

	SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY (UNIT OF MEDICAL RESEARCH FOUNDATION)	Minutes of the MRM Review Meeting - 27
	ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -27	


Minutes of the Management Review Meeting of SNSC Clinical Laboratory
performance based on Internal Audit (2020), Jan to Dec 2020 : Dated 27.01.2021

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, Commercial, IT Dept & NABH Co-ordinator

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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Audit Team Members and Audited labs / Support services:



- Internal audit conducted based on NABL standard ISO 15189 : 2012 for the following departments:
 - Lab Enquiry, Blood Collection area, & Reporting : Dr.S.R.Bharathi Devi & Ms.K.Vanitha
 - Clinical Haematology & Clinical Pathology : Dr.S.R.Bharathi Devi & Ms.K.Vanitha
 - Clinical and Special Biochemistry : Dr.S.Sripriya
 - Quality System : Ms.Rajalakshmi
 - Clinical Microbiology and Serology : Ms.R.Punitham
 - Histopathology and Cytopathology : Ms.Saumya.T.S
 - Commercial / Biomedical Dept : Dr.Anand AR
 - HRD/IT : Dr.R.Harini
 - CSFU : Ms.U.Jayanthi
 - SNSC Collection Centre-Pycrofts Road : Ms.R.Gayathri


Non-NABL

- SNSC Collection Centre-NSN (Non NABL) : Ms.R.Gayathri
- Genetics (Non NABL) : Dr.A.V.Kavitha

Internal audit conducted by Internal Assessors based on New Standard

ISO 15189:2012: all the NCs are closed. (Minor NC - 18, Major NC - 12)

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

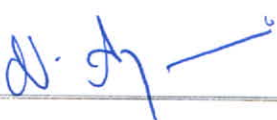

- This has been reviewed for the four quarters in the last 12 months, dept wise. Corrective Actions were taken wherever applicable.

Quality System:

- New option for Lab Report tracking in HMS- colour coded. This is enabled under the Lab reports Menu. From 26.09.2020. Main lab finds it very useful to track report status after registration. Microbiology has the system already in place.
- MOU with Apollo Hospitals for Examination as Referral Laboratory (for service during holidays when Lister lab service is not available as in Sunday afternoon) expired on 18.09.2020. However the system shall continue and is now made as SOP in the quality system and shall be implemented by the main lab.
- Internal Customer Feedback forms frequency: has been changed as once in a year since 2020
- SOPs were made for the staff during COVID-19 pandemic and implemented in respective depts. Of the lab
- SOP for emergency operation of the lab was submitted as per the management request

Clinical Hematology & Clinical Pathology:

- Reticulocyte counts was reported for patient care directly from DxH 800, from 01.02.2020 onwards
- Fully automated Urine Analyzer (Beckman Coulter) received on 12/02/2020 an Installation done.
- Declaration, EQAS & IQC details for "DIESSE VESCUBE-30 TOUCH" (ESR Analyzer) was updated NABL site on 30.01.2020 and the same was accepted by NABL

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Clinical Biochemistry :

- Hb Variants study: New test has been reported for patients sample from May 2020 using HbA1c analyser (D10). The test code is included in Eales workup and separate test code is created L-155.
- Biological reference interval are being reported for Indirect Bilirubin, Globulin & A/G ratio from June 2020.
- Lean Six Sigma was explored for IQC in Clinical Biochemistry since July 2020 and will be implemented after review of 6 months data.

Microbiology & Serology :

- Mispa i2 purchased as a replacement for out dated Mispa 1, (semi automated protein analyzer) installation and training completed by application specialist on 19th February 2020

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

- Histopathology & Cytopathology: (Jan - Dec'20) - **94.2%**, (Objective - 81%)
- Microbiology & Serology: (Jan - Dec'20) - **86%**, (Objective - 80%)
- Main lab (Hematology, Cl.Pathology and Cl.Biochemistry and SNSC Collection Centre -Pycrofts Road) : (Jan - Dec'20) - **88%**, (Objective - 80%)

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External customer feedback:

- SN Main lab: Collection, Cl.Haematology, Cl.Pathology, Cl.Biochemistry:
(Jan - Jun'20) - **94%**, (Jul - Dec'20) – **93%** (Objective - 85%)
- SNSC Collection Centre - Pycrofts Road:
(Jan - Jun'20) - **90%**, (Jul - Dec'20) – **92%** (Objective - 85%)

c. Staff suggestions: Nil (Jan - Dec'20).

d. Internal audits:

- Internal Audit (2020) conducted by Internal Assessors based on New Standard ISO 15189:2012: all the NCs are closed. (Minor NC - 18, Major NC - 12)

e. Risk management : (Based on CAPA) : Pre analytical & Post analytical the following risk were identified.

- Clinical Hematology:-

Pre-analytical error:

- Sample Collection missed
- Sample transport delay
- Improper patient identification

Post analytical error:

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

- Clinical Biochemistry:-

Post analytical error:

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

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- Microbiology :

Post analytical error:

- Inaccurate data entry in reporting
- Sample missed

- Histopathology :

Post analytical error:

- Paraffin Block discarded

Corrective and Preventive actions (CAPA) were taken for all the above and followed .

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'20). However, CAPAs documented wherever warranted.
- Analytical : (Internal & External QC, Equipment down time, calibration plans) All are within the objective from (Jan - Dec'20) except few parameters in each lab: CAPAs are documented .
- Post Analytical : (Turnaround time, Amendment test reports) All are within the objective From (Jan - Dec'20) except: Sp Biochemistry - Turnaround time exceeded by few hours. CAPA filed and it is mostly due to limited staff during COID 19 pandemic.
& Histopathology: CAPA documented
- Feedback forms (Internal & External) has been reviewed for the last 12 months from (Jan - Dec'20), dept wise. Actions were taken to either settle the issues or being followed up as stated in the section below : i. **Monitoring and resolution of complaints:**.

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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 Collection Centre - Pycrofts Road, Chennai. (filed)
- Absolute Alcohol Renewal of license done on April'20. Valid up to Mar-2021.
- Biomedical Department : Renewal of Calibration Certificate done From Jan – Dec'20
 - Digital Thermometer with Sensor 07.01.2021 – 06.01.2022
 - Digital Multimeter – 20.10.2020 – 20.10.2021
 - Digital Tachometer – 06.10.2020 – 05.10.2021
 - Weight box – 25.12.2020 – 25.12.2021
 - Digital stopwatch - 04.01.2021 – 03.01.2022
 - BP Apparatus - 30.12.2020 – 30.12.2021
 - Glass Thermometer - 23.12.2020 – 23.12.2021
- Maintenance Department : Renewal of Calibration Certificate done From Jan – Dec'20
 - Temperature Indicator with Sensor – 16.10.2020 – 16.10.2021
 - Hygrometer – 11.12.2020 – 11.12.2021

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'20
Department wise: Most are Satisfactory Results or the CAPA is documented as required for the random errors.

i. Monitoring and resolution of complaints:

Based on Internal & External feedback forms (Jan - Dec'20) actions were taken and the issues are either Settled or under follow-up as detailed below

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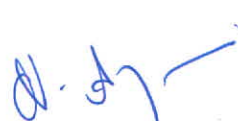

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- I. *Display of the sticker in the toilet area door " DO NOT SPILL WATER " outside toilet area, (Main Lab) was done as per request by patient*
- II. *Waiting time is more at Physician counter (9.30 am – 12.45 pm). Date:23.09.20. Action taken: was looked into and found that Urine report was delayed due to Equipment Calibration issues. Reply sent Quality management team of NABH Department by mail 1st Oct 2020.*
- III. *Scope for Overall Improvement. Action taken: QM has sent a mail to Dr.GSR and will follow up.*
- IV. *Toxacare Serology test requested by consultant . Action taken: Dr.Anand will be discuss with Uvea dept and decide since request numbers is very low for ELSIA. Under follow-up by Dr.Anand-Microbiology*
- V. *Central retinal vein occlusion severe exudative DR, request for including renal failure parameters by Dr.AV. Action taken: Details on package given by Dr.Doreen Gracias to Dr.Pramod Bhende. (Email dt Nov 30 2020) It is now with Dr.Cheran Rao who will look into it. Under follow-up by Dr.Harini.*
- VI. *Request for including COVID investigations for all surgery (LA/GA) patients. Action taken: Dr. Doreen Gracias sent a mail to the consultant informing that the Covid-19 test is done at Lister lab and in house testing has to be a management decision. Management Decision : Patient has to be sent to Lister Lab as per system in place.*
- VII. *HbA1c & RBC Package requested by consultant : Action taken: Dr.Doreen Gracias sent a mail to Dr.Thirumaran informing the existing test code 303*

