Minutes of the Management Review Meeting of SNSC Clinical Laboratory performance based on Re-Assessment Audit (2019), Jan to Dec 2019 : Dated 22.01.2020

Attendance:*(By Mail)*: 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 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:

- External audit conducted based on NABL standard ISO 15189 : 2012 for the following departments:
  - Quality Manual : Dr.D.Vijaya - Lead Assessor
  - Clinical and Special Biochemistry : Dr.Leena Chand– Technical Assessor
  - Clinical Pathology and Hematology : Dr. Anila Anna Mathan– Technical Assessor
  - Clinical Microbiology and Serology : Dr. G.Balajee – Technical Assessor
  - Histopathology and Cytopathology : Dr. S.Balamurugan– Technical Assessor
  - SNSC Collection Centre-Pycrofts Road : Dr. G.Balajee – Technical Assessor

External audit : NC Details based on NABL standard ISO 15189 : 2012:

- All the NCs are closed. (Minor NC - 6, Major NC - 18)

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.

Quality System:

- Dr Anand.A.R. & Dr.A.V.Kavitha got authorized signatory ship in the field of Microbiology & Serology on 24.10.2019
- CAPA format updated CAPA Number, Sub Category, Root Cause Analysis has been included on 26.08.2019

Clinical Hematology & Clinical Pathology:

- Method name included for the tests NRBC, MPV& Retic count on 11.02.2019
- External Customer Feed Back Form in Tamil Version included on 01.09.2019

Clinical Biochemistry :

- EQA Outlier Checklist/ Testing Checklist format has been introduced on 23.09.2019 (New Format)

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'19) were above the stipulated objectives in all the laboratories as evaluated half yearly. Details as below

- Histopathology & Cytopathology: (Objective - 81%)
  (Jan - Jun'19) - **94.3%,** (Jul - Dec'19) – **94%**
- Microbiology & Serology: (Objective - 80%)
  (Jan - Jun'19) - **94%,** (Jul - Dec'19) - **94%**
- Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and SNSC Collection Centre -Pycrofts Road) : (Objective - 80%)
  (Jan-Jun'19) – **88%,** (Jul - Dec'19) - **90%**

External customer feedback:

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry:
  (Jan - Jun'19) - **94%,** (Jul - Dec'19) – **94%** (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road:
  (Jan - Jun'19) - **87%,** (Jul - Dec'19) – **91%** (Objective - 80%)

c. Staff suggestions: Nil (Jan - Dec'19). .

d. Internal audits:

- Internal Audit - I (ISO 15189:2012) due on June 2019 was not conducted due to NABL External Audit. NABL Re-Certification audit conducted on 17th & 18th August 2019.

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

- *Clinical Hematology*:-

  Pre-analytical error:

  - Registration Error
  - Sample transport error (no icepack)
  - Wrong Anticoagulant used
  - Wrong patient identification done
  - Test missed (ESR/GTT)

  Post analytical error:

  - Data entry in report missed & Verification inappropriate
  - Incomplete data authorized and missed in verification

- *Clinical Biochemistry*:-

  Post analytical error:

  - Inaccurate data entry in reporting (FG reported as PP Glu)
  - Data entry in report missed & Verification inappropriate
  - Incomplete data authorized and missed in verification

- *Microbiology* :

  Post analytical error :

  - 19.04.19, KOH/Calcofluor report was sent as fungal filaments are not seen. But on 23.04.19 it was identified as few tiny bits of septate fungal filaments
  - 25.02.2019, Treponema Pallidum Haemagglutination test (TPHA) report was sent as positive till 1:1240 dilution. But on 19.03.19 it was found that the entry of dilution was wrong. Treponema Pallidum Haemagglutination test (TPHA) report was positive till 1:1280 dilution.

