Management Review meeting of SNSC performance based on internal audit
Audit cycle-II - July to December 2013; Dated 21.03.2014

Attendance: By list (list enclosed). The representations were from the SN main lab for Hematology and Clinical Pathology, Routine Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics and the Support Services, CSFU, HRD, Commercial, Housekeeping, Biomedical, Electrical, Training Dept, IT and all Internal auditors.

The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.

1. Follow up of previous management review
2. Status of Corrective and Preventive Actions taken (CAPA)
3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures
4. Out come of recent internal audits, NC’s.
5. Assessments of external bodies.
6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.
7. Volume and type of work undertaken.
8. Feedback including complaints and other relevant factors for Internal and external
9. Quality Indicators for monitoring the laboratories contribution to patient care
11. Monitoring Turn around time.
12. Continual improvements.
14. Points for Discussion for action

Audit Team Members and Audited labs/support services:

• Quality System : Ms. Saumya.T.S
• Front Office & Pre analytical area : Ms.K.Vanitha
• Clinical Pathology and Hematology: Ms.K.Vanitha
• Clinical and Special Biochemistry: Ms.Y.Faritha Banu
• Clinical Microbiology and Serology : Ms.B.Mohanambal
• Histopathology and Cytopathology : Dr.B.Mahalakshmi
• Human Resource Department : Ms.R.Punitham
• Commercial : Dr. N. Angayarkanni
• Central Sterilization Facility Unit : Dr.Doreen Gracias
• Biomedical Department : Dr.K.Lily Therese
• IT Dept : Ms.R.Punitham
• SNSC Cl.Lab, Pycrofts garden Road (Collection Centre) : Dr. K.Coral

Non NABL:
• NSN Lab : Ms.U.Jayanthi
• Cytogenetics : Ms.Kamatchi
1. **Follow up of previous management review:**

   * Validity of the NABL certificate: **14.08.2013 TO 13.08.2015**.
   * SNSC clinical laboratory at pycrofts road was approved as collection centre.
   * Quality plan 2013 implementation was discussed

2. **Status of Corrective and Preventive Actions taken (CAPA):** Daily non-conformances are documented in all the laboratories and discussed in the respective departmental lab meetings for corrective action. CAPA are documented for detailed ones.

3. **Report from Dy technical managers of each of the lab on QC/Measures:** This has been reviewed for the two quarters in the last 6 months, dept wise.
   
   * Quality control programme: verified every quarter with respect to **internal and external QC programme as well as in interlab comparisons**. Corrective actions were taken wherever applicable.
   
   * Measures of each lab verified quarterly and corrective actions taken as applicable. Cl Biochemistry analyzer (Dade Behring – Machine down time was high and so the measure unsatisfactory)

4. **Internal audit II outcome:** The Second internal audit July to December’13 has been conducted in he month of Jan 14, by the trained and Approved internal auditors of SNSC laboratory. Cytogenetics lab and Navasuja were also audited though not running any accredited tests. Collection center at Pycrofts road, (JKCN) was also audited. All the non-conformances were announced to be closed by the QM after corrective action.

5. **Assessments of external bodies: updated in all the laboratories:**

   - Tamil Nadu Pollution control Board certificate for disposal of waste Renewal of Certificate has done on October 2012 (Validity till February 2016) for SN Main Hospital.
   
   - Pollution Control Board renewal of the agreement done on October 2012, **Validity period is over Certificate is due for SNSC Clinical. Laboratory Pycrofts garden road (SNSC- Centre).**
   
   - Waste disposal is done by G.J Multiclave (approved) which will continue. Renewal of the agreement was done on May 2013 (**Validity till April 2014**) for SN Main & JKCN Centre at pycrofts road.

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**Issue Date:** 26.3.14

**Prepared & Issued by:** Quality Manager

**Approved by:** Management Representative

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6. **Outcome of Quality Control:** External/Internal/Daily of each lab: EQAS, ILQC.

- The QC of all the laboratories completed as per stipulated programme
- Assessment of the referral labs was updated by all the departments –
  (List of Referral labs: Lister Metropolis, Hitech Diagnostic Centre, Sundaram Medical Foundation, Microbiological Laboratory-Coimbatore, Ehrlich laboratory, Sandor Proteomics Pvt Ltd, SRMC – Porur, Anand Laboratory- Bangalore)
  EQAS is done with: Biorad, CMC, AIIMS, SRL Ranbaxy, IAMM, Euroimmun (Germany)

7. **Volume and type of work undertaken was reviewed**

- Revised Scope: Recertification audit completed on June 2013. We have received the NABL certificate with validity period of 14.08.2013 to 13.08.2015.
  a. **Clinical Haematology:** 17 and **Clinical Pathology:** 19
  b. **Clinical and Special Biochemistry:** 20
  c. **Clinical Microbiology and Serology:** 26
  d. **Histopathology:** 6 and **Cytopathology:** 4
  **Total:** 92 Tests

- The statistics of number of investigations in each lab was discussed. While 6 months data showed a fall in each of the lab, overall one year data showed a marginal increase in 2013, over 2012

<table>
<thead>
<tr>
<th>Name of the Lab</th>
<th>2012 (Jan – Dec)</th>
<th>2013 (Jan – Dec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Haematology &amp; Cl.Pathology</td>
<td>125534</td>
<td>140810</td>
</tr>
<tr>
<td>Clinical &amp; Special Biochemistry</td>
<td>60460</td>
<td>68656</td>
</tr>
<tr>
<td>Microbiology &amp; Serology</td>
<td>28238</td>
<td>28984</td>
</tr>
<tr>
<td>Histopathology &amp; Cytopathology</td>
<td>1480</td>
<td>1629</td>
</tr>
<tr>
<td>Outsource Tests</td>
<td>384</td>
<td>351</td>
</tr>
</tbody>
</table>
• New Signing Authority : Nil

• New post created : Nil. However the technical staff number is adequate.