j. Performance of suppliers :

- Vendor evaluation completed for the period of (Jan - Dec`20) is given by commercial dept
- Vendor Complaint for the period of (Jan - Dec`20) : Nil
- Warning Mail has been sent to Poor performers (4) as evaluated by the commercial Head

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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. 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'20)

Quality System:

- Directory of Services of SNSC Clinical Laboratory has been updated and uploaded in intranet (Feb 2020).
- External Customer Feed Back Form "Not Applicable" included in the rating grade in Both English & Tamil Version on 16.11.2020
- COVID- 19 safety protocol in lab was made and all the labs ensured the same as documented in respective labs (SOP on risk management during COVID-19)
- Protocol for Lab working during emergency was made in the context of Main Lab and sent to management.
- Biomedical Waste management guidelines was updated as per NABH and discussion with Ms. Punitha (Nursing Head) (14.9.2020)
- A format (controlled document) for performance evaluation of Referral Laboratories was created for Main lab to evaluate the Lister Lab services as referral lab. Other Labs can use the format if required or suitably modify to create new controlled formats through QM.
- MOU with Apollo Hospitals for Examination by Referral Laboratories expired 18.09.2020. SOP in QSP is now modified for testing at Apollo, Greams Rd, whenever Lister service is not available as on Sunday afternoon. Lister Lab services continue as before.

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- Ms Eunes Hana Curline QM-NABH (has been requested to Co-ordinate on insisting the Consultant/ Fellow signature in the test request form for traceability and not the ward sisters or consultant secretaries though they can help consultants /Fellow to tick the tests. Test Requisition form to go online is being followed up by Ms.Eunes.
- As part of Surveillance the Desktop Audit was conducted by NABL in December 2020. Subsequently, NABL recommended Continuation of the Accreditation status of the SNSC clinical Lab on 21.01.2021
- Risk Management protocol were implemented. COVID- 19 safety protocol made and implemented at all labs including main lab that included Collection area, inter departmental transport of sample, usage of mask guideline and BMW handling.
- 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.

Main Lab (Collection, Hematology & cl pathology AND Routine Cl biochemistry

Collection, Hematology and Cl Pathology:

- MOU copy for SNSC Collection centre & SN Main lab for Procurement of Blood / Blood Products at VHS Blood Bank received from NABH Co-ordinator on 09.03.2020
- IRIS IRICELL Fully Automated Urine analyser Installed on 19.02.2020 and scope revision shall be applied for as advised by NABL based on desktop audit.
- Lab Reports tracking system created in HMS on 26.09.2020. Helps in Main lab report status tracking
- LIS Backup system for all the equipment for Haematology and Cl.Pathology in place as on 30.12.2020 through the IT department.

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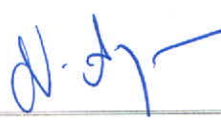

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Biochemistry:

- New test: Code No:155 A2/F – Hb variants is being done and reported for patients. Also Included in Eales workup from May'2020
- Review of Test: (Pre examination process): All log sheets: Temperature, statistics, calibration , QC for HbA1c will be maintained and LJ chart monitoring is now as soft copy alone.
- New equipment and improved method: (Examination process): Evaluation of HIL before testing.
- Review of Test: (Post examination process)
 - Clinically relevant Remarks and suggestions are added as part of the reporting system by the authorizing signatory as warranted.
 - Biological reference value are being reported for indirect bilirubin, globulin and A/G ration from June'2020
 - Blood collection for HbA1c at 7th floor MAHYCO block has been implemented with a TAT of 30 minutes from 21.12.20 to assist the VR consultants in patient care (One month data will be assessed and reported to VR dept to improvise if required)
 - Reporting of estimated average glucose along with HbA1c will be implementation shortly. It has been submitted to IT.
 - Reporting of DBI in LFT package will be introduced shortly. Awaiting interface process completion.
 - Lean Six Sigma has been evaluated for IQC in Clinical Biochemistry from July 2020. Will be monitored and implemented eventually with SOP
- Clinician Interactions: (Inter departmental interactions)

SOP was reviewed and updated for IEM and Paper chromatography for Galactose.

Sample volume has been decreased for the panel of tests requested for paediatric collection (request by Rainbow Hospital Physician).

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- LIS Backup system for all the equipment in Cl Biochemistry is in place as on 30.12.2020 through the IT department.
- Training: (Main Lab)
 - Training schedule has been implemented for the Lab staff until Mar 2020.
 - Internal Training : Laboratory Technical training: 6
HRD- Non technical training: 4
 - Due to Covid-19 in house training classes was not done as per schedule from Mar -Dec.
 - External Training: CME programme attended by Dr. Harini & Technical Manager
Biorad QC webinar, SN academy CME programme, on line
 - Dr. Harini took Webinar cum workshop about Principle and application of dry chemistry system.(30.12.20)

Microbiology:

- New Equipment :
 - Laboratory Refrigerator purchased for the for the purpose of Serology kits storage from CRYO Scientific on March 2020
 - New Equipment for Protein analyzer (RA, CRP) MISPA i2 installed on February 2020 by Agappe.
- External Quality Control Programme :
 - Scored 100% in March and 80% in December 2020 VIRO EQAS Distribution S275 conducted by IAMM EQAS, CMC Vellore.
 - Scored 92.5% in 103rd, 100% in 104th and 99.2% in 105th QC package conducted by IAMM EQAS, CMC Vellore.
 - Scored 95% in 22nd Batch and 80% in 23rd Batch Mycology EQAS Distribution No:45 conducted by PGIMER Chandigarh.

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- The parameters has been fulfilled for the Detection of Antinuclear antibody (Immunofluorescence technique) and Detection of Antinuclear antibody (ELISA method) conducted by EQAS Euroimmun, Germany for the year 2020.
- The parameters have been fulfilled for the Antibodies to Aquaporin-4 conducted by EQAS Euroimmun, Germany for the year 2020.

➤ 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 93% to 94% from Feb'2020


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 98% to 98% in Feb'2020
- 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). Time is reduced from 45 min to 40 min since Feb'2020

Post Analytical:

- Generation of Reports (Second Set), the time is reduced from 4.00 pm to 3.15 pm since Feb'2020
- 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 time is reduced from 60 min to 45 min since Feb'2020

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Histopathology:

- AMC initiated for Yorco Tissue Processor.
- Started to prepare cytopathology smears using charged slides
- Disposal of Biomedical waste guidelines are updated
- Standardized the immune marker Synaptophysin

m. Follow-up actions from previous management reviews :

- SNSC Technical Staff members participated in the CME Programme organized by Mehta Nursing Home (Feb'2020) & Webinar Training Classes
- Carryover of the Quality plan not completed this year to next year is suggested by QM

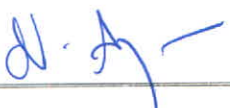

n. Changes in the volume and scope of work, personnel, and premises that affect QMS :

No major changes in volume and personal adequacy. However issues on higher attrition was discussed as raised by Dr.Anand. Accordingly it was proposed by Heads of lab that experienced and specialized Lab technicians have to be given revised designations (Suggestion: senior technician and further grading along with emoluments) that motivates them to continue.

