STATE OF NEW YORK : DEPARTMENT OF HEALTH

IN THE MATTER

OF

PENINSULA HOSPITAL CENTER
51-15 BEACH CHANNEL DRIVE
FAR ROCKAWAY, NEW YORK 11691

and

GUANGHUI KONG, M.D., Ph.D.

ORDER FOR SUMMARY ACTION

WHEREAS, Peninsula Hospital Center, located at 51-15 Beach Channel Drive, Far Rockaway, New York 11691, is a general hospital operated by the Peninsula Hospital Center and licensed by the New York State Department of Health (the "Department") pursuant to Article 28 of the Public Health Law ("PHL"); and

WHEREAS, on October 10, 2011, the Department issued a permit to the Peninsula Hospital Center, and Guanghui, Kong, M.D., Ph.D., pursuant to Article 5, Title 5 of the PHL, to operate a clinical laboratory at the Peninsula Hospital Center to provide numerous laboratory services, as set forth on the clinical laboratory permit. Peninsula Hospital Center and Guanghui Kong, M.D., Ph.D., are hereinafter referred to collectively as "Respondents"; and

WHEREAS, inspectors with the Department's Wadsworth Center Clinical Laboratory Evaluation Program inspected the clinical laboratory at the Peninsula Hospital Center on February 21 and 22, 2012, and found serious deficiencies in the administration and operation relating to the clinical laboratory operation. These findings include but are not limited to:

General Observations:

1) Lack of training, competency assessment and continuing education;

2) Lack of safety training including shipping of infectious materials;

3) No supervisor was on-site during the evening, the night shift and weekends and no appropriate chain of command was available to provide guidance to staff;

4) The day shift supervisor is knowledgeable in microbiology and has no experience or training in other clinical areas of the laboratory;

5) The Respondent laboratory director is not involved in the clinical laboratory and has not met the requirements of 10 NYCRR Part 19.3, by failing to provide effective administration of the laboratory, failing to ensure that sufficient qualified staff are employed with documented training or experience to supervise and perform laboratory testing, failing to provide education direction, and failing to ensure that policies and procedures are established to monitor employee competency;

6) An individual worked alone in the Blood Bank on January 1, 2012, after receiving only two days of training. She telephoned a co-worker not working that day to obtain assistance in how to perform testing. She did not perform quality controls or take the required daily temperatures to ensure that blood and blood components were stored in the appropriate conditions.

7) Standard Operating Procedures ("SOP"s) are unavailable, inaccurate or incomplete. Many SOPs have not been reviewed or updated since 2002. SOPs do not reflect the current testing performed at the laboratory. There is no evidence that the current laboratory director has reviewed or approved the SOPs;

8) Pipettes have not been calibrated since May 2011. Staff describe that calibration is required every six months to determine if appropriate volumes are dispensed;

9) Thermometer calibrations and timer accuracy checks are not performed;

10) Routine instrument preventative maintenance is either not performed or not documented as having been performed;

11) There is no system for reagent inventory and tracking. The laboratory has been unable to maintain an inventory of reagents and supplies to prevent disruption of services. Due to a lack of reagents, the laboratory was unable to perform the stat troponin and quantitative pregnancy testing requested from the emergency room;

12) Expired reagents are used in the Blood Bank, Hematology and Microbiology laboratories;

13) The laboratory has no back-up for the laboratory information system and is aware that if the computer system fails, the data will be irretrievable. The hospital has a substantial sickle cell and oncology population that receive multiple transfusions. Retrieval of prior transfusion history, antibody screen reactions, and antibody identification are critical to ensure safe transfusions;

14) The laboratory staff is entering results manually into the computer for some areas of the laboratory including Blood Bank and Blood Gases. There is no process for verifying that the results are entered accurately into the computer;

15) A lack of personal protective equipment in all areas of the laboratory. Staff was observed handling primary specimens in the Microbiology laboratory without wearing gloves. There are no safety shields in the laboratory and no use of face masks when manipulating samples;

16) A biohazard risk assessment has not been performed. Couriers and other non-laboratory personnel were observed in the laboratory. A safe laboratory environment is not provided to laboratory personnel;

17) The laboratory does not monitor the temperature of the storage room where reagents are stored;

18) The regulated medical waste is stored in an area that is not secured to prevent unauthorized entry or access by vermin; and

19) Proficiency testing results are not reviewed by the laboratory director. Remediation of proficiency testing failures has not been performed. Shifts and trends are not monitored.

Microbiology

1) The de-colorizer for gram stain and the disinfectant in the biological safety cabinet were not labeled with the identity, preparation data, date opened and expiration date;

2) The Gram Safranin stain to perform gram stains expired on August 31, 2011, but was currently in use and opened on February 2, 2012;

3) The laboratory is not monitoring the air flow in the biological safety cabinet. Air flow must be monitored to ensure that staff is not exposed to infectious organisms;

4) The carbon dioxide levels are not monitored in the incubator in the Microbiology laboratory to ensure the appropriate growth conditions;

5) The laboratory does not maintain the appropriate stock cultures to perform the necessary quality control;

6) The laboratory has not established an acceptable range for humidity in the Microbiology laboratory; and

7) The laboratory policy indicates that CSF and blood culture gram stains are stat tests; however, no staff is available to perform testing after 4 P.M. Patient care may be delayed or compromised.

Histopathology/Cytopathology

1) The laboratory is not changing staining reagents weekly, as required in the SOP;

2) The laboratory has not performed daily and weekly maintenance on the Microtome.

