Minutes of the Management Review Meeting of SNSC Clinical Laboratory

performance from Jan to Dec 2021 including the internal audit: Dated 08.02.2022

Attendance: By list (list enclosed). The representations were from the CI pathology Haematology Lab, Clinical Biochemistry, Microbiology and Serology, Histopathology, Cytogenetics and the Support Services: CSFU, HRD, Commercial, Biomedical, IT Dept & NABH Co-ordinator, Quality Manager, Laboratory Director and Medical Director (MRF).

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

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 conducted based on NABL standard ISO 15189 : 2012 for the following departments:
  ➢ Blood Collection area, Lab Enquiry & Reporting : Dr. A.V. Kavitha
  ➢ Clinical Haemotology & Clinical Pathology : Dr. A.V. Kavitha
  ➢ Clinical and Special Biochemistry : Ms. K. Vanitha
  ➢ MR and QM (Quality System) : Dr. R.Harini
  ➢ Clinical Microbiology and Serology : R. Rajalakshmi
  ➢ Histopathology and Cytopathology : Ms R.Punitham
  ➢ Commercial : Ms.V.Gayathri & Dr. Harini
  ➢ HRD : Dr. A.R. Anand
  ➢ IT : Ms. T.S. Saumya
  ➢ Biomedical Dept : Dr. S. SriPriya
  ➢ CSFU : Dr. S. R.Bharathi Devi

Non-NABL
- SNSC Collection Centre-Pycrofts Road : Ms.U.Jayanthi
- Genetics (Non NABL) : Ms. R. Gayathri

Internal audit conducted by Internal Assessors based on New Standard
ISO 15189:2012: all the NCs are closed. (Minor NC - 29, Major NC - 19)

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:
  ➢ Lab Requisition Form online was implemented 23.09.2021 onwards after review
  ➢ Incident Reporting form implemented for SNSC Clinical Laboratory from Feb’2021 (safety committee)
Referral Lab Performance Evaluation Form - Newly introduced format for outsourced tests done at Metropolis

Critical Alert Value Document - New version updated (Medical intervention/follow up stated explicitly)

**Clinical Biochemistry:**

- Test Report format was improvised in terms of uniformity in test name/code, test sequence in panel, method tallying with scope since February 2021.

**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’21) were above the stipulated objectives in all the laboratories as evaluated yearly. Details as below

- Histopathology & Cytopathology: (Jan - Dec’21) - 94.4%, (Objective - 81%)
- Microbiology & Serology: (Jan - Dec’21) - 94%, (Objective - 80%)
- Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and SNSC Collection Centre -Pycrofts Road): (Jan - Dec’21) - 86%, (Objective - 80%)

**External customer feedback:**

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry: (Jan - Jun’21) - 94%, (Jul - Dec’21) – 97% (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road: (Jan - Jun’21) - 91%, (Jul - Dec’21) – 89% (Objective - 85%)

c. **Staff suggestions:** (Jan - Dec’21): 1

- To introduce Barcode for Mantoux test: Label to be put up in the log book. suggested by Ms.Jayashree RV- from Collection - Main lab dt 30.10.2021. Approved and implemented by Dr.Doreen Gracias on 26.11.2021

d. **Internal audits:**

- Internal Audit (2021) conducted by Internal Assessors based on New Standard ISO 15189:2012: all the NCs are closed. (Minor NC - 29, Major NC - 19)
e. Risk management (Based on CAPA): Pre analytical & Post analytical.
   - **Clinical Hematology:**
     - Pre-Examination error:
       - Needle Stick Injury: 3
       - Patient details discrepancy in Outsource specimen transportation: 1
       - Mantoux (Eales work up package) missed to give for the patient: 2
     - Post Examination error:
       - Mantoux reading - wrong entry in HMS
       - High ESR value released without remarks
       - Incomplete urine LFT report updated and verified
       - APTT control value was updated wrongly
       - Inaccurate data entry in reporting (Hb, TC value)
   - **Clinical Biochemistry:**
     - Examination error:
       - Sodium value discrepancy in hemolyzed / normal sample
       - Urea creatinine values for 2 patients were interchanged in report due to sample sample cups that was interchanged. (child collection)
     - Post Examination error:
       - Inaccurate data entry in reporting
       - HbA1C report was authorized without remarks
       - Incomplete LFT report verified
       - Data entry in report missed & Verification inappropriate
   - **Histopathology:**
     - Post Examination error:
       - Patient details discrepancy in requisition form

f. Quality Indicators:
   - Pre Examination: Sample collection, Transport time, Repeat & Rework: All are within the objectives (Jan - Dec'21)
SRI NATHELLA SAMPATHU CHERTY CLINICAL LABORATORY  
(UNIT OF MEDICAL RESEARCH FOUNDATION)  
ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -28

