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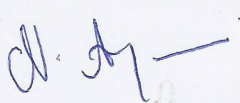

**Minutes of the Management Review Meeting of SNSC performance based on Internal Audit**

**Audit cycle I & II (2017), Jan to Dec 2017 : Dated 05.03.2018**


**Attendance:** By list (list enclosed). The representations were from the SN main lab for Haematology and 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.

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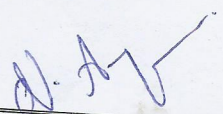
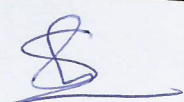
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**Audit Team Members and Audited labs/Support services:**


- External audit conducted based on NABL standard ISO 15189 : 2012 for the following departments:
  - Quality Manual : Dr.TaduryMadhukarSubbarao - Lead Assessor
  - Clinical Pathology and Hematology: Dr.Jayashree D Kulkarni – Technical Assessor
  - Clinical and Special Biochemistry : Dr.K.Sowmya – Technical Assessor
  - Clinical Microbiology and Serology : Dr.J.Jayalakshmi – Technical Assessor
  - Histopathology and Cytopathology : Dr.RekhaRadhesh– Technical Assessor
  - SNSC Collection Centre-Pycrofts Road :Dr.RekhaRadhesh– Technical Assessor
- Internal audit conducted based on new standard ISO 15189 : 2012 for the following departments:
  - Quality System : Ms.Rajalakshmi
  - Front Office & Pre analytical area : Dr.J.Malathi & Dr.Amrita Talukdar
  - Clinical Pathology and Hematology : Dr.J.Malathi & Dr.Amrita Talukdar
  - Clinical and Special Biochemistry : Ms.K.Vanitha
  - Clinical Microbiology and Serology : Dr.S.Sripriya
  - Histopathology and Cytopathology : Ms.R.Punitham & Dr.Premalatha
  - Human Resource Department : Ms.U.Jayanthi
  - Commercial Department : Ms.Saumya.T.S
  - Central Sterilization Facility Unit : Dr.S.R.Bharathi Devi
  - Biomedical Department : Ms.Saumya.T.S
  - Information Tech Dept : Ms.U.Jayanthi
  - SNSC Collection Centre-Pycrofts Road : Ms.R.Punitham & Dr.Premalatha

**Non-NABL**

- Genetics : Dr.S.R.Bharathi Devi
- SNSC Collection Centre - NSN : Ms.R.Punitham & Dr.Premalatha

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**External audit (June 24<sup>th</sup>&25<sup>th</sup>2017) conducted by External Assessors based on**

**New Standard ISO 15189:2012:** all the NCs are closed. (Minor NC - 4, Major NC - 6) .  
 NABL recommended for renewal of accreditation in accordance with ISO 15189:2012.  
Certificate Validity period : 14.08.2017 - 13.08.2019

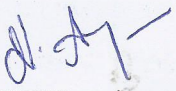

**a. The periodic review of requests, and suitability of procedures and sample requirements :**

This has been reviewed for the four quarters in the last 12 months, dept wise.


- **MOU for outsourcing /QC /Emergency** : (A) MOU for Inter Lab Comparison between SNSC Clinical Laboratory& Lister Metropolis is Renewed. (B) MOU between SNSC Collection Centre (HTP Block) & SN Referral Lab (Sri Sivasailam block) has been implemented.
- **Implementation of MCI regulation done:** An email received from Ms.Devaki, NABL regarding Medical Council of India (MCI) to comply with MCI regulation on signing lab reports: "Lab reports to be signed/counter signed by persons registered with MCI / State Medical Council" : Implemented
- **Major equipment installation** : (a)Dade Clinical chemistry analyzer was replaced and installation completed . This was put into patient care from 06.01.2017.  
 (b) Yorco Tissue Processor YS1-103 was installed in Histopathology on 25.05.17,
- **QC: New inclusion / revision in protocol as in point h.** (CI Pathology , Haematology and Biochemistry)
- **Histopathology procedure /reporting updated:** (a) Started to upload microphotographs of interesting cases inpatient's file from November 2017 onwards (b) All impression cytology using Millipore paper stained using Modified PAS Staining from November 2017 onwards

**b. Assessment of user feedback :**

This analysis is done in SN-Main lab (CI.Haematology, CI,Pathology, CI.Biochemistry & SNSC Collection Centre – Pycrofts Road), Microbiology and Histopathology labs.