3) The semi-annual maintenance has not been performed on the Heker automated stainer as required in the SOP;

4) There is no preventative maintenance on the scale used for grossing;

5) There is no preventative maintenance on the microscopes or timers;

6) Temperatures for the various areas in the laboratory are taken with one thermometer. Temperature readings are exactly the same every day of the year. When asked to take a reading of room temperature, the histo-technician read the temperature as 65 degrees on the thermometer when, in fact, the thermometer read 23.5 degrees. This was verified by two surveyors;

7) There are no records that the pathologist has determined whether stain quality is acceptable for each day of testing; and

8) The laboratory has not performed a correlation between the automated stainer and the manual stain process. The histo-technician was unable to describe when manual staining is performed versus automated staining. The SOP does not address this issue.

Chemistry/Toxicology/Endocrinology/Blood Gases

1) There is no correlation between the two Gem Premier blood gas analyzers;

2) No SOP for when and what quality control materials should be performed on the blood gas analyzers;

3) There is no planned maintenance schedule for the distilled water system used on the chemistry analyzer and other areas;

4) There is no planned maintenance schedule for the cooling system. Filters were dirty;

5) There were no specimen rejection criteria;

6) Six blood gas specimens were delivered by a courier to the laboratory for testing from the nursing home. No time of collection was indicated on the specimen. Blood specimens should be performed within 30 minutes of collection to provide accurate results; and

7) Lack of documentation for remedial action when daily start-up records on the Dimension indicate that the instrument failed specific parameters.

Hematology

1) Erythrocyte sedimentation rates ("ESR") are performed next to the rack mixer for complete blood count samples. The vibration from the mixer can affect the outcome of the ESR test results;

2) No check of the timer used for ESRs;

3) No lot-to-lot verification or kit-to-kit verifications of reagents;

4) For urine pregnancy, the laboratory does not consistently receive the same kit and does not validate when a different kit is received;

5) No specimen rejection criteria for Pro-times and activated partial thromboplastin time ("APTTs");

6) No correlation between the two hematology instruments to ascertain consistency of results;

7) No quality control for body fluid specimens;

8) The laboratory information system is discordant with the instrument in terms of the time of testing;

9) The laboratory is documenting maintenance and quality control for instruments that are no longer in use;

10) The laboratory does not document reagent expiration dates; and

11) Calibration was not performed on the XT-1000 in 2011. No calibration was performed on the XT-2000 in 2012. These are required calibrations performed by the manufacturer.

Blood Bank

1) Incorrect temperature charts were observed on the packed red cell refrigerator for an extended length of time. Red cells are stored at 1-6 degrees Celsius and the chart on the refrigerator was reading 46 degrees F. The laboratory was unable to determine if red cells transfused to patients were stored at the acceptable temperature. These charts were changed weekly and went unnoticed by laboratory staff;

2) A blood bank technologist performed ABO/Rh typing and resulted the patient as A positive. The blood type was repeated with a new sample and determined to be A negative. The first was retyped and found to be A negative. No investigation was performed to determine if there was a technical or clerical error. The technologist went into the computer system without authorization and changed the result:

3) There was no controlled access to the LIS system to prevent unauthorized editing or modification of test results:

4) There was no documentation that a cross match was performed on two units of RBC's issued and transfused to the individual where the Rh error occurred. This is noted for unit numbers W121612104802 and W091012100939:

5) An antibody identification panel was performed on patient LM on October 19, 2011. Anti-E was identified; however, no reactions were recorded on the panel worksheet. This panel worksheet was reviewed by a second individual and determined to be acceptable. The patient was transfused with two units of RBC's on October 20, 2011:

6) There is no documentation that any positive or negative quality control is performed on the anti-sera used to screen patients and donor antigens. This was noted on a daily exception report: however, exception reports are not reviewed by management and corrective action is not taken:

7) Three units of expired plasma were identified in the Blood Bank freezer:

8) No testing, quality control, temperatures or maintenance is reviewed by laboratory administration:

9) 2012 RPM and timer checks were performed but neither the laboratory nor the biomedical engineering staff knew the acceptable ranges:

10) The laboratory stored platelets at 26.4 degrees Celsius and the acceptable storage temperature is 20-24 degrees Celsius. The temperature record indicates that the acceptable range is 20-25 degrees; however, this is not in keeping with the requirement of 10 NYCRR 58-2.6(i). Platelets were transfused to the patient when the temperature was observed by the surveyor to be out of the acceptable range:

11) Blood warmer temperatures are recorded but the acceptable range is not known since a manufacturer's manual is not available;

12) Transfusion slips received from nursing are incomplete in regards to date and time started, completion time, and signatures of both transfusionists;

13) Tissue used for transplant purposes is stored in a freezer in the Blood Bank. The temperature has not been monitored for two years; and

14) The laboratory director and laboratory Blood Bank staff stated that albumin was not administered at the hospital. After interviewing pharmacy staff, it was determined that the hospital pharmacy issues albumin.

WHEREAS, the Department has determined that, as a result of the above deficiencies, the public health, safety and welfare is in imminent danger.

NOW, THEREFORE, THE COMMISSIONER OF HEALTH DOES HEREBY ORDER THAT:

1) Pursuant to PHL § 577(3), the categories identified on the Respondents' laboratory permit are suspended for thirty days from the effective date of this Order. Notwithstanding this suspension,

FURTHER, I DO HEREBY give notice that the Respondents are entitled to a hearing, to be held within thirty (30) days of service of this Order, at 90 Church Street, Fourth Floor, New York, New York 10007, to contest this Order. The Commissioner will set a time and place of the hearing and provide notice of the hearing and charges against the Respondents at least 15 days before the date set for the hearing.

DATED: Albany, New York
February 23, 2012

STATE OF NEW YORK
DEPARTMENT OF HEALTH

NIRAV R. SHAH, M.D., M.P.H.
Commissioner of Health

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