- Examination: (Internal & External QC, Equipment down time, calibration plans) All are within the objective from (Jan - Dec’21) except few parameters: Clinical Haematology – EQAS & IQC, Clinical Biochemistry – EQAS, IQC & Equipment Down Time, Histopathology- EQAS: CAPAs are documented as warranted.

- Post Examination: (Turnaround time, Amendment test reports) All are within the objective From (Jan - Dec’20) except Sp Biochemistry & Histopathology - Turnaround time exceeded. CAPA filed as warranted.

- Feedback forms (Internal & External) has been reviewed for the last 12 months from (Jan - Dec’21), 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 2020 (Validity till 31.03.2022) for SNSC Clinical laboratory & SNSC Collection Centre - Pycrofts Road, Chennai.


- Biomedical Department: Renewal of Calibration Certificate done From Jan – Dec’21
  - Digital Thermometer with Sensor 05.01.2022 – 04.01.2023
  - Digital Tachometer – 06.11.2021 – 05.11.2022
  - Digital stopwatch – 03.11.2021 – 02.11.2022

- Maintenance Department: Renewal of Calibration Certificate done From Jan – Dec’21
  - Temperature Indicator with Sensor – 22.11.2021 – 22.11.2022
  - Hygrometer – 22.11.2021 – 22.11.2022

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’21 Department wise: Satisfactory Results.
i. Monitoring and resolution of complaints:
   - Based on Internal & External feedback forms (Jan - Dec’21) actions were taken and the issues Settled as detailed below

   (i). Culture report form print out when filed the left border gets covered. So if it can be adjusted (to see the left part of the report):
   
   **Action taken:** Dr. Anand sent a mail to IT Dept. IT dept. improved the format as on 11.01.2022. Implementation details informed to Dr. Elizabeth Sonu John on 11.01.2022.

   (ii). Simple format for basic investigations & present format for detailed investigations.
   
   **Action taken:** All forms are now available in simplified format online. **Abnormal results should be in Bold letter & underlined.** **Action taken:** Checked with Ms.Sumathy (IT Dept). who informed that it is not possible and the whole alignment of the reports will be changed,

   that was conveyed to Dr.Vinata Muralidharan

   (iii). Template for Urea, Creatinine and Lipid Profile. **Action taken:** Asked IT to help Dr.GSI to Create template. All consultants shall be able to do it by themselves.

   (iv). Provide water outside. There is no water available till 11.30am.
   
   **Action taken:** Informed Housekeeping in charge to do the necessary action. The water is now available from morning 8.00am onwards.

   (v). Suggested to place slope in Indian Toilet. **Action taken:** Mail sent to Mr.Kamalakannan (Maintenance Dept) for further action. Comments from Mr.Kamalakannan (Maintenance Dept): It is under process (Quotation received) will be followed up until done.

   (vi). Payment of fee should be made online. **Action taken:** Mail sent to Ms.Susila (Finance Dept). Comments from Ms.Susila (Finance Dept): We are collecting fees through NEFT/IMPS providing our bank details, but some patients are expecting to pay through QR scan, which we are currently working on with bankers and will keep posted on the Feb’2022. Comments from Ms.Geetha (IT Dept): UPI Payment mode Implemented from 08.02.2022 onwards by IT Dept

   (vii). Need much staff for special patient. **Action taken:** Extra technician posted at SNSC
Collection centre from 08.07.2021 onwards (8.00 am - 4.00 pm) & (9.00 am - 5.00 pm) (viii). *More information for various lens and their process and about surgery are required.*

**Action taken:** Suggestion forwarded to Ms.Rajamani (DPS-Head) Comments from Ms.Rajamani, (DPS-Head): We have instructed the SFC secretaries both Main and JKCN to explain the process clearly and also ensure that the consultants do it.