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Internal customer feedback : The observed measures (Jan - Dec'17) were above the respective stipulated objectives in all the laboratories as evaluated half yearly.

- Histopathology & Cytopathology: (Objective - 80%)  
(Jan - Jun'17) - **92.4%**, (Jul - Dec'17) - **94%**
- Microbiology & Serology: (Objective - 80%)  
(Jan - Jun'17) - **91%**, (Jul - Dec'17) - **94%**
- Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and  
SNSC Collection Centre -Pycrofts Road) : (Objective - 80%)  
(Jan-Jun'17) - **90%**, (Jul - Dec'17) - **84%**

External customer feedback:

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry:  
(Jan - Jun'17) - **91%**, (Jul - Dec'17) - **91%** (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road:  
(Jan - Jun'17) - **92%**, (Jul - Dec'17) - **92%** (Objective - 80%)

**C. Staff suggestions** : Nil (Jan - Dec'17).

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

**d. Internal audits** :


- Internal audit - II (2017) (11<sup>th</sup> December 2017 to 10<sup>th</sup> January 2018) conducted by Internal Assessors based on New Standard ISO 15189 : 2012. . (Minor NC - 25, Major NC - 20): All are closed.

**e. Risk management** : (Based on CAPA) : mostly pre analytical and post analytical.

Clinical Hematology : Pre-analytical error: eg.Blood collection done for wrong patient, Swab collection done for wrong patient. Reporting error: eg.Hb value wrong updation & Verification, Smear study wrong updation & Verification .

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Clinical Biochemistry: Pre-analytical : Without processing the test the blood vacutainer tube was discarded . Reporting error: Glucometer value updated in HMS wrongly, Bilirubin value was authorized with out the Direct & Indirect Bilirubin value

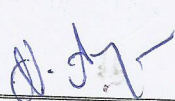

Microbiology: Reporting error: Staphylococcus epidermidis was wrongly updated as Staphylococcus aureus; Gram stain: Gram negative bacteria was not mentioned in report as bacterial agents could not be made out.

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

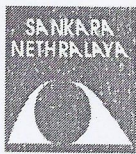
- Pre Analytical : Sample collection, Transport time, Repeat & Rework : All are within the objective (Jan - Dec'17)
- Analytical : (Internal & External QC, Equipment down time) All are within the objective from Jan - Dec'17 except : Clinical Haematology – EQAS & IQC, Clinical Biochemistry – EQAS & IQC, Microbiology & Serology – EQAS, Histopathology –EQAS: CAPAs documented
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From Jan - Dec'17 except : Clinical Biochemistry & Histopathology- Turn around time : CAPA documented.
- All the Dy Technical managers are requested to display the quantitative measures, in the form of graph. (Quarterly/half-yearly/one year data with a comparison of the previous corresponding set) and now it is done graphically.
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 12 months from Jan - Dec'17, dept wise. Corrective actions were taken wherever applicable.

**g. Reviews by external organizations** :

- Tamil Nadu Pollution control Board certificate for disposal of waste (Air, Water & Biomedical waste) Renewal of Certificate done on March 2016 (Validity till 31.03.2018) for SNSC Collection Centre at Pycrofts road (JKCN Centre), Chennai.

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- Absolute Alcohol Renewal of license done on April'17. Valid up to Mar-2018.
- GJ Multiclave (For Biomedical waste) renewal has been done on May 2015 for SN Main, SNSC Collection centre – Pycrofts road (Valid upto May 2018)
- Biomedical Department : Renewal of Calibration Certificate done as below
  - Digital Thermometer with Sensor 25.04.2017 – 25.04.2018
  - Digital Multimeter – 05.10.2017 – 05.10.2018
  - Digital Tachometer - 25.09.2017 – 25.09.2018
  - Weight box – 27.12.2017 – 27.12.2018
  - Digital stopwatch - 23.12.2017 – 23.12.2018
  - BP Apparatus - 23.12.2017 – 23.12.2018
  - Glass Thermometer - 20.12.2017 – 20.12.2018
- Maintenance Department : Renewal of Calibration Certificate done From Jan – Dec'17
  - Temperature Indicator with Sensor – 05.12.2017 – 05.12.2018
  - Hygrometer – 05.12.2017 – 05.12.2018

**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'17 dept wise : Satisfactory Results.
- With reference to the NABL 112 Issue No:04, Issue date- 9/May/2016 Examination processes (Clause:5.5) the Inter laboratory comparisons for the following tests in clinical pathology and Haematology department will be discontinued
- Clinical pathology: 1. Routine Urine Analysis, 2. Stool Routine analysis and Occult blood  
Alternative approach : Split sample testing by different technicians will be performed once in 3 months - Cross check dipstick method with manual method every 6 months
- Haematology: 1. ESR (Erythrocyte sedimentation Rate) As per NABL 112 Split testing or exchange of samples between laboratories for ESR is also not required.

