Minutes of the Management Review Meeting of SNSC performance based on Internal Audit Audit cycle I & II (2018), Jan to Dec 2018 : Dated 16.03.2019

Attendance: By list (list enclosed). The representations were from the SN main lab for Haematology, Clinical Pathology, Clinical Biochemistry, Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics and the Support Services, CSFU, HRD, Commercial, Biomedical, Training Dept, IT Dept, All Internal auditors & NABH - Coordinator

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

a) The periodic review of requests, and suitability of procedures and sample requirements.
b) Assessment of user feedback.
c) Staff suggestions.
d) Internal audits.
e) Risk management.
f) Use of quality indicators.
g) Reviews by external organizations.
h) Results of participation in inter laboratory comparison programmes (PT/EQA).
i) Monitoring and resolution of complaints.
j) Performance of suppliers.
k) Identification and control of nonconformities.
l) Results of continual improvement including current status of corrective actions and preventive actions.
m) Follow-up actions from previous management reviews.
n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system.
o) Recommendations for improvement, including technical requirements.

Audit Team Members and Audited labs / Support services:

- Internal audit – I conducted on Jun'18 based on NABL standard ISO 15189 : 2012 for the following departments:
  - Quality System Management : Dr.P.Premalatha
  - Front Office & Pre analytical area : Dr.S.R.Bharathi Devi & Dr.R.Harini
  - Clinical Pathology and Hematology : Dr.S.R.Bharathi Devi & Dr.R.Harini
  - Clinical and Special Biochemistry : Dr.Amrita Talukdar
  - Clinical Microbiology and Serology : Ms.Saumya.T.S
  - Histopathology and Cytopathology : Ms.U.Jayanthi & Dr.R.Harini
  - Human Resource Department : Ms.R.Punitham
  - Commercial : Ms.R.Rajalakshmi
  - Biomedical Department : Ms.R.Rajalakshmi
  - Central Sterilization Facility Unit : Ms.Saumya.T.S
  - Information Technology Dept : Ms.R.Punitham
  - SNSC Collection Centre (Pycrofts Road): Dr.S.Sripriya

  Non-NABL

  - Cytogenetics : Ms.K.Vanitha
  - SNSC Collection Centre -NSN : Dr.S.Sripriya
- Internal audit- II conducted on December'18 based on NABL Standard ISO 15189 : 2012 for the following departments:
  - Quality System Management : Ms.K.Vanitha & Ms.V.Gayathri
  - Front Office & Pre analytical area : Ms.U.Jayanthi & Dr.M.K.Janani
  - Clinical Pathology and Hematology : Ms.U.Jayanthi & Dr.M.K.Janani
  - Clinical and Special Biochemistry : Ms.Saumya.T.S & Dr.Anand.A.R
  - Clinical Microbiology and Serology : Dr.R.Harini
  - Histopathology and Cytopathology : Ms.R.Punitham & Dr.A.V.Kavitha

- Human Resource Department : Dr.P.Premalatha
- Commercial : Dr.S.Sripriya
- Biomedical Department : Dr.S.Sripriya
- Central Sterilization Facility Unit : Ms.R.Rajalakshmi
- Information Technology Dept : Dr.P.Premalatha
- SNSC Collection Centre (Pycrofts Road) : Dr.S.R.Bharathi Devi

Non-NABL

- Cytogenetics : Ms.R.Rajalakshmi
- SNSC Collection Centre –NSN : Dr.S.R.Bharathi Devi

Internal audit I & II conducted by Internal Assessors based on New Standard ISO 15189:2012: all the NCs are closed. Internal Audit – I (Minor NC - 11, Major NC - 25), Internal Audit –II (Minor NC - 15, Major NC - 37).

a. **The periodic review of requests, and suitability of procedures and sample requirements** :

- This has been reviewed for the four quarters in the last 12 months, dept wise. Corrective actions were taken wherever applicable.