**j. Performance of suppliers:**
- Vendor evaluation completed for the period of (Jan - Dec’21) is given by commercial dept
- Vendor Complaint for the period of (Jan - Dec’21): Nil

**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:**

**Quality System:**
- Referral Lab Performance Evaluation form implemented from 04.02.2021 onwards
- Critical Alert form was updated with new version no. with effect from 25.06.2021
- Incident Report form was effectively utilized by SNSC Clinical Laboratory from August’2021 onwards. -Safety committee
- Lab form F/SNSC/ML/LRF/1.24 was implemented from 02.08.2021 onwards (Code No.384-CRVO Package was included)
- The error of Automatic generation of sample collection details, if an EP request is clicked in the barcode generation HTML page was corrected by the IT department. (Nov 2021)
- Lab report tracking of sample status has been implemented from September’2021
Online Requisition Form: Lab forms online trial started from 23.07.21. Ms.Geetha and the team from IT along with Dr.Sudhir, presented the online version of the Lab Requisition form: trial at various places, SFC, OT, Enquiry etc. This was discussed for fine-tuning on 11.08.2021. All Heads of the Lab, in-charge, TM & Dy.TM attended. Online Lab form successfully implemented from October 2021 onwards at all centres including SN-Kolkata.

- Due to the implementation of Online request for blood the following changes have been made in the Lab request:
  2. FFA given details of the patient highlighted with a yellow color.
  3. Lab request tracking of samples has been implemented from August 2021 to prevent delay or missed sample collection and reduction of overall waiting time.
  4. Lab report tracking of samples has been implemented from September 2021 due to which Post-examination errors (in clinical biochemistry/Clin.Pathology & Clin.Hematology) due to missed verification is reduced.
  5. The error of Automatic generation of sample collection details, if an EP request is clicked in the barcode generation HTML page was corrected by the IT department. (Nov 2021).


- Web page & Directory of Services for SNSC Clinical Laboratory updated on 03.08.2021

Others:

- Lister Lab MOU for ILQC and Outsource tests was renewed with effect from 13.09.2021 (Validity for two years)

- SNSC Staff members vaccinated for COVID-19 and the COVID protocols followed in the Lab.

- SN - RA Puram branch was inaugurated on 12.07.2021. SNSC Collection Centre - RA Puram branch started functioning from 15.07.2021 onwards.
Dr.DG, Dr.AK, Dr.KK, Dr.Harini, Dr.Anand, were appointed as Board of Studies Member for Laboratory Tech Sciences Program at TSNA from 01.07.2021 - 30.06.2023

Dr.AK was appointed as Member in Board of Studies-Biochemistry at University of Madras from 01.09.2021-31.08.2024 (Three Years). It was an extension from previous term of 3 years

Cl pathology and Hematology:

- Routine + CBC Reports: TAT reduced to 2 hours from 2 ½ hours
- Enrolled BIORAD EQAS Urinanalysis Programme for IRIS IRISCELL Mar’21
- DXH 560 AL Haematology Analyzer (Upgrading Act 5 diff AL by Beckman Coulter Pvt Ltd) installed on 7/7/21
- Single use Plastic Pasteur pipette introduced in clinical pathology dept for transferring the sample to the secondary tube from 5/7/21 onwards
- Online form acceptance on trial basis and trouble shotted. Started from 23/9/21
- Stand by AC installed at Coulter room on 17/10/21
- TAT for all regular test requests are reduced to 3 hours from 24 hours on trial basis from Nov’21 month onwards and implemented in Jan 2022

Cl Biochemistry:

Pre examination process

- Volume Analysis - For paediatric package test blood collection-sample volume reduced by regular risk assessment process.
- CRVO package created: LRF 1.24 includes the tests urea, creatinine lipid profile, HbA1c and Homocysteine
- Prevention of Vacutainer wastage done before expiry by regular risk assessment process.