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2. PT & APTT: Alternative approach: (i).Monitoring of CV% will be done for the automated method for ESR (ii).EQAS with CMC Vellore &Biorad for PT APTT testing

- With reference to the NABL 112 Issue No:04, Issue date- 9/May/2016 'Control of Records' from 01.Aug.2017 on wards follow the minimum retention period 1 week for Haematology (CBC) physical copies of instrument printouts the same will be stored electronically in the Data base of the equipment upto 20000 reports ( approximately 5 months). Final report of the patients will be stored permanently inthe HMS server .

Biochemistry: (a) Electrolyte analyzer liquid QC , ISTEROL introduced For electrolytes analysis ;  
(b) ILQC samples are sent monthly twice for HbA1C and Bicarbonate to Lister.

**i. Monitoring and resolution of complaints :**

- Based on Internal & External feedback forms (Jan - Dec'17) actions were taken and the issues settled .
  - (i). English news channel should be displayed on TV: Multimedia Dept (Dr.Sheila John) has implemented
  - (ii). Cleanliness of the toilets marked as average reason: Provide tissue box and not toilet roll in the toilet: Action taken: Now inside the toilet the tissue roles are provided.

**j. Performance of suppliers :**


- Vendor evaluation completed for the period of (Jan - Dec'17) is given by commercial dept.
- Vendor Complaint for the period of (Jan - Dec'17) : Two was evaluated as poor 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.

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

**Continual Improvement : (Jan – Dec'17)**

**Quality System :**

- NABL logo procedure has been included in the Release of Reports procedure
- NABL Logo has been implemented with New certificate Number for reporting.
- Details for Disinfection protocol has been updated in QSM and impletmented in all labs
- Three different color coded bags (Red, Yellow & Blue) with barcode sticker implemented for Biomedical waste discard from 01.09.17 onwards.
- Revised appraisal format has been introduced for all labs (RUBRICS)
- MOU between SNSC Collection Centre (HTP Block) & SN Referral lab (Sri Sivasailam block ) has been implemented
- Amended test report will now state teh exact test code which is ameded.
- NABH Surveillance audit was on Main laboratory of SNSC Clinical Laboratory on 13.05.17
- NABH Recertification audit was done in SNSC Clinical Laboratory on 24.02.18

**Haematology & Clinical Pathology :**

- Collection area : Documenting Hematoma for Measure of incidence initiated from Jan'17 (Objective fixed as < 1.0%)
- Installed new barcode generator (Standby) at collection area on 23.05.17
- Updation of Critical alert in EMR: RED colour highlighting for easy identification 30.12.2017
- Updation of HMS format for specimen sending to other dept: Included name of the house keeping staff who is transporting the specimens to other dept 30.12.2017
- Training in Pre analytical area through webinar sessions July'17 onwards for technical staff

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**Clinical & Special Biochemistry Lab :**

New Equipment: clinical biochemistry analyzer, (DADE Behring RxL Max from Siemens)  
and put into patient care from 06.01.2017

- Electrolyte analyzer liquid QC-ISTEROL introduced in addition to the pooled plasma and BIORAD quality control to check the lower sensitivity of the equipment

**Kits:**

- Critical alert values are informed to those who raised request (Consultant, Physician). Now both consultant and physician too are informed.
- REH (now named as CUSSN) Collection center fluorides samples are separated and brought from the centre for analysis. This prevented lysis during transportation

**Training:**


- Ms.Punitham, Senior Manager-Lab: participated in the CME programme organized by TSNA; CME , programme organized by MIOT Hospitals
- Ms.Punitham conducted training class for House keeping/ Discard procedure for all the labs.
- Ms.Logeshwari & Ms.Kajal, technicians in Biochemistry were trained to handle the Dade Behring cl chemistry analyzer.
- Dr.Spandana, MD biochemistry started authorising the Clinical Biochemistry reports from 1<sup>st</sup> April 2017 after approval from NABL.
- All department of the SNSC lab conducted the in house dept wise training program as scheduled on the relevant technical aspects. Fire safety; other soft skills training was given by HR for the whole institution including lab.