• Promotions/resignations :
  Three Senior Lab Technicians (Ms.Shobana, Ms.Priya, Ms.Rubella Nancy) and One Secretary (Ms.Anwar Nisha) from Microbiology lab, One Lab Assistant (Ms.Bharthana) from Hematology & Cl.Pathology resigned the job

• Refilling of the post: One Junior Executive (Ms.Vaidegi), Three Senior Lab Technicians (Mr.Hariram, Mr.Evangelin, Mr.Sivasankaran), One Secretary (Ms.Gayathri) has joined in Microbiology lab.

8. Feedback analysis : This analysis is done in Main lab, Microbiology and Histopathology labs based on feedback from our consultants (internal customer). Actions were taken and the issues settled as monitored by QM

a. Internal customer feedback : The observed measures (Jul – Dec 2013) were above the expected norms in all the laboratories.

b. External customer feedback : Feedbacks (after grouping them on similarity in issues) were analyzed (Jul – Dec 2013) proceeded with action and settled by the main lab

9. Quality Indicators for monitoring the laboratories contribution to patient care as measured

a. Specimens receiving on time - Above objective of the measure.

b. Turn around time – well within objective except in histopathology with delay in 16.25% cases

c. Machine downtime – Clinical Haematology Unsatisfactory – Corrective action taken
  Clinical Biochemistry : Unsatisfactory – Corrective action taken
  Microbiology : Satisfactory
  Histopathology : Satisfactory
10. The entire NCs raised in the internal audits are closed. (20 major and 45 minor)

11. The measures of Pre analytical/Analytical/ Post analytical issues addressed under quality indicators (Refer Point No.9)

12. Continual Improvement:

   a. Improvement on the reporting and documentation
   
   b. Regularization of the Instrument asset numbers.
   
   c. Sign Board for placement of the urine containers has been fixed in Main Lab toilet on 19.9.13 as per the patient’s feedback form.
   
   d. Patient registration for laboratory will be blocked for 24 hours after FFA is done, so that ACE / Quantiferon tests done thereafter are not influenced by the flourascein in the blood.
   
   e. Sun medica is supporting for the PMT RA-50 semi auto analyzer (Standby equipment)
   
   f. Daily NC summary is recorded in all the laboratories.
   
   g. Biolyte-2000 electrolyte analyzer sent for condemnation.
   
   h. Used Microtips are discarded everyday from 16.07.2013 in main lab
   
   i. GGTP test preliminary standardization and validation completed. It will be implement to patient care on next lab form revision (in process) in cl biochemistry at main lab
   
   j. Fast track service has been started for cataract patients from 1st October 2013 in main lab.
   
   k. Asset managers are nominated for equipments in each of the laboratory.
   
   l. New AC installed in clinical biochemistry to maintain the temperature at night time in the main lab.
   
   m. Refrigerator cleaning done every month in the main lab
   
   n. SNOWMED Coding of histopathology specimens in HMS implemented in histopathology lab
   
   o. Inter lab comparison initiation for special stains with SMF from July 2013 histopathology lab
   
   p. Separate record for Frozen Section histopathology lab
   
   q. Records maintaining for inter quality check for Microtome blades, reagents for deparaffinization, H&E Staining in histopathology lab
   
   r. SOP Updated for processing of urgent samples and for providing paraffin block and slides to patients histopathology lab.
s. SOP for spill management kits made in the QSM.

t. NABL Accreditation for cANCA, pANCA tests. Reports sent with logo from Sep’13 onwards in the microbiology lab

u. Version numbers of documents revised in 2013 (July to December) : Quality system
   - Lab Requisition Form : F/SNSC/ML/LRF/1.15
   - PMT / Calibration Plan : New Version 1.0
   - Quarterly reporting : SNSC Collection Centre
   - Quarterly reporting : Dy Technical Managers to the QM
   - UPS Maintenance Check list : UPS/Aug 2013/Ver 1.0

v. New Machines : in main lab
   - LH 750 Beckman Coulter has been installed
   - New AVL analyzer started functioning from July 1st 2013 (Standby :old AVL )

w. Training programme for laboratory : Ms. Karpagapriya and Ms.Chandrika training department conducted 16 classes (Jul – Dec’13) on soft skills. Details are recorded in the training record and also entered in the HMS. Internal training programme were given in each of the department as weekly scheduled classes. Participation in 6 external programme were there. 2 prizes won at LISTER CME programme by Ms. Sowmya and Ms.Rajalakshmi of Main lab.

x. Promotions & New posts created & New signing Authority : No new posts. Signing authority proposed to NABL for Dr.Coral (Biochemistry) and Dr.Gayathri (Microbiology) was not approved based on the parity on Masters degree vs specialization

13. Vendor Evaluations :
   - The approved vendor list prepared by the commercial after evaluation was presented. 10 of them were under the category of “Fair performance”. No vendor is removed from the list.
   - The list for 2013-14 will be circulated by the commercial. Revisions in manual on the SOP of vendor evaluation completed to ensure flow of information from end user and appropriate documentation
14. **Other information:**

- Interaction with clinical consultants to be documented and sent to QM for record along with quality indicators.
- New version of Technical books to be purchased to update the SOPs in all the laboratories.
- **All Manuals have to be updated as per new NABL 15189 : 2012 standard and implementation of standard to be ensured through audits before the end of 2014.**
- The next Surveillance / Desktop audit is due in June (or) July 2014.

Thank You

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**Date: 26.03.2014.**

**Forwarded by:**

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