Clinical Haematology & Clinical Pathology:

- LE Cell Preparation, Occult Blood: Sputum, Occult Blood: Vomitus, Occult Blood: Aspirate test codes has been removed on New Lab Form : F/SNSC/ML/LRF/1.21

Biochemistry :

- Biological Reference Range : For all clinical biochemistry tests, age wise reference range was updated.
- Sp.Cl Biochem: for Vitamin A test was updated for reference range on 01.04.2018 based on age.
- Iinterpretation were introduced in the reporting format.

- HbA1C & Microalbumin tests under Special Biochemistry shifted to Biochemistry Master List

- **Quality System:**

- Internal Assessor training of ISO 15189 : 2012 completed by Dr.A.R.Anand, Dr.M.K.Janani, Dr.A.V.Kavitha, Dr.Dhanurekha, Ms.V.Gayathri & Ms.R.Gayathri
- Received Communication form NABL Authorized Signatory for Dr.R.Harini for Clinical Biochemistry with effect from 10.07.18
- Received Desktop audit communication from NABL on 14.09.18 and NABL has recommended the continuation of the accreditation.
- As per NABL instructions SNSC Clinical Laboratory "Mark Location of Laboratory" was updated on Google Map
- NABL Issued Sample Collection Centre Recognized Certificate (for SNSC Collection Centre, 21, Pycrofts Road) on 31.01.19. Certificate (Photo copy) for the same given to SNSC Collection Centre-Pycrofts Road for display

b. Assessment of user feedback :

- This analysis is done in SN-Main lab (Cl.Haematology, Cl,Pathology, Cl.Biochemistry & SNSC Collection Centre – Pycrofts Road), Microbiology and Histopathology labs.
- *Internal customer feedback* : The observed measures (Jan - Dec'18) were above the respective stipulated objectives in all the laboratories as evaluated half yearly.
  - Histopathology & Cytopathology: (Objective - 80%)
    (Jan - Jun'18) - **94.4%,** (Jul - Dec'18) – **94.4%**
  - Microbiology & Serology: (Objective - 80%)
    (Jan - Jun'18) - **94%,** (Jul - Dec'18) - **93%**
  - Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and SNSC Collection Centre -Pycrofts Road) : (Objective - 80%)
    (Jan-Jun'18) – **88.2%,** (Jul - Dec'18) - **86%**

- *External customer feedback:*
  - SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry: (Jan - Jun'18) - **92%,** (Jul - Dec'18) – **94.6%** (Objective - 85%)
  - SNSC Collection Centre - Pycrofts Road: (Jan - Jun'18) - **92%,** (Jul - Dec'18) – **90%** (Objective - 80%)

C. **Staff suggestions** : Nil (Jan - Dec'18).

- A format will be made to capture staff suggestion on various areas of the Laboratory function.

d. **Internal audits** :

- Internal audit – I & II (2018) conducted by Internal Assessors based on New Standard ISO 15189 : 2012. (Minor NC - 26, Major NC - 62): All NCs are closed.

e. **Risk management : (Based on CAPA) : Pre analytical &Post analytical.**

- **Clinical Hematology**:-
  - Pre-analytical error:
    - Barcode wrongly stuck,
    - Heparin Sample collected for LFT Testing (Wrong Anticoagulant)
    - Sample collected in ESR tube for the test Hb, PCV, TC, DC & Platelet Count (Wrong Anticoagulant)
    - GTT Blood collection : Missed to collect 3rd sample
    - ILQC sample sent to Lister Lab with wrong patient details
  - Post analytical:
    - WBC Count value wrong updation & Verification
    - PT & INR value wrong updation & Verification
    - Report released without second opinion for high Platelet count

- Mantoux reading documented wrongly in the note book Incomplete
- Report of urine routine analysis verified & given for authorization