**Histopathology lab :**

- Ms.Vanitha, senior technical, Histopathology participated in the workshop on Histo techniques conducted by Anand Laboratory Bangalore on 19.03.17
- Ms.Vanitha participated CME programme organized by MIOT Hospitals

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- Purchased the following equipments :(i). Waterbath – 04.04.17, (ii). Yorco Tissue Processor YS1-103 on 25.05.17, (iii).Refrigerator – 07.06.17
- Started to upload microphotographs of interesting cases inpatient's file from..
- All impression cytology using Millipore paper stained using Modified PAS Staining from November 2017 onwards

**Microbiology lab :**

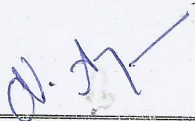
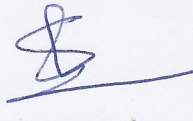
- Colour codes such as Black, Blue and Red have been provided for indicating the completion of typing.
- Verification and uploading of authorized reports to HMS respectively along with colour codes test requests for direct smear HMS reports in which bacteria seen in Gram's stain or fungal filaments seen in KOH/Calcofluor stain shall be highlighted in green colour and indicated as BAC+ for bacteria and FUN+ fungus positive smear next to the test requests for facilitating generation of accurate reports at all stages.
- Dr.Amrita Talukdar & Dr.Premalatha got the NABL Authorized Signatoryship

**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.AmritaTalukdar&Dr,Premalatha
- SNSC Staff members attended CME Programme organized by SN Academy
- SNSC Staff members attended CME Programme organized by MIOT Hospitals
- Requisition form to be made in HMS- shall be followed up

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**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 2017)**

- Haematology: 1,48,070 (↓ by 3.65%)
- Clinical Pathology : 31,397 (↓ by 2.43%)
- Clinical & Special Biochemistry : 92,721 (↑ by 1.09%)
- Histopathology & Cytopathology : 2,288 (↓ by 6.33%)
- Microbiology & Serology : 35,845 (↓ by 2.08%)
- SNSC Collection Centre (Pycrofts Garden Road): 5,730 (↑ by 22.46%)
- SNSC Collection Centre (NSN – Non NABL) : 1,665 (↑ by 1.64%)
- SNSC Collection Centre (CUSSN – Non NABL) : 1,820 (↑ by 8.07%)
- Cytogenetics (Non NABL) : 539 (↑ by 36.8%)
- Out source : 643 (↓ by 5.71%)

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

- Dr.Premalatha MD Microbiology joined as Assistant Professor in Microbiology & Serology Lab on Feb'17
- Dr.Amrita Talukdar MD Microbiology joined as Assistant Professor in Microbiology & Serology Lab on 01.04.17.

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- Dr.Amrita Talukdar & Dr.Premalatha attended training programme in ISO 15189: 2012 and subsequently got authorized signatory ship in the field of Clinical Microbiology & Serology as on 08.08.17

Resignations:

- Haematology: Junior Executive - 1 (Ms.Hema)  
Lab Assistant-1 (Ms.Sumathi)  
Lab Technician - 2 (Ms.Suganya (Senior), Ms.Suganya (Junior)  
Lab Secretary - 1 ( Ms.Saranya)
- Biochemistry Lab : Assistant Professor - 1 (Dr.T.Spandana)  
Junior Executive - 1 (Ms.Logeshwari)
- Microbiology: Junior Scientist - 3 (Mr.Murugan, Dr.Vimalin Jeyalatha, Ms.Hema)  
Junior Executive - 3 (Ms.Shobaba, Ms.Imaya Kumari), (Ms.D.Vaidehi )  
Lab Attender – 1 (Mr.Sivaraman)
- Histopathology Lab : Lab Attender -1 (Mr.Annadurai)
- Cytogenetics (Non NABL): Junior Executive - 1(Mr.Jayaprakash) Transferred to  
SN Academy

Appointments :Refilling of the post:

- Haematology: Lab Technician - 4 (Ms.Durga Devi, Ms.Tamil Selvi,  
Mr.Senthil Kumar & Ms.Helen Pushpa)  
Lab Assistant - 1 (Ms.Monika)  
Lab Secretary - 1 (Ms.Asvini)
- Biochemistry : Junior Executive - 1 (Ms.Logeshwari)  
Lab Technician - 1 (Ms.Kajal)
- Histopathology : Lab Attender - 1 (Mr.Patrick)
- Microbiology: Assistant Professors -- 2 (Dr.P. Premalatha, Dr.AmritaTalukdar)  
Junior Executive -3 (Ms.Imayakumari, Ms.Shobaba & Ms.Caroline)