Examination process:

- Processing of ALT in Cobas, the ALT is now reverted to processing in Dade equipment from November 2021 as there was no significant difference in the cuvette cartridge usage.
- For all Diabetic patients Code 303 (instead of code 302) and for patients above 40 years code 302 (instead of code 301) are requested in Routine packages from 27.07. Tests number increased and detection of DM in NKD is enabled.
QC protocols improvised:

(i). Bicarbonate: Bio-Rad IQC implemented from 01.10.2021. EQAS -Bio-Rad EQAS Initiated from Jan'2022. Discontinued the ILQC.


(iii). HbA1c: CMC EQAS implemented from January’2022. ILQC discontinued

Up gradation of Glucometer:

(i). The Grading system of glucometer calibration upgraded according to the 2013 new accuracy standards (ISO 15197:2013) from April 2021 and OneTouch select simple glucometer replaced by one touch select plus glucometer for monitoring capillary blood glucose (CBG). Totally 56 glucometers evaluated and put to use based on Successful fulfilment of criteria for method verification according to ISO 15197:2013.

Post Examination Process:

- Critical alert reporting protocol of capillary blood glucose (CBG) for collection centers has been revised and implemented from March 2021 for effective communication of alert and better patient management, as in Hypoglycemia. Critical alert values communication form is amended SNSC/CRI–ALD/2021/Ver-1.2 that documents medical intervention and follow up implemented from June 2021.(F/SNSC/CB/CAVCF)

- Revision of TAT: Based on the Dec month TAT data, the TAT for clinical biochemistry investigations had been revised from Jan 2022

- Selection option of secondary specimen of Sample: Serum/Plasma for LFT in HMS has been implemented from MARCH 2021.

Personnel:

- Induction Training updated protocol for new joiners has been implemented from December’ 2020 and record maintained R/SNSC/CB/LP & ITR.

- Lab report tracking of samples has been implemented from September’2021 due to which post examination errors in clinical biochemistry due to missed verification is reduced.

Manual Review:

- The departmental manual and SOP has been revised with issue no: 7 dated 22.7.2021
Microbiology:
- A new computer was installed in the microbiology lab to facilitate routine microbiology services, particularly for NABL documentation and online receipt of clinical samples from the main lab.
- We stopped using the hard copy of the OPD requisition forms and all the requisition were made online.
- Developed the new form for OT Surveillance purpose and in use now.
- With inputs from the Uvea department on the lack of significance of Brucella agglutination tests in our setting in corroboration with our data showing lack of Brucella antibodies in patients for several years, the Brucella agglutination test, that was part of the uveitis workup package has been removed.
- Training: Internal Training has been conducted as per Training Plan 2022

External Quality control program:
- Scored 100% for Distribution no. 121, 221 and 321 VIRO EQAS 2021 conducted by IAMM EQAS, CMC Vellore.
- Scored 100% in 106th QC, 94.3% in 107th QC and 98.6% in June 2021 QC package conducted by IAMM EQAS, CMC Vellore.
- Scored 100% in Batch 24 and 80% in Batch 25 Mycology EQAS – EQMM, Chandigarh
- The parameters were fulfilled for the Detection of Antinuclear antibody (Immunofluorescence technique) and (ELISA method) conducted by EQAS Euroimmun, Germany for the year 2021.
- The parameters were fulfilled for the Antibodies to Aquaporin-4 conducted by EQAS Euroimmun, Germany for the year 2021.
- The parameters were fulfilled for the Antibodies to pANCA and Antibodies to cANCA conducted by EQAS Euroimmun, Germany for the year 2021

Histopathology:
- Started to generate reports with NABL Logo for Ophthalmic specimens received from External patients from 18.06.2021
The equipment down time grading maintained as “Good” (Observed Measure above the Objective) during all 4 quadrants of the year 2021

**Cytogenetics: (Non NABL)**
- SOP for Molecular diagnostic tests prepared
- Assignment submitted on Pre PCR guidelines for Molecular tests and documented

**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 Technical Staff members participated in the CME Programmes organized by SN Academy / Other Institutes
- Proposed plans have been implemented largely. Carryover of the Quality plan not completed this year to next year.