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 objectives (Jan - Dec'19), except Re-collections : (CAPAs documented)
- Analytical : (Internal & External QC, Equipment down time, calibration plans) All are within the objective from (Jan - Dec'19) except few parameters: Clinical Haematology – EQAS & IQC , Microbiology – EQAS, Clinical Biochemistry – EQAS, IQC & Equipment Down Time, Histopathology - Equipment Down Time:
  CAPAs are documented as applicable
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From (Jan - Dec'19) except: Sp Biochemistry - Turn around time exceeded. CAPA filed.
- Feedback forms (Internal & External) has been reviewed for the two quarters in the last 12 months from (Jan - Dec'19), 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 Jan 2019 (Validity till 31.03.2022) for SNSC Clinical Laboratory, (SN Main) Chennai.
- Absolute Alcohol Renewal of license done on April'19. Valid up to Mar-2020.
- Biomedical Department : Renewal of Calibration Certificate done From Jan – Dec'19
  - Digital Thermometer with Sensor 09.01.2020 – 08.01.2021
  - Digital Multimeter – 16.10.2019 – 16.10.2020
  - Digital Tachometer – 03.10.2019 – 02.10.2020
  - Weight box – 31.12.2019 – 31.12.2020
  - Digital stopwatch - 17.12.2019 –16.12.2020
  - BP Apparatus - 30.12.2019 – 30.12.2020
  - Glass Thermometer - 26.12.2019 – 26.12.2020

- Maintenance Department : Renewal of Calibration Certificate done From Jan – Dec'19
  - Temperature Indicator with Sensor – 26.08.2019 – 26.08.2020
  - Hygrometer – 11.12.2019 – 11.12.2020

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'19 department wise : Satisfactory Results.

i. Monitoring and resolution of complaints:

- Based on Internal & External feedback forms (Jan - Dec'19) actions were taken and the issues Settled as detailed below
  - *Some basic level learning of Hindi can help patient & Staff in better communication.* Action taken: Technician Mr.Sathish attended the communication class conducted by HRD.
  - *Tell any representative to either talk to patient in more clearer English as understanding them is little bit difficult.* Action taken: Mr.Karthick informed him that in case of any language problem kindly call the seniors for clear communication.
  - *Please give priority for outsiders during all treatment.* Action taken: Suggestion forwarded to Ms.Rajamani (Department of Patient Services - Head). Explained to the patient that most of the patients who come are outsiders.
  - *Appreciate if the waiting hall to be centralized with Air conditioned.* Action taken: Explained that to Stair case in the laboratory area it is not possible to do, However the feed back form forwarded to Management
  - *HbA1c are routine for diabetics* Action taken: Routine Diabetic work up with HbA1c included in lab form 01.02.2020

j. Performance of suppliers :

- Vendor evaluation completed for the period of (Jan - Dec'19).
- Vendor Complaint for the period of (Jan - Dec'19)

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'19)

Quality System:

- Organization chart was updated through Ms.Akila Ganesan, Director-Administration.
- As per Mr.Suresh Kumar, (DGM) request we have submitted the following documents on 23.03.2019. (This is as per the new mandate of the State Government, we have to register each of our centre under Tamil Nadu Clinical Establishments Act before March 31st).
  - (i). SNSC List of Departments,
  - (ii). Tests being carried out in all the departments,
  - (iii). List of Technical Staff,
  - (iv). List of Staff who are authorized to sign the reports.
- SOP for Guidelines for Vaccination was updated on 26.03.2019. No titre of circulating antibodies will be checked. (After completion of 5 years booster dose will be given)
- Name Board has been changed in "JKCN Centre" SNSC Collection Centre has been changed as "SNSC Clinical Laboratory Collection Centre" on July'2019
- CAPA Format has been changed from. 26.08.2019. CAPA Number, Sub Category & Root Cause Analysis details has been updated and distributed to the Heads of the Department

- Based on NC raised by Lead Assessor, External Feed Back Form Tamil version was implemented from 01.09.2019 onwards.
- Based on NC raised by Lead Assessor, Risk Assessment protocol has been implemented.
- The frequency of Internal Audit was revised as once in a year instead of 6 months.
- As per NC raised by Lead Assessor, MOU between Apollo Hospitals, Chennai & SNSC Clinical Laboratory implemented from 18.09.2019 for the purpose of diagnostic services to patients of SNSC Clinical Laboratory (Unit of Medical Research Foundation) beyond the Working hours in the late evening/ Sundays/ Holidays of SNSC Clinical Laboratory, MRF, Chennai.
- After Re-Certification Audit, NABL Logo was implemented for SNSC Clinical Laboratory test reports from 01.11.2019 onwards (Previous NABL Certificate expired on 13.08.2019)
- NABL ILAC – MRA (International Laboratory Accreditation Co-operation – Mutual Recognition Arrangement) Logo (NABL/ILAC/0402) approval letter was received from NABL on 07.11.2019. SNSC Clinical Laboratory test reports carry the two logos from 09.11.2019 onwards for Haematology, Cl.Pathology, Cl.Biochemistry, Microbiology& Serology & Histopathology.
- SNSC Clinical laboratory received the 7th NABL Accreditation Certificate on 26.12.2019. Valid from 17.10.2019 – 16.10.2021.
- SNSC Received the 2nd NABL Recognized Certificate for SNSC Collection Centre, 21, Pycrofts Road on 03.01.2020. Valid from 17.10.2019 – 16.10.2021
- SNSC Clinical Laboratory PT/ILC Plan for next four years (as per given NABL 163 format) was submitted to NABL on 03.01.2020
- MOU between SNSC Collection Centre – Pycrofts Road & SN Main lab is renewed
- Web page for SNSC Clinical Laboratory has been updated.
- SNSC Directory of Services updated (Revised charges/New scope) is put up on website

