL QUALITY ASSURANCE

As per required by law, the different sections of the laboratory shall participate in the National External Quality Assurance Surveys conducted by the appropriate National Reference Laboratory. Specimens from the Reference Laboratories conducting the said program shall be processed in the same manner as specimens from patients. Results shall be submitted promptly to the agency conducting the survey. The result of the agency shall be reviewed and used as the basis to evaluate the integrity and performance of the laboratory's machines, reagents, procedures, and personnel. Certificates of participation from these surveys shall be displayed in the laboratory. Refer to the Laboratory's Procedure for NEQAS for more details on the processing of specimens in the different sections

IV. QUALITY IMPROVEMENT

A. INTRODUCTION

The laboratory is dedicated to improving its services and ensuring the appropriateness of its policies to the needs of the patient. In order to achieve this, events and occurrences that may affect these should be identified and the necessary action/s be taken to rectify or prevent any occurrence which affects patient care. Revisions on existing policies and technical procedures for the improvement of laboratory services of each section are primarily the responsibility of the Medical Technologist. Any revision is subject to the approval and review of the CMT and Pathologist. In situations involving the performance of the laboratory as a whole, the Pathologist and CMT must be consulted before any major revision to existing policies is done.

B. SYSTEM FOR QUALITY IMPROVEMENT

1. Identification of Areas that need improvement.

The following are the tools for identification:

- Occurrence/Incident reports
- Complaints of Patients or Physicians
- Flags in the control data
- Problems discovered by staff
- Client feedback form A written report of these problems must be made for record purposes.

2. Investigation

a. All data pertinent to the problem must be gathered
b. Interviews should be conducted and involved personnel must submit a written report on the circumstances surrounding the incident.
c. Evaluation of the cause and extent of the problem must be done.
d. Current policies and procedures must also be reviewed in the context of the problem that has occurred.

3. Definition of the Problem

All issues and aspects of the problem including people, equipment, communication, supplies, and the workflow itself must be defined. There must be a clear picture as to the exact extent, boundaries, and urgency of the problem so that specific solutions to rectify it and prevent it from happening again can be established.

GUIDELINES

- Was the occurrence merely a symptom of a more serious or widespread problem?
- Is it a one-time deviation from the standard? Is it a random human error? Is it caused by a flaw in the existing system?
- Is the problem only effective (surface problem)? Can this uncover the cause or root of the problem?

4. **Identification of Alternatives**
   Different alternative solutions must be considered. The advice can be solicited from reliable sources. Ideas coming from the staff should also be welcomed.
5. **Evaluation and Selection of Best Result**
   Each alternative solution must be examined and its corresponding effect considered. A T-Chart method can be used to evaluate the advantages and disadvantages of each solution presented. The best solution can then be chosen from the different alternatives.
6. **Implementation of the solution**
   Once the solution has been selected, it is then integrated into the laboratory system and its policies. All staff is informed of the decision and its effectiveness on the problem is monitored.
7. **Follow-up and Modification**
   A system must be devised to monitor how effective the solution to the problem was. Feedback must be taken and reviewed after an appropriate period so that modification or revision to the original decision can be made necessary.

C. MANAGEMENT REVIEW

Areas that need improvement in terms of policies, methodologies, and service shall be discussed during the regular staff meeting of the Department. Special meetings outside of the regular staff meeting of the Department may be conducted for special cases as deemed by the CMT or Pathologist. Minutes shall be maintained for all meetings for future reference and record.

PROCEDURE IN THE PERFORMANCE OF QUALITY ASSURANCE PROGRAM (EQAP)

Prepared By:	Reviewed By:	Approved by:
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GENERAL PROCEDURE:

1. Administrative Order No. 2007-2007: Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines and Department Memorandum No. 2009-0086: Implementation of External Quality Assessment Program as a Regulatory Requirement for Licensing of Clinical Laboratories mandate clinical laboratories to participate in the EQAP administered by the designated National Reference Laboratories (NRLs).
2. The Laboratory shall regularly participate in the EQAP testing done by the different National Reference Laboratories (NRLs). With its present secondary category, the Laboratory is presently mandated to participate in Hematology, Clinical Chemistry, and Parasitology EQAP testing.
3. The Laboratory shall receive all EQAP testing materials sent by the respective NRLs. Upon receipt, the medical technologist on duty shall ascertain for the viability of the samples based on the guidelines from the NRLs. He/shall coordinate with the sending NRL in cases of an incomplete set of materials sent or non-viability of the samples received, for possible acceptance and rejection of the materials sent.
4. The medical technologist who received the testing material shall secure and store the materials in the proper conditions stipulated in the guidelines set by the sending NRLs. He/she shall then inform the chief medical technologist and head Pathologist of such receipt.
5. chief medical technologist shall, upon consultation with the Head Pathologist, schedule the testing of the materials received and shall inform the medical technologist who will perform or assist in performing the testing.
6. All equipment/ machines to be used in the testing shall be properly prepared and calibrated, and shall be evaluated for their proper operation. Internal quality control measures shall be done prior to the testing.
7. The medical technologist shall perform the tests separately from the patient samples of the day. He shall record all results, and/or problems in testing to the chief medical technologist and Head Pathology.
8. The chief medical technologist shall collate the results and report to the Pathologist. The

latter shall review and possibly recommend re-testing with different medical technologists if needed.

9. The final report of the results shall then be prepared and signed by proper laboratory personnel and eventually will be submitted to the sending NRLS

SPECIFIC PROCEDURE:

1. CLINICAL CHEMISTRY

1.1. Application/Registration

1.1.1. Download and complete all data required herein

1.1.1.1. All original LCP-NRL 2017 NEQAS-CC Forms

1.1.1.2. Photocopy of 2017 LICENSE TO OPERATE 2007 2012

1.1.1.3. Machine validated transaction/deposit slip (for bank to bank transactions)

1.1.1.4. Send the forms by mail together with the participation fee of Php 8000.00

1.1.2. For Check Payments: shall be made payable to **LUNG CENTER OF THE PHILIPPINES**. A personal check is NOT acceptable. Official Receipt shall be delivered to the participating laboratory together with the NEQAS-CC samples & accompanying documents when the check is cleared.

1.1.3. **For bank-to-bank transaction**:

payment can be deposited at Landbank of the Philippines, West Avenue branch, Quezon City under the account name NRL (Lung Center of The Philippines), account #: 07 - 02105587.

1.1.4. For Direct Payment: please coordinate first with the LCP-NRL office.
1.1.5. Unknown samples are to be delivered semi-annually. Samples are always accompanied by instruction sheets for testing and sending of results.

1.2. Receiving

1.2.1. Read the documents attached to the panel upon receipt.
1.2.2. Check for the complete proficiency test panel depending on the enrolled proficiency test program
1.2.3. Check the documents and panels for correct identification. Any discrepancy from the panel labels and documents must be reported to the external quality assessment provider as soon as possible.
1.2.4. If the containers are damaged or leaked (during transit) inform the external quality assessment provider and make inquiries on how to proceed. Provide the Lab Name, Lab ID no., Enrolled Programs, and Test Sample Number and arrange for resending.

1.3. Handling

1.3.1. The pack contains 6 vials of lyophilized 5 ml samples. The vials are labeled with the sample number. Inspect the said vials containing the lyophilized samples to ensure if there is any manufacturing defect.
1.3.2. The unopened eqas samples should be kept at refrigerator temperature (4ºC) until use. 1.3.3. Treat eqas samples like routine specimens.

1.4. Analysis / Testing

1.4.1. Open the vial very carefully, avoiding any loss of material and use a calibrated pipette, reconstitute the sample with 5 ml of double distilled

water. Ensure that the lyophilized contents are completely dissolved by gentle swirling.

1.4.2. Stand for 60 minutes and analyze patients' samples. Present results to the chief medical technologist and pathologist.

1.5. Reporting

1.5.1. Report results through online encoding before the said deadline, results will be released after a few days. If the said results reflect some flagging, actions would be done for corrective measures.

1.5.2. Corrective measures would be checking the lot number and expiry of the reagent, and checking if the reagent containers are clean without any impurities. Check the calibration of the machine and control if it is within range.

1.5.3. Corrective actions are to be logged to ensure proper documentation.

1.6. Receiving of EQAS results

Results are released monthly via electronic mail by the accredited NEQAS provider of the National Reference Laboratory. The section supervisor maintains a soft copy of the results. Results are analyzed and used as a basis for troubleshooting and quality improvement. A hard copy is kept on file in the chemistry Section. The Certificate of Participation and Certificate of Achievement is sent by the NRL via Regular Mail. The said Certificates are displayed at the Laboratory.