(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

- **NABL Extended Scope of Accreditation Validity period : 17.10.2021 to 16.10.2022 (ONE YEAR) as per communication from NABL**

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(ii) Statistics of all the tests in the lab: 2020. There is nearly 40-50% drop overall

• **Total No. of Investigations Jan – Dec 2020 (Change compared to 2019)**

- Haematology: 77,869 (↓ by 46.5%)
- Clinical Pathology : 18,574 (↓ by 40.9%)
- Clinical Biochemistry : 50,985 (↓ by 50.7%)
- Special Biochemistry : 877 (↓ by 58%)
- Histopathology : 1,351 (↓ by 50.1%)
- Cytopathology : 79 (↓ by 65.2%)
- Microbiology : 8,855 (↓ by 47%)
- Serology : 8,935 (↓ by 48.5%)
- Microbiology Surveillance: 3,335 (↓ by 18.9%)
- SNSC Collection Centre (Pycrofts Garden Road): 3,081 (↓ by 54%)
- SNSC Collection Centre (NSN – Non NABL) : 595 (↓ by 67%)
- SNSC Collection Centre (REH – Non NABL): 1,067 (↓ by 43.5%)
- Cytogenetics (Non NABL) : 189 (↓ by 61.7%)
- Out source : 557 (↓ by 38.6%)

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

Resignations:

- Haematology Lab : Lab Technician - 4 (Ms. Bagyalakshmi, Mr. Rajesh.

Ms.Thilothamma, Mr. Dineshkumar)

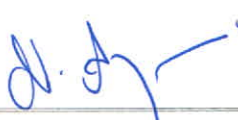

Lab Secretary - 1 (Ms.Anitha Devi)

- Biochemistry Lab : Lab Technician - 2 (Ms. Sakthidevi, Ms. Divyasree)

- Microbiology Lab : Head of the Department - 1 (Dr.K.Lily Therese)

Junior Executive -2 (Ms.Swarnalatha, Ms.Mohana Priya)

Lab Technician -1 (Mr.Thamizhan)

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- Histopathology Lab : Lab Technician -1 (Ms.Bhuvana)
- Cytogenetics (Non NABL) : Junior Executive - 1 (Ms.Karthiyayini)

Appointments: Refilling of the post:

- Haematology Lab: Lab Technician - 2 (Ms. Shobana sree, Ms. Vaisali)
Lab secretary -1 (Ms. Kavitha)
- Biochemistry Lab: Lab Technician - 2 (Ms. Chandrabai, Ms. Kavitha)
- Histopathology Lab: Lab Technician - 1 (Ms.Swetha)
Lab Secretary - 1 (Ms.Kirthika)
- Microbiology Lab: In-charge - 1 (Dr.Anand)
Lab Technician - 1 (Ms.Ms.Divya)
- Cytogenetics (Non NABL) : Junior Executive - 1 (Ms.Kamatchi)

(iv) Document control: Version numbers of documents revised in 2020 (Jan - Dec'20) :

Quality System :

- Lab Requisition Form: F/SNSC/ML/LRF-1.22
- Document Change Request: SNSC/DCR/20/Version-1.2
- Customer Feed Back Forms (External) : SNSC/CFF/MAIN LAB/EX-1.4
(Cl.Haematology, Cl.Pathology & Cl.Biochemistry)
- Customer Feed Back Forms (External) : SNSC/CFF/SNSC CC/EX-1.4
(SNSC Collection Centre – Pycrofts Road)

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

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Quality Manager	Management Representative		



SRI NATHELLA SAMPATHU CHETTY CLINICAL LABORATORY
(UNIT OF MEDICAL RESEARCH FOUNDATION)

ISO 15189 : 2012 - MANAGEMENT REVIEW MEETING -27

Minutes of the
MRM Review
Meeting - 27

- 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/Training : to be ensured and documented. Virtual training program advised. To enhance the training program and include general SOP topics apart from technical.
- MIS (Management Information System) presentation done every month as per NABH requirement needs to be minute on lab related issues by the main lab. The lab meeting will be conducted once month on second Wednesday of every month post lockdown period ie since 11.11.2020
- Quality plan 2020 was Implemented: Out of 27 proposed points, 18 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 should be submitted during quarterly reporting.
- Review of Quality Plan 2020 implementation and proposals for 2021 by all the labs were done.


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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