- **Clinical Biochemistry**:-
  - Post analytical error:
    - GTT missed to update 2 hours plasma glucose in HMS & verified
    - GTT missed to update urine sugar value & verified
    - Total Bilirubin value updated with direct bilirubin value & verified
    - HbA1C value was wrongly updated & verified
- **Microbiology :**
  - Post analystical :
    - 29.03.18 ELISA report for HBs Ag test sent as Positive and rapid test report was held for the clarification for the blood specimen. On 10.04.2018 the Rapid and the ELISA report for the same specimen was found negative
    - 12.04.18 The Bacterial Culture report was sent as significant number of Gram negative bacilli is grown in culture. But on 19.04.2018 it was identified as Gram positive bacillus
    - 13.04.18 the Gram Stain report was sent as bacterial agents. On 14.04.18 the smear was reviewed and reported many pleomorphic Gram positive cocci (in swollen forms)
    - 05.06.18 the culture report was sent as Enterobacter aerogens isolated in culture. On 11.06.18 the organism was identified as Enterobacter cloacae by Automated method by VITEK compact 2
    - Primary sample Corneal scraping (OS) reported as Conjunctival Scraping (OS)

f. **Use of quality indicators** : Monitored by QM & TM every quarter based on data from all labs.

- Pre Analytical : Sample collection, Transport time, Repeat & Rework : All are within the objective (Jan - Dec'18) except Re-collections : CAPAs documented
- Analytical : (Internal & External QC, Equipment down time) All are within the objective from Jan - Dec'18 except : Clinical Haematology – EQAS & IQC , Clinical Biochemistry – EQAS & IQC : CAPAs documented
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From Jan - Dec'18 except : Clinical Biochemistry - Turn around time : CAPA documented.
- All the Dy Technical managers are requested to display the quantitative measures, in the form of graph.
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 12 months from Jan - Dec'18, dept wise. Corrective actions were taken wherever applicable.

g. **Reviews by external organizations** :

- Tamil Nadu Pollution control Board certificate for disposal of waste (Biomedical waste) Renewal of Certificate done on Jan 2019 (Validity till 31.03.2020) for SNSC Collection Centre - Pycrofts road (JKCN Centre), Chennai.
- Absolute Alcohol Renewal of license done on April'18. Valid up to Mar-2019.
- GJ Multiclave (For Biomedical waste) renewal has been done on May 2018 for SN Main & SNSC Collection centre – Pycrofts road (Valid upto May 2021)
- Biomedical Department : Renewal of Calibration Certificate done From Jan – Dec'18
  - Digital Thermometer with Sensor 27.04.2018 – 27.04.2019
  - Digital Multimeter – 09.10.2018 – 09.10.2019
  - Digital Tachometer - 27.09.2018 – 27.09.2019
  - Weight box – 26.12.2018 – 26.12.2019
  - Digital stopwatch - 31.12.2018 –31.12.2019

- BP Apparatus - 25.12.2018 – 25.12.2019
- Glass Thermometer - 26.12.2018 – 26.12.2019

➢ Maintenance Department : Renewal of Calibration Certificate done From Jan – Dec'18

- Temperature Indicator with Sensor – 30.11.2018 – 30.11.2019
- Hygrometer – 04.12.2018 – 04.12.2019

h. Results of participation in inter laboratory comparison programmes (PT/EQA) :

- This has been reviewed for the four quarters in the last 12 months, From Jan - Dec'18 dept wise : Satisfactory Results.

i. Monitoring and resolution of complaints :

- Based on Internal & External feedback forms (Jan - Dec'18) actions were taken and the issues settled .

➢ The meditape used after blood collection hurt at the time of removing. It would be great if you use such type of meditape that does not hurt at the time of removing it. Action taken: The issue was discussed in the lab meeting and for each patient Johnson plaster will be used and implemented immediately.

➢ Iinstructions given for collection of blood are clear and adequate marked as Average : Checked with the patient: He told that the instruction for the blood collection was not clearly given by the SFC Department. Action taken: Suggestion forwarded to Ms.Rajamani. She informed over the phone that this will not happened again

➢ Grade the Blood collection marked as average : Due to Pain Patient marked as average. Action taken: The technician was informed that it should not happened again. In the lab meeting discussed and announced that the Rubric quality of work marks will be given less

➢ Waiting area is not hygienic : Patient told that the chairs in the waiting area is not hygienic.