1.7. Filing of Reports and Results

A hard copy of the reports submitted onlineis kept on file in the section as well as the monthly (summary) and end-of-cycle results given by the NRL Neqas provider. Certificates of Participation/Achievement from previous years are also kept in the file.

1.8. Disposal **WARNING: POTENTIALLY INFECTIOUS MATERIAL

1.8.1. The source materials from which the samples were derived have been tested as non-reactive for HBsAg and negative for antibodies to HIV-1, HIV-2 and Hepatitis C virus using FDA-specified techniques. However, no current test can assure the complete absence of these pathogens.

The survey sample must still be handled like any potentially infectious materials. UNIVERSAL PRECAUTIONS should be taken.

1.8.2. After completing the tests on the samples, it is autoclaved together with other infectious waste and is collected and disposed of with the other hospital's other hazardous waste.

2. HEMATOLOGY

2.1. Application/Registration

2.1.1. Download and fill out the registration form.

2.1.2. Send the forms by mail together with the participation fee of Php 3500.2.1.2.1. Payment can be deposited at Landbank of the Philippines, West Avenue branch, Quezon City under account name: NKTI Special Project, account #: 0232-1086-22. Send the slip together with the registration form.

2.1.2.2. Official receipt will be sent together with the unknown sample. Samples are always accompanied by instruction sheets for testing and sending of results.

2.2. Receiving Upon receipt of the proficiency test sample always:

2.2.1. Read the accompanying documents first.

2.2.2. Check the color of the supernatant. Slight hemolysis of the supernatant is expected (light pink) but excessive hemolysis of the supernatant may result from exposure of the sample to extreme temperatures. NOTE: If sample deterioration is suspected or incorrect material has been sent, proceed with sample processing and analysis and indicate the problem in the corresponding box on the resulting form.

2.2.3. Process the sample in not later than two (2) weeks upon receipt as this material has a very short life span (less than 30 days). If a delay in processing cannot be avoided, refrigerate and keep the samples at 4-8ºC until such time that the analysis may be performed.

2.3. Handling *

PRE-ANALYSIS CHECK Before analyzing the samples, follow the

procedure recommended by the manufacturer to ensure that the instrument is in optimal functioning conditions. Perform daily preventive maintenance and run controls before analysis of the survey samples.

2.4. Analysis / Testing

2.4.1. Allow previously refrigerated vials to stand at room temperature (15-30ºC) for at least 15 minutes.

2.4.2. Verify that the vial cap is securely in place. Mix the vial by the gentle end to end inversion until the cell button in the bottom is completely resuspended.

2.4.3. Roll the vial gently between the palms of the hands for 20 seconds in the upright position; invert the vial and roll it 20 seconds more.

2.4.4. Run the sample like other patientsamples using the main and backup automated Hematology Machines

2.5. Reporting

2.5.1. Report results for both machines on separate result forms.

2.5.2. Make sure that the survey result form/s are completely, clearly, and legibly filled up. Send the result by mail to: National Kidney and Transplant Institute (NKTI) National Reference Laboratory for Hematology, East Ave., Diliman, Quezon City. ***Remember that the results are required to be submitted within two (2) weeks upon receipt of survey samples.

2.6. Receiving of EQAS result The Hematology Eqas result as well as the Laboratory's Certificate of Participation is sent to the Laboratory via Regular Mail.Results are analyzed and used as a basis for troubleshooting and quality improvement. The documents are endorsed for safekeeping to the Section Supervisor or his/her representative

2.7. Filing of Results Hematology Eqas results are kept in file in the Hematology Section. The latest Certificate of Participation is displayed at the Main Laboratory. Certificates of previous years are also kept in a file in the section.

2.8. Disposal **WARNING: POTENTIALLY INFECTIOUS MATERIAL

2.8.1. The source materials from which the samples were derived have been tested as non-reactive for HBsAg and negative for antibodies to HIV-1, HIV-2 and Hepatitis C virus using FDA-specified techniques. However, no current test can assure the complete absence of these pathogens. The survey sample must still be handled like any potentially infectious materials. UNIVERSAL PRECAUTIONS should be taken.