Haematology:

- 27.01.2019 onwards Bar-code id's format have been changed in Haematology analyser as follows:
  - 001: Location-wise lab reference number(Main)
  - 201: Location-wise lab reference number(JKCN)
  - 301: Location-wise lab reference number(NAVA)
  - 401: Location-wise lab reference number(REH)

- Introduced 23G (Butterfly wing set) & 24G needle for paediatric blood collection from 07.11.2019
- ACCU VEIN [AV400] has been installed in the paediatric collection area on 03.12.2019.
  - Major equipment installation :
    - Cube 30 touches –Fully automated ESR analyzer installed on 14/12/2019.
    - IRIS IRICELL Fully Automated Urine analyzer Operating lease and Service Agreement received on 03.12.2019. Installation expected on Feb 2020
  - Measures:
    - Sample collection and identification measure initiated at pre examination area from Mar'2019 (Objective – 100%)

Training:

- Ms.Rajalakshmi participated "NABL 112 –Specific criteria –Latest Amendments" on 16.03.2019
- Ms.Saumya participated "Workshop on Fundamentals of Biostatistics for Diagnostics Laboratories on 01.08.2019 to 03.08.2019 at CMC Vellore
- Mr.Senthil kumar participated CME Programme "HEMOGLOBINOPATHY WORKSHOP" on 23.11.19 at MIOT Hospital.
- Ms.Rajalakshmi and Ms.Sagaya Shylaja participated the "URICON 2019"at MIOT Hospital on 20.09.2019 & 21.09.2019

Biochemistry:

- Dr. Harini and Dr AK had a discussion in Vitreo Retinal department consultants meet about the "Recent trends, importance, uses and clinical interpretation of HbA1C values in Diabetic retinopathy "on 26-06-2019.
- At the Lab enquiry section a dedicated trolley for shifting emergency patients has been installed on April'2019.

- Review of Test : (Pre examination process)
  - HIL index was done for all hemolysed and lipemic samples and with this sample rejections showed a decreased from 26.8.2019.
  - Heparin sample collected for chemo package workup patients and sample volume decreased for pediatric patients from October 2019.
- Review of Test: (Post examination process)
  - Clinically relevant remarks and suggestions are added as part of the reporting system from May 2019.
  - Daily QC trend analysis by technicians who handle is started in practice as part of quality monitoring from September 2019
- New test :
  - GGT and LDL test scope submitted to NABL and approved by NABL in the month of October 2019.
- New equipment and improved method: (Examination process)
  - Vest frost Laboratory Refrigerator installed in the sample storage area on 15.02.2019 for better storage space and maintenance of sample integrity.
  - Haier Small Refrigerator installed within the work space in the laboratory on 25.02.2019 for storing the day to day use of samples.
  - AVL Electrolyte analyser purchased on 28.02.2019.

- Roche 9180 electrolyte analysers, Electrode slope monitoring according to recent NABL 112 has been initiated as a part of monitory self-calibration process from March 2019

- Risk Management
  - Identify the risk, data collected from the daily non-conformance record and appropriate steps taken to eliminate risks noted from October 2019

Training:

- Dr.R.Harini participated in the 3rd National Conference and Workshop on "Managing Quality in Clinical Laboratories" on 11th& 12th January 2020 at Tata Memorial Hospital, Mumbai. Report was circulated
- Ms.Punitham participated in the "NABL 112 –Specific criteria –Latest Amendments" on 16.03.2019
- Dr.Harini participated in the "BIO-RAD South Asia Symposium on Hemoglobin update 2019" on 29.08.2019
- Dr.Harini & Ms.R.Punitham participated in the CME on "Prematurity" on 21.11.2019.
- Ms.R.Punitham & Ms.Gayathri Participated "BIORAD 6th Scientific Symposium on QC Practices" on 11.06.2019.