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Lab Attender (CSFU) - 1 (Mr.Ruthresh Kumar)

➤ Cytogenetics (Non NABL) : Junior Executive - 1 (Ms.Karthiyayini)

**Promotions:** Nil

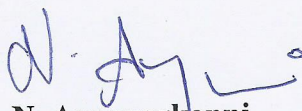
**(iv) Document control: Version numbers of documents revised in 2017 (Jul - Dec'17) :**

**Quality System :**

- Lab Requisition Form : F/SNSC/ML/LRF/1.20


**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 follow
- 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
- Statistics of the labs to be sent to the MD, MRF.
- Quality plan implemented in all the dept of the lab in 2017 was discussed and Quality plan for 2018 was proposed

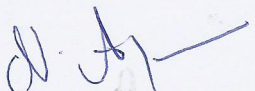
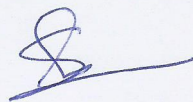
  
**Dr. N. Angayarkanni,**

Quality Manager,  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai – 600 006.

**Forwarded by:**

  
**Dr.S.B.Vasanthi**  
Management Representative  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai – 600 006.

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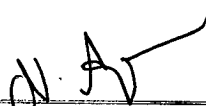

**Management Review Meeting of SNSC performance based on Re-Assessment Audit**

**Jan to Jun 2018 : Dated: 19.09.2018**


**Attendance:** Heads of the labs: Haematology and Clinical Pathology, Clinical Biochemistry,  
Sp. Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics

**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 interlaboratory 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.

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	ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -24	

**Audit Team Members and Audited labs/Support services :**

- Internal audit conducted based on NABL standard ISO 15189 : 2012 for the following departments:

- Quality System : Dr.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.AmritaTalukdar
- Clinical Microbiology and Serology : Ms.Saumya.T.S
- Histopathology and Cytopathology :Dr.R.Harini&Ms.U.Jayanthi
- Human Resource Department : Ms.R.Punitham
- Information Tech Dept : Ms.R.Punitham
- Central Sterilization Facility Unit : Ms.Saumya.T.S
- Biomedical Department : Ms.Rajalakshmi
- CcommercialDépartement :Ms.Rajalakshmi
- SNSC Collection Centre-Pycrofts Road : Dr.S.Sripriya

***Non-NABL***

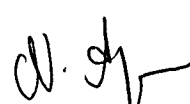

- Genetics : Ms.K.Vanitha
- SNSC Collection Centre - NSN : Dr.S.Sripriya

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

This has been reviewed for the two quarters in the last 6 months, dept wise.

Corrective actions were taken wherever applicable.

- Dr.Harini MD Biochemistry joined as Assistant Professor in Clinical Biochemistry on 11<sup>th</sup>April'18
- Dr.Harini MD Biochemistry got authorized signatory ship in the field of Clinical Biochemistry on 10.07.18

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- Dr.A.R.Anand joined as Senior Associate Professor in Clinical Microbiology & Serology lab on 20.04.18
- Dr.A.R.Anand, Dr.M.K.Janani & Ms.V.Gayathri attended training programme in ISO 15189: 2012 on 23<sup>rd</sup> – 26<sup>th</sup> August 2018.

**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-Jun'18) were above the objective in all the laboratories.

- Histopathology & Cytopathology (Jan-Jun'18) –**94.4%** (Objective - 81%)
- Microbiology & Serology (Jan-Jun'18) –**94%**(Objective - 80%)
- Main lab (Hematology, Cl.Pathology, Cl.Biochemistry, SNSC Collection Centre– Pycrofts Road) (Jan-Jun'18) –**88.2%** (Objective - 80%).One CAPA

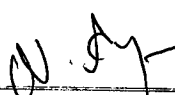
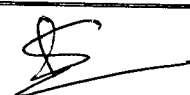
*External customer feedback:*

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


**c. Staff suggestions :Nil (Jan -Jun'18)**

**d. Internal audits :**

- Internal audit - I (2018) conducted by Internal Assessors based on NABL Standard ISO 15189 : 2012, all the NCs have been closed on stipulated time interval.  
(Minor NC- 11, Major NC- 25): All are closed.