2.8.2. After completing the tests on the samples, it is discarded onto the infectious waste material bin.

3. PARASITOLOGY

3.1. Application/Registration

3.1.1. Go to NRL website, download and fill up the application form. (http://ritm.gov.ph/wp-content/uploads/2016/04/NEQAS-Enrollment-FormV6.0.pdf). Make a copy of the registration form for the document record of the Microbiology section.

3.1.2. Submit the original application form together with NEQAS certification from the previous year and payment: National External Quality Assessment Scheme Research Institute for Tropical Medicine, Filinvest, Alabang, Muntinlupa City, Metro Manila

3.1.3. Make a confirmation call to the National Reference laboratory to make sure the application was successful. Tel. no. 807 2631

3.1.4. Upon submission of forms official receipt is given on the same date. Unknown samples are delivered through a courier and always accompanied by instruction sheets for testing and sending of results.

3.2. Receiving

3.2.1. Read the documents attached to the panel upon receipt.

3.2.2. Check for the complete proficiency test panel depending on the enrolled proficiency test program.

3.2.3. Check the documents and panels for correct identification. Any

discrepancy from the panel labels and documents must be reported to the external quality assessment provider as soon as possible.

3.2.4. If the containers are damaged or leaked (during transit) inform the external quality assessment provider and make inquiries on how to proceed. Provide the Lab Name, Lab ID no., Enrolled Programs, and Test Sample Number and arrange for resending.

3.2.5. Contact the external quality assessment provider within 3 days if the package is received more than 5 days from the date of mailing and the analyte did not grow even on repeat culture.

3.3. Handling

****BIOSAFETY WARNING**

3.3.1. The analytes must be handled following Biosafety Level 2 (BSL-2) practices as the proficiency test panels can cause diseases in healthy individuals and may cause moderate risk to the environment.

3.3.2. The analytes should be treated as infectious and pathogenic hence Personal Protective Equipment is required.

3.3.3. The analytes should be handled and disposed by authorized personnel working with pathogenic microbes following bio-safety guidelines upon completion. Steam autoclaving is recommended.

3.4. Analysis / Testing

3.4.1. Parasitology

3.4.1.1. Stool Suspension

3.4.1.1.1.Mix the stool suspension well.

3.4.1.1.2. Place a small amount of stool suspension on a glass slide and apply a coverslip.

3.4.1.1.3. Focus and search with the low power objective; shift objectives for higher magnification and

detailed observation.

3.4.1.1.4. Scan the preparation thoroughly from end to end by sequentially advancing the slide by one field to another and moving in one direction at a time.

3.4.1.1.5. Identify all the parasite species present in the suspension. Failure to do so will result in incomplete and inaccurate reporting.

3.4.1.1.6. Write the analyte ID number and identified parasite species in the provided form

3.4.1.2. Blood Films for Blood Parasites

3.4.1.2.1. Scan and identify the parasite species using Oil Immersion Field (OIF).

3.4.1.2.2. Write the analyte ID number, and identified parasite species, and indicate in the provided form.

3.4.1.2.3. A minimum of 500 OIF should be read before declaring a slide as NEGATIVE

3.5. Reporting

3.5.1. All identification answers should be written in proper form.

3.5.2. All proper names should be in their correct form and spelling. Wrong spelling will not be accepted.

3.5.3. Do not leave any spaces blank. If it is indicated in the form, make sure to answer it.

3.5.4. The technologist should not send out or refer to other laboratories the test samples for testing.

3.5.5. Record/write your results in the Laboratory Result Forms (must be photocopied) which is provided with the proficiency panel.

3.5.6. Submit the results thru courier on or before the submission date

3.5.7. It is the technologist's responsibility to confirm if the forms were received by the assessment provider.

3.6. Receiving of EQAS result The Eqas result as well as the Laboratory's Certificate of Participation is sent to the Laboratory via Regular Mail. Results are analyzed and used as a basis for troubleshooting and quality improvement. The documents are endorsed for safekeeping to the Section Supervisor or his/her representative

3.7. Filing of ResultstheEqas result as well as the Laboratory's Certificate of Participation is sent to the Laboratory via Regular Mail. Results are analyzed and used as a basis for troubleshooting and quality improvement. The documents are endorsed for safekeeping to the Section Supervisor or his/her representative

3.8. Disposal

****BIOSAFETY WARNING**

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