Action taken: The feedback form sent to Ms.Rama Devi house keeping incharge to the necessary action. All the visiting area chairs were then painted and one broken chair was removed from the area.

j. Performance of suppliers :

- Vendor evaluation completed for the period of (Jan - Dec'18) is given by commercial dept.
- Vendor Complaint for the period of (Jan - Dec'18) : One was evaluated as fair and warning letter sent.

k. Identification and control of non- conformities :

- Daily non conformances are documented in all the laboratories and discussed in the respective labs for corrective action. CAPA are documented . Daily NC are stated on the same day in the records followed by supervisors' attestation and CAPA documented for warranted ones as decided by the supervisor / Head.

l. Results of continual improvement including current status of corrective actions and preventive actions :

Continual Improvement : (Jan – Dec'18)

- **Quality System:**
  - MOU for Inter Lab Comparison between SNSC Clinical Laboratory & Lister Metropolis is renewed.
  - MOU between SNSC Collection Centre – REH & SN Main lab is renewed
  - MOU between SNSC Collection Centre – NSN & SN Main lab is renewed
  - G.J.Multiclave MOU for Biomedical waste was received from House keeping department for SN Main, JKCN, NSN, CUSSN Valid up to March 2021.
  - Internal Assessor training of ISO 15189 : 2012 completed by Dr.A.R.Anand, Dr.M.K.Janani, Dr.A.V.Kavitha, Dr.Dhanurekha, Ms.V.Gayathri & Ms.R.Gayathri

- Received Communication form NABL Authorized Signatory for Dr.R.Harini for Clinical Biochemistry with effect from 10.07.18
- Received Desktop audit communication from NABL on 14.09.18 and NABL has recommended the continuation of the accreditation.
- As per NABL instructions SNSC Clinical Laboratory "Mark Location of Laboratory" was updated on Google Map
- NABL Issued Sample Collection Centre Recognized Certificate (for SNSC Collection Centre, 21, Pycrofts Road) on 31.01.19. Certificate (Photo copy) for the same given to SNSC Collection Centre-Pycrofts Road for display
- Laboratory Safety Manual has been updated.
- Web page for SNSC Clinical Laboratory has been updated.
- SNSC Directory of Services updated on NABL website

- **Haematology**:
  - Implemented Qualitative gel card method for Blood grouping.
  - <u>Major equipment installation :</u>
    - Beckman Coulter DXH 800 Hematology analyser : Operating lease/Service agreement received:27.12.2018
    - Cooling Centrifuge REMI CM-12 was installed in Hematology on 12.09.2018
  - <u>Measures:</u>
    - Collection Area: Documenting registration errors – Measures initiated from Jan'18 onwards and Objective fixed as < 1.0%. It will be implemented from July'18 onwards.
    - Based on 2 year data Objective changed from 95% to < 97% for OP Specimens transportation to other departments (Microbiology & Sp.Biochemistry Lab)
    - Turn Around Time (TAT) for 2 hours Clinical Hematology & Clinical pathology reports. It will be implemented from Jan 2019 onwards.

- **Biochemistry**:
  - The existing method of HbA1C – Turbidimetric inhibition immunoassay (TANIA) for hemolysed whole blood was being done in Cobas C111 equipment which is now updated with Ion exchange chromatography method D-10-HbA1C analyser; implemented for patient care on 19.10.2018.
  - Microalbumin particle-enhanced turbidimetric inhibition immunoassay (PETINIA) method started in Dade equipment with 5 point calibration. The report are given as: Urine albumin / Creatinine ratio
  - In Liver function test included GGT (Gamma GT) from 1.8.2018.
  - Direct estimation of LDL in Lipid Profile from 1.8.2018
  - Gamma GT & Direct estimation of LDL tests: Daily QC Level 1 & 2, ILQC, EQAS carried out and implemented from 01.08.2018
  - Biological Reference Range and Clinical Interpretation for all tests added in report format from 01.08.2018
  - GTT, LFT-GGT & Lipid Profile – LDL test SOP were updated in the manual
  - GTT reference range for pregnant and non-pregnant cases included in the report format from 01.08.2018
  - Report correlation with clinical diagnosis and reporting – post analytical QI from May 2018 onwards implemented