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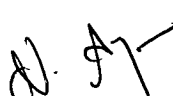

- NABL examined Desktop documents and recommended for continued accreditation in accordance with ISO 15189:2012. Certificate Validity period : 14.08.2017 - 13.08.2019

**e. Risk management:(Based on repeated CAPA)**


- Clinical Hematology: Error in result entry & Verification for PT & INR. ITSR was raised and report was amended
- Microbiology : (i). Bacterial Culture reported as Gram Negative Bacilli is grown in culture but later reported as Gram Positive Bacillus.  
 (ii). Grams Stain report was sent as bacterial agents could not be made out (Later it was reviewed and reported as many pleomorphic Gram positive cocci (in swollen forms)  
 (iii). ELISA report for HBs Ag test is sent as Positive for the blood specimen (Later the ELISA report for the same specimen was found Negative for the same. ITSR was raised and report was amended
- Histopathology :While handling the slides / paraffin block to the patient for further management the slide was wrongly given. Later rectified and correct slide was given to patient.

**f. Use of quality indicators: Quarterly reports submitted by all the labs/Collection centre, monitored by QM.**

- Pre Analytical :Sample collection, Transport time, Repeat & Rework : All are within the objective (Jan-Jun'18)
- Analytical: (Internal & External QC, Equipment down time) All are within the objective from Jan-Jun'18 except: Clinical Haematology – EQAS & IQC, Clinical Biochemistry– EQAS&IQC: CAPA documented
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective from Jan-Jun'18 except :Biochemistry -Turn around time :CAPA documented.

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- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 6 months from Jan-Jun'18, dept wise. Corrective actions were taken wherever applicable.

- Suggestions on fresh quality indicators have been requested from the Heads of the Lab

**g. Reviews by external organizations :**

- Tamil Nadu Pollution control Board certificate for disposal of waste (Air, Water & Biomedical waste) Renewal of Certificate applied: Validity till 31.03.2018 for SNSC Clinical Laboratory & SNSC Collection Centre at Pycrofts road (JKCN Centre), Chennai. Renewal in process. Inspection is just over.
- Absolute Alcohol Renewal for the year 2018-19 was done (Validity till 31.0.2019)
- GJ Multiclave (For Biomedical waste) renewal has been done on May 2018 for SN Main, SNSC Collection center – Pycrofts road (Valid upto March 2021)
- Biomedical Department : Renewal of Calibration Certificate valid as on date i.e. sep 2018)

**h. Results of participation in Interlaboratory comparison programmes (PT/EQA) :**


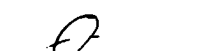
- This has been reviewed for the two quarters in the last 6 months, from Jan-Jun'18 dept wise : Satisfactory
- MOU with Lister lab for ILQC / Inter Lab Comparison: (Validity till 30.11.2018)

**i. Monitoring and resolution of complaints:**


- Based on Internal & External feedback forms (Jan - Jun'18) actions were taken and the issues Settled (as in point b)

**j. Performance of suppliers :**

- Vendor evaluation completed for the period of (Jan - Jun'18).
- Vendor Complaint for the period of (Jan-Jun'18) : Nil

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**k. Identification and control of nonconformities :**

- Daily non conformances are documented in all the laboratories and discussed in the Respective departments for corrective action. CAPA are documented as applicable.

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

**Continual Improvement :(Jan to Jun 2018)**

**Quality System :**


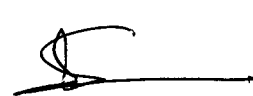
- Directory of Services for the SNSC laboratory is done. Further improvements will be done.
- NABH External auditing has been completed for NSN LAB on 27.03.18. No NCs received.
- Renewed G.J.Multiclave MOU for Biomedical waste for SN Main, JKCEN, NSN, CUSSN Valid upto March 2021.
- An IOM copy was received from Dr.H.N.Madhavan, that the Sankara Nethralaya Referral Laboratory is under process of applying NABL Accreditation and that we have to help them with internal audit. This shall be done.

**Haematology & Clinical Pathology :**


- New Cooling Centrifuge Remi CM-12 plus & Remi R8C was installed on 12.09.18
- Purchase of Beckman Coulter DXH 800 Hematology analyzer (under process)

**Clinical & Special Biochemistry**

- Dr.Harini MD Biochemistry got authorized signatory ship in the field of Clinical Biochemistry on 9.07.18
- Age wise reference range for most parameters in clinical biochemistry has been approved by Physician. SOP has been amended. It was implemented in HMS through IT Dept.