Microbiology:

- The Bunsen burner connection in the Bio safety cabinet is removed on April 13th 2019 as the level II cabinets can be used even without the Bunsen burner.
- The Nichrome loops have been stopped using and only the sterile Hi-media loops are being used now from January 2019
- The oxacillin disc has been used to detect the Methicillin resistant Staphylococcus species. It has been replaced with the Cefoxitin disc from 20th January 2019 with reference to the CLSI guidelines.

- New Test:
  - Antibodies to Myelin Oligo dentrocyte glycoprotein (MOG) was newly added to the scope of testing from May 2019 and received NABL Accreditation for the same.
- New Equipment:
  - Nikon Fluorescent Microscope with imaging camera has been purchased with the Accessories on 28.03.2019
- *Measures:*

Pre Analytical:

- Duration for collection / receiving the specimen from the ophthalmic consultant room /OT to Microbiology lab from the time of information of specimen collection, The Objective on compliance is now increased from 92% to 93% from Feb'2019

Analytical:

- Time of direct smear report informed to consultants over phone after receiving the Clinical specimens in the Microbiology lab: The Objective on compliance is increased from 97% to 98% in Feb'2019
- Antibodies to HIV1&2, Antibodies to HCV and HBsAg by rapid screening methods (Time taken from the time of receipt of specimen in SNSC Microbiology and serology to the completion of rapid tests). Objective increased 85% to 92% from Feb'2019

Post Analytical:

- Generation of Reports (Second Set), the time is reduced from 4.15 pm to 4.00 pm since Feb'2019
- Authorization of Direct smear reports of clinical specimens by HMS from the time of receiving in the department. Time reduced from 4 hours 45 minutes to 4 hours
- Soft copy of the Critical alert reports uploaded in HMS (time taken from the time of completion of the rapid tests). The Objective increased from 85% to 92% -Feb'2019

- Time for uploading final reports of positive serology test results (from the time of completion). The Objective is increased from 90% to 93% from Feb'2019

- *External Quality Control program:*
  - Scored 100% in VIRO EQAS Distribution No.S119 conducted by IAMM EQAS,CMC Vellore for the year 2019.
  - Scored 98% in 101st and 94.2% in 102nd QC package conducted by IAMM EQAS, CMC vellore.
  - The parameters has been fulfilled for the Detection of Antinuclear antibody (Immunofluoresence technique) and Detection of Antinuclear antibody (ELISA method) conducted by EQAS Euroimmun, Germany for the year 2019.
  - The parameters has been fulfilled for the Antibodies to Aquaporin-4 conducted by EQAS Euroimmun, Germany for the year 2019.

Training:

- Dr. A. R. Anand, Ms. D. Caroline & Ms. K.Selvi participated CME program entitled "Nephelometry & Its Clinical Applications" on 16.10.2019 .
- Dr.A.R.Anand and Dr.P.Durgadevi attended the ISSHID 2019 International science symposium on HIV & Infection Diseases conducted by Sri Ramachandra Institute of Higher Education and Research (SRIHER), Porur, Chennai on 12th to 14th October 2019.
- Dr. K. Lily Therese and Dr. P. Durgadevi participated in the WHO-IAMM Network for Surveillance of Antimicrobial Resistance (WINSAR)AMR on 28th &29th March 2019.

- *Histopathology:*
  - New Tissue Processor (Leica TP 1020) installed on 22.10.2019
  - New Floatation bath installed on 17.06.2019, as standby equipment
  - Started to participate in QA Programme conducted by RML, Lucknow from Sep'2019
  - Information about the number of stained slides reviewed captured in the Histopathology / Cytopathology reports from Sep'2019

Training:

- Ms. Pavithra Mukesh (Junior Scientist) participated in the CME Programme "HEMOGLOBINOPATHY WORKSHOP" 23.09.2019

- *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
  - Quality Indicators are verified quarterly by QM Lab wise.

m. Follow-up actions from previous management reviews :