Training:

- Ms.Punitham & Ms.Gayathri participated CME programme
- Dr.N.Angayarkanni presented (invited talk) entitled "ADA Guidelines for Diabetes care: Role of Laboratory." CME done by the clinical biochemists of Tamil Nadu association (CBAT) on "Total Quality Management in Clinical Lab Practices" at Cancer Institute on 21.04.2018. Ms. Punitham participated for the same

- Ms.Saranya participated : Workshop on "Method Validation & Verification – A CLSI Perspective"
- Dr.Harini participated BioRad QC Meet workshop on 06.07.2018

Authorized Signatory :

- Dr.Harini MD Biochemistry got the Authorized Signatory from 09.07.2018

Expansion of Laboratory:

- Clinical Laboratory renovation work done on 14.10.2018 to improve the environment and space utilization

- **Microbiology**:
  - Imaging camera for the LED Immunofluorescence microscope has been purchased with the accessories.
  - Microplate reader (ELISA) reader has been purchased as a replacement (under buy back offer) with the accessories.
  - Refrigerator has been purchased exclusively for storing Culture Media plates.

External Quality Control program:

- Scored 99% and 100% in 98th and 99th QC package conducted by IAMM EQAS. CMC Vellore.
- 100% Excellent score in Mycology QC
- 100% score (All parameters fulfilled) in Euroimmun-Germany

Training:

- Ms.V.Gayathri, Ms. S. Janaki & Ms. R.Nathiya participated CME Programmes
- Ms.V.Gayathri participated Faculty Development Programme (FDP)
- Mr.Kaviyarasan K, Ms.Gayathri V & Ms.Caroline D participated Live Webinar in Innovative Diagnostics in Microbiology
- Dr. Durga Devi.P and Mr. Kaviyarasan .K participated workshop on Indirect immunoflorescence in Hep2 cells

- **Histopathology**:
  - Started Grading of Tumors
  - Standardized Immuno histochemistry for markers Ki67, Adepophylin
  - Ms.Vanitha, Ms.Bhuvana & Ms.Anitha was participated CME Programmes
- **Corrective action & Preventive action :**
  - Quality Control Programme : Internal and External QC, ILQC, PT programme in each of the lab has been verified. The labs have taken appropriate corrective actions as required
  - Measure on QC is verified quarterly by QM as part of Quality Indicator.

m. Follow-up actions from previous management reviews :

- ISO 15189 : 2012 Internal Audit & Quality Management System Training attended by Dr.A.R.Anand, Dr.M.K.Janani, Dr.A.V.Kavitha, Dr.Dhanurekha, Ms.V.Gayathri & Ms.R.Gayathri
- SNSC Staff members participated CME Programme organized by SN Academy
- SNSC Staff members participated CME Programmes organized by MIOT Hospitals & Cancer Institute
- Requisition form to be made in HMS- shall be followed up

n. Changes in the volume and scope of work, personnel, and premises that affect QMS :

(i) ***List of NABL Accreditation tests at SNSC Clinical laboratory approved in the recertification audit (validity) : 14.08.17 – 13.08.19 :*** **Total: 99 Tests**

- Clinical Haematology : 25 and Clinical Pathology : 19
- Clinical and Special Biochemistry : 19
- Clinical Microbiology and Serology : 27
- Histopathology : 6 and Cytopathology – 3