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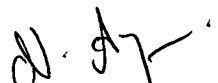
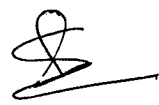


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- Clinical biochemistry report format has been revised to include updated age related Biological reference range along with clinical interpretation of the values from 1<sup>st</sup> Aug 2018.
- New analytes GGT in Liver function test and LDL direct estimation in Lipid Profile have been newly included after revised pricing changes and is being reported for all since 1<sup>st</sup> Aug 2018.
- Interactions with Physicians, Anaesthetist, Dept of patient service (DPS),. Surgical fixing centre to bring about the patient preparation for Cl. biochemistry testing especially for Diabetes work up and the appropriate tests to be ordered : Dr.Harini, Ms. Punitham and Dr.N.Angayarkanni. Dr.Harini made a presentation to the DPS secretaries (consultant secretaries).
- Proposal made for D-10 Biorad HbA1C analyser ( rental). Room modifications in main lab are proposed to accommodate this.
- Reporting improved with clinical correlations of the parameters from May 2018

**Histopathology lab :**

- Ms.Vanitha participated in the CME on Quality Management in Clinical Laboratories (SMART LAB) at MIOT hospital on 02.02.18
- Ms.Vanitha participated CME Programme on Total Quality Management in laboratory practices at Cancer Institute, Chennai on 21.04.18
- Ms.Bhuvana&Ms.Anitha participated National conference on Recent trends and advancement of medical laboratory science and diagnostics markers on 05.04.18 & 06.04.18
- Started MYD88L265 gene mutation on Vitreous aspirates to rule out intraocular lymphoma (Non NABL)

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**Microbiology lab :**

- **Pre Analytical:** Duration of collection / receiving the specimen from the ophthalmic consultant room / OT to Microbiology lab from the time of information of specimen collection (Time : 35 min) Current Objective: 90%, Revised Objective: 92% (from Feb'18 onwards)
- **Analytical:** Time of direct smear report informed to consultants over phone after receiving the clinical specimen in the Microbiology lab (Time: 40 min). Current Objective: 97%, Revised Objective: 98% (from Feb'18 onwards).
- **Analytical:** Antibodies to HIV 1 & 2, Antibodies to HCV and HBs Ag by rapid screening methods (Time taken from the time of receipt of specimen in SNSC Microbiology and Serology to completion of rapid tests (Time: 45 min) Current Objective: 85%, Revised Objective: 90% (from Feb'18 onwards)
- **Post Analytical:** Generation of Reports (Time: 2.00pm, 4.15pm, 5.15pm) Current Objective: 85%, Revised Objective: 90% (from Feb'18 onwards)
- **Post Analytical:** Authorization of Direct smear reports of clinical specimens by HMS from the time of receiving the same in the department (Time: 4 hrs 45 min) Current Objective: 90%, Revised Objective: 92% (Time : 4 hrs 30 min) (from Feb'18 onwards).
- **Post Analytical:** Soft copy of the Critical alert reports uploaded in HMS (Time taken from the time of completion of the rapid tests) (Time: 50 min) Current Objective: 85%, Revised Objective: 85% (Time: 48 min) (from Feb'18 onwards)
- **Post Analytical:** Time for uploading final reports of Positive serology test results (from the time of completion) (Time: 60 min) Current Objective: 90%, Revised Objective: 92% (from Feb'18 onwards)

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**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.

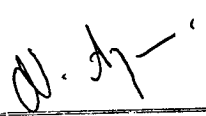

**m. Follow-up actions from previous management reviews :**

**(1). Training program for technical skill improvement through RUBRICS system:**


**Technical /Non Technical:** Technical is conducted lab wise internally and Non Technical is conducted by HR in various soft skill weekly. The details are documented lab wise by the Heads of the lab.

**External :**

- Ms.Punitham, Ms.Vanitha, Ms.Saumya, Ms.Gayathri (Main Lab), Ms.Gayathri (Microbiology lab) participated in SMART Lab CME Programme on 03.02.18 at MIOT Hospital.
- Ms.Punitham(Technical Manager) presented a topic entitled “National Accreditation Board for Testing and Calibration Laboratories ISO 15189:2012” in the training class on 24.03.18.
- Ms.Anitha R &Ms.Bhuvana S (Histopathology Lab) attended the National conference on “Recent trends and advancements of Medical laboratory Science and Diagnostic Biomarkers” organized by Department of Medical Laboratory Technology, Apollo Medskills, Chennai from 5<sup>th</sup> to 6<sup>th</sup> April 2018. Report is enclosed.
- Dr.N.Angayarkanni, Ms.Punitham (Biochemistry), Ms.Vanitha (Histopathology), Ms.Janaki & Ms.Nathiya (Microbiology) from SNSC Clinical Laboratory are participated CME on “Total Quality Management in Clinical Lab Practices” at Cancer Institute, Chennai on 21<sup>st</sup> April 2018. Dr.N.Angayarkanni presented a invited talk in the CBAT on “Diabetes mellitus: Role of Laboratory .”