**n. Changes in the volume and scope of work, personnel, and premises that affect QMS:**
No major changes in volume and personal adequacy

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

- NABL Scope Extension (Clinical Pathology) Audit conducted by Dr. Mamta Soni- Apollo Hospital on 20.10.2021. 2 NCs were received on Scope Extension Audit. Quality System - 1 (Major NC), Clinical Pathology - 1 (Minor NC).
SNSC Clinical Laboratory reports generated without NABL Logo from 21.10.2021 onwards, Since Desktop Audit for the year 2021 was pending, delayed by NABL Scope extension audit

Dr. AK discussed with Ms. Syed Tahira Rizvi, NABL Dealing officer on 01.12.2021 regarding Scope extension results (NABL site showing Under NABL Review for last 20 days). NABL informed us that the validity of the certificate is expired meanwhile no result will be given to the scope extension audit done, and we need to apply as a fresh application.

(ii) Statistics of all the tests in the lab: 2021
- Total No. of Investigations Jan – Dec 2021 (Change compared to 2020)
  However it is almost 75% back to the statistics status in 2019, as 2020 had a dip due to COVID lockdowns
  - Haematology: 1,43,792 (↑ by 45.8%)
  - Clinical Pathology: 28,535 (↑ by 34.9%)
  - Clinical Biochemistry: 91,397 (↑ by 44.3%)
  - Special Biochemistry: 1,362 (↑ by 35.6%)
  - Histopathology: 2,112 (↑ by 36%)
  - Cytopathology: 181 (↑ by 56.3%)
  - Microbiology: 13,538 (↑ by 34.6%)
  - Serology: 12,483 (↑ by 28.5%)
  - Microbiology Surveillance: 3,532 (↑ by 7%)
  - Out source Tests: 1,235 (↑ by 54.9%)

(Clinical Haematology & Clinical Pathology)
- SNSC Collection Centre (Pycrofts Garden Road): 5,171 (↑ by 40.4%)
- *SNSC Collection Centre (SN:RA Puram – Non NABL): 492 (↓ by 20.9%)
- SNSC Collection Centre (CUSSN – Non NABL): 2,085 (↑ by 48.8%)
- Genetics (Non NABL): 448 (↑ by 57.8%)

((Including Pedigree & Counselling))

* SNSC Collection Centre - RA Puram branch started functioning from 15.07.2021 onwards
(iii) Staff adequacy: It was declared to be Adequate by all the Heads of the lab

**Resignations:**
Haematology Lab: Executive - 1 (Ms. Tamilselvi - Retired);
Lab Technician - 2 ((Mr. Gunasekar, Ms. Suchithra)
Microbiology Lab: Junior Executive - 1 (Ms. Jeyadevasena); Lab Technician - 1
(Ms. Selvi)

**Appointments: Refilling of the post:**
- Haematology Lab: Lab Technician - 2 (Yet to be appointed) Lab secretary - 1
  (Ms. Anitha Devi)
- Microbiology Lab: Junior Executive - 1 (Ms. Jeevitha); Lab Technician - 3
  (Ms. Sumitra, Mr. Karthikeyan, Ms. Saranya)

(iv) Document control: Version numbers of documents revised in 2021 (Jan - Dec’21):

**Quality System:**
- Referral Lab Performance Evaluation Form: SNSC/RLPE/2021/Ver-1.0
- Critical Alert Value Document: SNSC/CRI-ALD/2021/Ver-1.2 (25.06.2021)
- Lab Requisition Form: F/SNSC/ML/LRF-1.23 (25.03.2021 onwards)
- Lab Requisition Form: F/SNSC/ML/LRF-1.24 (02.08.2021 onwards)
- Lab Requisition Form: October 2021 onwards online form
- Annual Audit Plan: SNSC/AAP/2021/Ver-1.1 (14.08.2021 onwards)
- Ocular Pathology - Lab Requisition Form: F/SNSC/OP/RF-Rev.4 (08.10.2021)

**0. Recommendations for improvement, including technical requirements:**
- Communications on submission of details: New joiners in SNSC at Lab with
designation and outline of scope of their to be submitted to the Quality Manager
- Induction Protocol for New Joiners: Documentation of the protocol and
  Implementation is made mandatory in each Lab
- Review of labs involved in MOU and ILQC to have documented evidences on
Complaints/ feedback/ instructions etc (controlled formats to be used).