(ii) Statistics of all the departments in the lab reviewed

- **Total No. of Investigations (Jan – Dec 2018)**
  - Haematology: 1,51,405 (↑ by 2.20%)
  - Clinical Pathology : 32,954 (↑ by 4.72%)
  - Clinical Biochemistry : 1,03,077 (↑ by 11.90%)
  - Special Biochemistry : 2,036 (↑ by 6.33%)
  - Histopathology : 2,409 (↑ by 7.55%)
  - Cytopathology : 230 (↑ by 10.43%)
  - Microbiology : 15,753 (↓ by 2.70%)
  - Serology : 16,909 (↑ by 5.02%)
  - Microbiology Surveillance : : 3,977 (↑ by 9.60%)
  - SNSC Collection Centre (Pycrofts Garden Road): 5,909 (↑ by 3.02%)
  - SNSC Collection Centre (NSN – Non NABL) : 1,806 (↑ by 7.80%)
  - SNSC Collection Centre (REH – Non NABL) : 2,054 (↑ by 11.39%)
  - Cytogenetics (Non NABL) : 963 (↑ by 44.02%)
  - Out source : 556 (↓ by13.53%)

(iii)Staff adequacy: It was declared to be Adequate by all the heads of the lab.

- Dr.Harini MD Biochemistry joined as Assistant Professor in Biochemistry Lab on April'18
- Dr Anand.A.R. joined as Assistant Professor in Microbiology & Serology Lab on August'18
- Dr.A.V.Kavitha MD Microbiology joined as Assistant Professor in Microbiology & Serology Lab on Lab on October'18
- Dr.Harini MD Biochemistry got authorized signatory ship in the field of Clinical Biochemistry on 09.07.2018

Resignations:

- Haematology: Lab Technician - 2 (Ms.A.Tamil Selvi - Junior & Ms.Logeshwari)
  Lab Secretary - 1 (Ms.Hemamalini)
- Biochemistry Lab : Lab Technician - 1 (Ms.Saranya)
- Microbiology: Assistant Professor -2 (Dr.Malathi & Dr.Amrita Talukdar)
  Lab Technician -1 (Mr.Dhivakar)
  Lab Attender – 1 (Mr.Subramanyam – Transferred to SN-Tirupathi)
  Lab Attender-1 (Mr.Alex Pandian-Transferred from CSFU to Microbiology Lab)
- Histopathology Lab : Lab Secretary -1 (Ms.Parvathy Devi)

Appointments : Refilling of the post:

- Haematology: Lab Technician - 1 (Mr.Sathish Kumar)
  Lab Assistant - 4 (Ms.Mahalakshmi, Ms.Devi, Mr.Karthick & Ms.Mythili)
  Lab Secretary - 1 (Ms.Anusha)
- Biochemistry : Assistant Professor -1 (Dr.R.Harini)
  Lab Technician - 1 (Ms.Devi Uma)
- Histopathology : Lab Secretary - 1 (Ms.Geetha Krishna)
  Junior Scientist -1 (Mr.Mayur Joshi)
- Microbiology: Senior Associate Professor- 1 (Dr.Anand.A.R)
  Assistant Professor - 1 (Dr.A.V.Kavitha)
  Senior Scientist - 1 (Dr.Vimalin Jeyalatha)
  Lab Attender (CSFU) - 1 (Mr.Suresh)

Promotions: Ms.Saumya.T.S. Promoted as Senior Executive

(iv) Document control: Version numbers of documents revised in 2018 (Jan - Dec'18) :

Quality System :

- Lab Requisition Form : F/SNSC/ML/LRF/1.21
- SNSC/C&P/2019/Version-1.6

o. **Recommendations for improvement, including technical requirements** :

- Communications on new joiners in SNSC along with designation and outline of scope of their work to Quality Manager
- Manual awareness/ Induction Protocol: Documentation of the protocol and Implementation
- Review of labs involved in MOU and ILQC to have documented evidences on Complaints/ feedback/ instructions etc (use formats).
- Staff adequacy / Proficiency: to be ensured and documented
- MIS (Management Information System) presentation done every month as per NABH requirement.
- Quality plan 2018 was Implemented: Out of 29 proposed points, 26 points were Implemented.

Forwarded by:

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Date: 21.03.2019