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- Ms.Punitham (Biochemistry Lab), Ms.T.S.Saumya (Main Lab), Ms.V.Gayathri (Microbiology Lab) participated the Faculty Development programme on "Innovative Approaches in Teaching" conducted by SN Academy.Vanagaram on 31.05.18.
- Ms.Rajalakshmi (Main Lab) & Ms.Saranya (Biochemistry) participated the Workshop on "Method Validation & Verification – A CLSI Perspective" SRMC – Porur on 13<sup>th</sup> & 14<sup>th</sup> June 2018.
- Dr. Harini participated Scientific Symposium on "QC Practices in Clinical Laboratory" Seminar & Workshop on 6<sup>th</sup> July 2018 at Hotel Radisson Blu, Chennai. Organized by Bio-Rad Laboratories.
- Dr. P. Durgadevi & Mr.K. Kaviyarasan participated in the "Indirect Immunofluorescence in Hep2 cells CME & State level Workshop" on 26<sup>th</sup> July 2018 from 9:00 am to 5:00 pm at Madras Medical College, Chennai.
- Dr. A. R. Anand, Dr. M.K. Janani and Ms.V.Gayathri (Microbiology Lab) participated "Quality Management System and NABL Internal auditor's training program" at Neuberg Ehrlich Laboratory, Chennai from 23<sup>rd</sup> August to 26<sup>th</sup> August 2018.

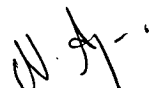

(2). Requisition form to go online is still incomplete.

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


**List of NABL Accreditation tests at SNSC Clinical laboratory approved in the recertification audit (validity) :**

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

**Total: 99 Tests**

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**Staff adequacy:** It was declared to be Adequate by all the heads of the lab

**Resignations/Long leave:**

- Haematology: Lab Technician-2 (Ms.Helen Pushpa &Ms. M.Logeshwari)
- Biochemistry Lab : nil. But Ms.Gayathri, Senior Technican on 6 months maternity leave
- Histopathology Lab : Nil
- Microbiology: Associate Professor-1 (Dr.J.Malathi has resigned)  
 Assistant Professor-1 (Dr. Amrita Talukdar has resigned )  
 Lab Technician – 1 (Mr.Divakar)

**Appointments :Refilling of the post:**

- Haematology:Lab Technician-2(Mr.Sathish Kumar&Ms.Manju)  
 Secretary-2 (Leave vacancy for 6 months. Ms.Anusha&Ms.Hemamalini)
- Biochemistry : Assistant Professor-1 (Dr.R.Harini)
- Histopathology : Nil
- Microbiology :Senior Scientist-1 (Dr. P.Durga Devi)  
 Associate professor-1 (Dr. A. R. Anand)

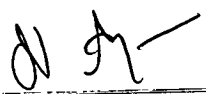

**Promotions:-1**


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

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

**Quality System :**

- Lab form "F/SNSC/ML/LRF/1.21" is in printing after revision.

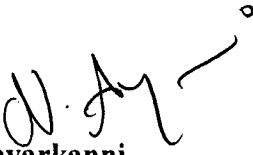
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**o. Recommendations for improvement, including technical requirements :**


- Communications on new joiners in SNSC along with designation and outline of scope of work .
- Manual awareness: The controlled copy of the manual to be freely available in the lab for extensive use
- Review of labs involved in MOU and ILQC should have documented evidences on Complaints/ feedback/ instructions etc (use formats).
- Quantitative Rubrix for evaluation for the staff and technicians based on log book
- Extensive feed back on the training program

**Thank You**

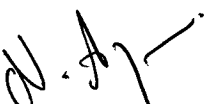

  
**Dr. N. Angayarkanni,**

Quality Manager,  
 Medical Research Foundation  
 SNSC Clinical Laboratory  
 Chennai – 600 006.

**Forwarded by:**

  
**Dr.S.B.Vasanthi**  
 Management Representative  
 Medical Research Foundation  
 SNSC Clinical Laboratory  
 Chennai – 600 006.

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