➢ Staff adequacy / Proficiency: to be ensured and documented. Virtual training program advice.

➢ MIS (Management Information System) presentation done every month as per NABH requirement.

➢ Quality plan 2021 was implemented: Out of 22 proposed points, 14 points were implemented.

➢ Review of Documents, creation of NABL records, formats, Document control. Inter-lab and interactions with others documented, improving Quality indicators and all details submitted during quarterly reporting.

➢ Main Lab: 27.05.21, 02.06.21, 13.08.21: ceiling in main lab had a water seepage and dripping that affected Main lab: coulter room / Cl pathology space / pediatric collection area and Cl biochemistry room; All were rectified by the Maintenance dept. Monitored periodically by maintenance department until permanent solution.

➢ Quality Plan 2022 is proposed.

Additional information: Dr. N. Angayarkanni Ph.D, Head-Biochemistry and Quality manager is the new Director, SNSC clinical laboratory and the Management Representative, MRF from 17th Jan 2022 as appointed by the Management

Dr. N. Angayarkanni, Ph.D 10.02.2022

Director - SNSC Clinical Laboratory
Medical Research Foundation
41, College Road, Chennai – 600 006.
Minutes of the Management Review Meeting of SNSC Clinical Laboratory
performance based on Internal Audit (2021), Jan to Jun 2021: Dated 08.02.2022

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, IT Dept & NABH Co-ordinator

The stipulated agenda points presented by Dr. N. Angavarkanni.

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o) Recommendations for improvement, including technical requirements.

Audit Team Members and Audited labs / Support services:

- Internal audit conducted based on NABL standard ISO 15189:2012 for the following departments:
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Clinical Haematology & Clinical Pathology : Dr. A.V. Kavitha
Clinical and Special Biochemistry : Ms. K. Vanitha
MR and QM (Quality System) : Dr. R. Harini
Clinical Microbiology and Serology : R. Rajalakshmi
Histopathology and Cytopathology : Ms. R. Punitham
Commercial : Ms. V. Gayathri & Dr. Harini
HRD : Dr. A.R. Anand
IT : Ms. T.S. Saumya
Biomedical Dept : Dr. S. Sripriya
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Non-NABL
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- Referral Lab Performance Evaluation Form - Newly introduced format for outsourced tests done at Metropolis
- Critical Alert Value Document - New version updated (Medical intervention/follow up stated explicitly)
Clinical Biochemistry:
- Test Report format was improvised in terms of uniformity in test name/code, test sequence in panel, method tallying with scope since February 2021.

Microbiology:
- Brucella Agglutination Test removed.

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: Internal Customer Feedback analysis schedule changed.
  Decided to do once in a year. w.e.f. 27.08.2020, Next scheduled on December’2021

- External customer feedback:
  - SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry:
    (Jan - Jun’21) - 94% (Objective - 80%)
  - SNSC Collection Centre - Pycrofts Road:
    (Jan - Jun’21) - 91% (Objective - 80%)

c. Staff suggestions: (Jan - Jun’21) - 1
Leakage of Vitreous fluid from the syringe, suggested to use tight fitting cork instead of cotton plug. Approved and implemented by Dr.Anand on 06.05.2021

d. Internal audits:
- Internal Audit (2021) conducted by Internal Assessors based on New Standard ISO 15189:2012: all the NCs are closed. (Minor NC - 29, Major NC - 19)

e. Risk management: (Based on CAPA) : Pre analytical & Post analytical.
- Clinical Hematology:
  Pre-Examination error:
  - Mantoux (Eales work up package) missed to give for the 2 patients
Post Examination error:
- Mantoux reading - wrong entry in HMS
- High ESR value released without remarks
- Incomplete urine LFT report updated and verified
- APTT control value was updated wrongly

**Clinical Biochemistry:**
Post Examination error:
- Inaccurate data entry in reporting
- Incomplete LFT report verified
- Data entry in report missed & Verification inappropriate
- Sodium value discrepancy in hemolysed / normal sample