- SNSC Staff members participated in the CME Programmes organized by MIOT Hospitals, SRMC-Porur & Agappe to accommodate more participation of technical staff
- Rrequisition 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 :

No major changes in volume and personal adequacy

(i) Scope: List of NABL Accreditation tests at SNSC Clinical laboratory approved in the recertification audit (validity) : 17.10.2019 – 16.10.2021 : **Total: 115 Tests**

- Clinical Haematology : 29 and Clinical Pathology : 19
- Clinical and Special Biochemistry : 21
- Clinical Microbiology and Serology : 28
- Histopathology : 15 and Cytopathology : 3

(ii) Statistics of all the tests in the lab: **2019**

- **Total No. of Investigations Jan – Dec 2019 (Change compared to 2018)**
  - Haematology: 1,45,641 (↓ by 3.8%)
  - Clinical Pathology : 31,447 (↓ by 4.57%)
  - Clinical Biochemistry : 1,03,529 (↑ by 0.43%)
  - Special Biochemistry : 2,093 (↑ by 2.8%)
  - Histopathology : 2,712 (↑ by 12.57%)
  - Cytopathology : 228 (↓ by 0.86%)
  - Microbiology : 16,719 (↑ by 6.13%)
  - Serology : 17,354 (↑ by 2.63%)
  - Microbiology Surveillance: 4,114 (↑ by 3.44%)
  - SNSC Collection Centre (Pycrofts Garden Road): 6,694 (↑ by 13.28%)
  - SNSC Collection Centre (NSN – Non NABL) : 1,808 (↑ by 0.1%)
  - SNSC Collection Centre (REH – Non NABL): 1,889 (↓ by 8%)
  - Cytogenetics (Non NABL) : 1,675 (↑ by 74.%)
  - Out source : 907 (↓ by28.9%)

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

Resignations:

- Haematology Lab : Lab Technician - 1 (Ms.Divya Bharathi)
  Lab Assistant -1 (Ms.Durga Devi)
  Lab Secretary - 2 (Ms.Anuradha & Ms.Shanthi)
- Biochemistry Lab : Lab Technician - 1 (Ms.Devi Uma)
- Microbiology Lab : Junior Executive -3 (Mr.Kaviyarasan, Ms.Janaki & Ms. V. Lakshmi priya)
  Lab Technician -1 (Ms.Isabella Mary)
- Histopathology Lab : Lab Secretary - 2 (Ms.Geetha Krishna & Ms. Eniya)
  Junior Scientist -1 (Mr. Mayur Joshi)

Appointments: Refilling of the post:

- Haematology Lab: Lab Technician - 4 (Ms.Suganya, Mr.Rajesh, Ms.Thelothamma & Ms.Baggiyalakshmi)
  Lab Assistant - 2 (Ms.Shanthi & Mr.Gunasekaran)
  Lab Secretary - 2 (Ms.Gayathri & Ms.Mohanapriya)
- Biochemistry Lab: Lab Technician - 2 (Ms.Rani & Ms.Sakthidevi)
- Histopathology Lab: Lab Secretary - 1 (Ms.Mary Sonia)
  Junior Scientist -1 (Mr.Swaminathan)
- Microbiology Lab: Junior Executive - 2 (Ms Jeyadeva Sena & Ms.Saraswathi)

(iv) Document control: Version numbers of documents revised in 2019 (Jan - Dec'19) :

Quality System :

- Customer Feed Back Form (External) : SNSC/CFF/MAIN LAB/EX-1.3
- Corrective & Preventive action Report : SNSC/C&P/2019/Version-1.7
- EQA Testing Checklist : SNSC/EQA-TCL/2019/Version-1.1 (New Format)
- EQA Outlier Checklist : SNSC/EQA-OCL/2019/Version-1.1 (New Format)

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

- Communications on new joiners in SNSC Cl Lab along with designation and outline of scope of their work to be sent to Quality Manager in the quarterly report
- Manual awareness/ Induction Protocol: Documentation of the protocol and Implementation for new joinees
- Review of labs involved in MOU and ILQC to have documented evidences on Complaints/ feedback/ instructions etc (use formats).
- Staff Proficiency: to be ensured and documented
- MIS (Management Information System) presentation done every month as per NABH requirement to be included in the quarterly report
- Quality plan 2019 was Implemented: Out of 22 proposed points, 16 points were Implemented.
- Quality Plan 2020 is proposed.

Forwarded by:

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