Risks identified for scoring and action:
1. Follow up of patients reporting for Mantoux in Main Lab collection
2. Data entry and verification in HMS

Scoring and follow up to monitor the score shall be done for one year for the 2 risks identified

**f. Quality Indicators:**
- **Pre Examination**: Sample collection, Transport time, Repeat & Rework: All are within the objectives (Jan - Jun’21)

- **Examination**: (Internal & External QC, Equipment down time, calibration plans) All are within the objective from (Jan - Jun’21) except few parameters: Clinical Haematology – EQAS & IQC, Clinical Biochemistry – EQAS, IQC & Equipment Down Time: CAPAs are documented as warranted
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Feedback forms (External) has been reviewed for the last 6 months from (Jan - Jun’21), dept wise. Corrective actions were taken wherever applicable.
g. Reviews by external organizations:

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- Biomedical Department: Renewal of Calibration Certificate done From Jan – Dec’20
  - Digital Thermometer with Sensor 07.01.2021 – 06.01.2022
  - Digital Tachometer – 06.10.2020 – 05.10.2021
  - Digital stopwatch - 04.01.2021 – 03.01.2022

- Maintenance Department: Renewal of Calibration Certificate done From Jan – Dec’21

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

- This has been reviewed for the four quarters in the last 6 months, From Jan - Jun’21
  Department wise : Satisfactory Results.
i. Monitoring and resolution of complaints:
- Based on Internal & External feedback forms (Jan - Jun’21) actions were taken and the issues settled as detailed below
  - Patient Complaint at Main Lab (Feed Back Form) Provide water outside. There is no water available till 11.30am. (dt: 19.03.2021)
    - Action taken: Informed House keeping in charge to do the necessary action. The water is now available from morning 8.00am onwards.

j. Performance of suppliers:
- Vendor evaluation completed for the period of (Jan - Jun’21) is given by commercial dept
- Vendor Complaint for the period of (Jan - Jun’21): Nil

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 – Jun’21)

Quality System:
- Referral Lab Performance Evaluation form implemented from 04.02.2021 onwards
- Critical Alert form was updated with new version no. with effect from 25.06.2021
- SNSC Staff members vaccinated for COVID-19 and the COVID protocols were followed in the Lab.
- SN - RA Puram branch was inaugurated on 12.07.2021. SNSC Collection Centre - RA Puram branch started functioning from 15.07.2021 onwards.
- Dr.AK, Dr.KK, Dr.DG, Dr.Harini, Dr.Anand, were appointed as Board of Studies Member for Laboratory Tech Sciences Program at TSNA from 01.07.2021 - 30.06.2023
**Haematology:**
- Routine + CBC Reports: TAT reduced to 2 hours from 2 ½ hours
- Enrolled BIORAD EQAS Urinalysis Programme for IRIS IRISCELL Mar’21
- DXH 560 AL Haematology Analyzer (Upgrading Act 5 diff AL by Beckman Coulter Pvt Ltd) installed on 7/7/21
- Single use Plastic Pasteur pipette introduced in clinical pathology dept for transferring the sample to the secondary tube from 5/7/21 onwards

**Biochemistry:**

**Pre examination process**
- Volume Analysis - For pediatric package test blood collection-sample volume reduced by regular risk assessment process.
- CRVO package created: LRF 1.24 includes the tests urea, creatinine lipid profile, HbA1c and Homocysteine
- Prevention of Vacutainer wastage done before expiry by regular risk assessment process.

**Examination process:**
- Up gradation: Glucometer
  (i). The Grading system of glucometer calibration upgraded according to the 2013 new accuracy standards (ISO 15197:2013) from April 2021 and OneTouch select simple glucometer replaced by one touch select plus glucometer for monitoring capillary blood glucose (CBG). Totally 56 glucometers evaluated and put to use based on successful fulfillment of criteria for method verification according to ISO 15197:2013.

**Post Examination Process:**
- Critical alert reporting protocol of capillary blood glucose (CBG) for collection centers has been revised and implemented from March 2021 for effective communication of alert and better patient management, as in Hypoglycemia. Critical alert values communication form is amended SNSC/CRI–ALD/2021/Ver-1.2 that documents medical intervention and follow up implemented from June 2021.(F/SNSC/CB/CAVCF)
- Selection option of sample specimen of Sample: Serum/Plasma for LFT in HMS has been implemented from MARCH 2021.
Personnel:
➢ Induction Training updated protocol for new joiners has been implemented from December 2020 and record maintained R/SNSC/CB/LP& ITR.

Microbiology:
➢ With inputs from the uvea department on the lack of significance of Brucella agglutination tests in our setting in corroboration with our data showing lack of Brucella antibodies in patients for several years, the Brucella agglutination test, that was part of the uveitis workup package has been removed.
➢ Training: Internal Training has been conducted as per Training Plan 2021

External Quality control program:
➢ Scored 100% for Distribution no.121, 221 and 321 VIRO EQAS 2021 conducted by IAMM EQAS,CMC Vellore.
➢ Scored 100% in 106th QC, 94.3% in 107th QC and 98.6% in June 2021 QC package conducted by IAMM EQAS, CMC Vellore.
➢ Scored 100% in Batch 24 and 80% in Batch 25 Mycology EQAS – EQMM, Chandigarh
➢ The parameters were fulfilled for the Detection of Antinuclear antibody (Immunofluoresence technique) and (ELISA method) conducted by EQAS Euroimmun, Germany for the year 2021.
➢ The parameters were fulfilled for the Antibodies to Aquaporin-4 conducted by EQAS Euroimmun, Germany for the year 2021.
➢ The parameters were fulfilled for the Antibodies to pANCA and Antibodies to cANCA conducted by EQAS Euroimmun, Germany for the year 2021

Histopathology:
➢ Started to generate reports with NABL Logo for Ophthalmic specimens received from External patients from 18.06.2021

Cytogenetics: (Non NABL)
➢ SOP for Molecular diagnostic tests prepared
➢ Assignment submitted on Pre PCR guidelines for Molecular tests and documented
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 Technical Staff members participated in the CME Programmes organized by SN Academy / Other Institutes

n. Changes in the volume and scope of work, personnel, and premises that affect QMS:
No major changes in volume and personal adequacy

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

NABL Extended Scope of Accreditation Validity period: 17.10.2021 to 16.10.2022
(ONE YEAR) Subject to submit the desktop documents before validity period

(ii) Staff adequacy: It was declared to be Adequate by all the Heads of the lab.
Resignations: Nil
Appointments: Refilling of the post:
- Microbiology Lab: Junior Executive - Lab Technician - 2
  (Ms.Sumitra, Mr. Karthikeyan)

(iii) Document control: Version numbers of documents revised in 2020 (Jan - Dec’21):
Quality System:
- Referral Lab Performance Evaluation Form: SNSC/RLPE/2021/Ver-1.0
  (New Format)
- Critical Alert Value Document: SNSC/CRI-ALD/2021/Ver-1.1
  (25.02.2021 onwards)
- Critical Alert Value Document: SNSC/CRI-ALD/2021/Ver-1.2
  (25.06.2021 onwards)

- Lab Requisition Form: F/SNSC/ML/LRF-1.23 (25.03.2021 onwards)

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

- Communications on submission of details: New joiners in SNSC Cl. Lab with designation and outline of scope of their to be submitted to the Quality Manager.

- Induction Protocol for New Joiners: Documentation of the protocol and Implementation is made mandatory in each Lab.

- Review of labs involved in MOU and ILQC to have documented evidences on Complaints/ feedback/ instructions etc (controlled formats to be used).

- Staff adequacy / Proficiency: to be ensured and documented. Virtual training program advice.

- MIS (Management Information System) presentation done every month as per NABH requirement.

- Review of Documents, creation of NABL records, formats, Document control. Inter-lab and interactions with others documented, improving Quality indicators and all details submitted during quarterly reporting.

**Additional Information:** Dr. N. Angayarkanni Ph.D, Head-Biochemistry and Quality Manager is the new Director, SNSC Clinical laboratory and the Management Representative, MRF from 17th Jan 2022 as appointed by the Management.

Dr. N. Angayarkanni

Director - SNSC Clinical Laboratory
Medical Research Foundation
41, College Road, Chennai – 600 006.

10.02.2022