

**CME ON**

**“NABL – IMPACT ON LABORATORY MEDICINE”**

**Organised by**

**Department of Biochemistry**

**Government Medical College Surat.**

**In Association with AMBI Gujarat Chapter**

**On Dated 27th September 2014, at SURAT**



**CME**  
on  
**“NABL- Impact on Laboratory Medicine”**  
Jointly organized by  
**Biochemistry Department**  
**Govt. Medical College Surat**  
&  
**Association of Medical Biochemists of India (Gujarat Chapter)**  
On  
**27/09/2014**  
Venue: Auditorium  
**Mahavir Cardiac Hospital**  
**Opp. Vanita Vishram Ground**  
**Surat**

**Chairperson**

Dr. R. Dixit  
Dean  
GMC Surat

**Co-Chairperson**

Dr. M. K. Vadel  
Medical Superintendent  
NCH, Surat

**Organizing secretary**

Dr. Shailesh M. Patel  
Professor & Head  
Department of Biochemistry  
GMC, Surat



## Oral Presentation

Sr. No.	NAME	TOPIC	Page No
1	Dr. Deepak Parchwani <b>[Award Winning]</b>	Analysis of an I/D polymorphism in ACE gene and the risk of diabetic nephropathy in type 1 diabetes mellitus patients.	
2	Dr Manisha Kapadia	Ambiguity in iso 15189:2012	
3	Dr. Sarita Mangukiya	Nonconformity analysis in biochemistry NCHSLS	
4	Dr. Ashish Agrawat	Effect of implementing methodological root cause analysis on EQAS performance	
5	Dr. Herat Soni	Effect of SDS and albumin blank on jaffe's creatinine assay	
6	Dr. Kinjal Patel	Evaluation of the impact of fasting blood glucose, serum total cholesterol and body mass index in the patients of the skin tags and healthy controls.	
7	Dr. Lipi Patel	Performance check of newly installed fully automated biochemistry analyzer in clinical chemistry laboratory of s.s.g.hospital, baroda	
8	Dr Ankit G Patel	Effect of pre-donation motivation sessions on voluntary blood donation experience	
9	Dr. Mittal Panchal	Alpha – 1 antitrypsin in smokers and non smokers patients of chronic obstructive pulmonary disease	
10	Dr.Sagar Gangwani	Study of post-prandial triglyceride levels in patients of type-2 diabetes mellitus	

## Poster Presentation

Sr No	NAME	TOPIC	Page No
1	Dr. Dhara Kanani <b>[Award Winning]</b>	A comparison of egfr based on s-creatinine value estimated with different methods	
2	Dr. Payal Dangar	Effect of Progressive Muscle Relaxation on pulse rate and blood pressure of medical students.	
3	Dr. Pratik Raghavani	To evaluate reliability of Friedwald's formula for LDL- cholesterol estimation	
4	Dr. Vishwal Patel	Effects of TSH level on HbA1C in Nondiabetic Subjects	
5	Dr. Hinal Shah	Antisense technology & its therapeutic potentials	
6	Dr. Vaidehi Patel	To study specimen stability for certain biochemical parameters	
7	Dr. Amit Bhut	Gamna Gandy bodies of spleen :Autopsy finding in four cases of different etiology	
8	Dr. Heta Modi	A case series of liver FNAC under USG guidance	
9	Dr. Juhi Mahadik	A case report of Multiple Myeloma diagnosed on Bone Marrow Examination in an elderly male	
10	Dr. Pragnesh K. Limbachiya	Solid- Pseudopapillary Neoplasm of pancreas: An unusual case	
11	Dr. Himanshu Patel	Evaluation of anti- TPO and TSH in diabetes mellitus.	
12	Dr. Jayna Devalia	Computer related health problems among IT professionals	
13	Dr. Sajid Sayad	Leptin :Diet in obesity control Leptin King Of Hormone	
14	Dr. Payal Gamit	Quality Assurance in Point of care testing (POCT)	
15	Dr. Trupti Patel	Autopsy Case Presentation as Fatal Myocardial Sarcoidosis	
17	Dr. Hardik Mistry	eosinophil count in petrol pump workers in and around the surat city	
18	Dr. Kamal Modi	Laboratory Turnaround time evaluation of OPD Samples	
19	Dr. Shaesta Samol	Liver enzymes- An overview	
20	Dr Khushbu Soni	Number Of Data Points For Calculating SD And Mean:How Much Enough Is Enough???	
21	Dr. Neelam Karbhari	Root cause analysis and Prevention of Needle Stick Injury	
22	Dr Riddhi Patel	Direct LDL and calculated LDL comparision	
23	Dr. Mayur Makadia	Estimation of serum Vitamin D3 level in patients with Subclinical Hypothyroidism.	

## Chief Speaker & Moderator

1. Dr Pramod Ingale  
He is the Professor and Head Of Department Of Biochemistry , Lokmanya Tilak Municipal Medical College, Sion Mumbai . He is also the technical assessor , NABL India. He has done many NABL assessments across India.
2. Dr Shailesh Patel  
He is the Professor and Head Of Department Of Biochemistry , Government Medical College Surat. He is also the MCI Inspector and has done many MCI inspection.
3. Dr Puneet Saxena  
He is the Associate Professor in Department Of Biochemistry , Government Medical College Surat . He is member of Medical Education Unit of the college and deputy quality manager, NCHSLS surat.
4. Dr S.S. Ghosh  
He is the Ex-Professor in Department Of Biochemistry , Government Medical College Baroda.He is the president of AMBI- Gujarat Chapter.
5. Dr Shilpa Jain  
She is the Professor and Head Of Department Of Biochemistry , Government Medical College Baroda. She is the jt.secretary of AMBI- Gujarat Chapter.

## CME Schedule

	27th September 2014	Time	Speaker
	Registration, Tea, Breakfast	8.30AM – 9.30AM	
	Inauguration	9.30AM -10:30AM	
<b>Session I</b>	NABL Accreditation Process – An overview	10:30 AM-12.00AM	<b>Dr Pramod Ingle</b>
<b>Session II</b>	Changes in post graduate syllabus, training, evaluation, scope and opportunity – an NABL perspective	12.00AM-01PM	<b>Dr Puneet Saxena</b>
	LUNCH	01PM-02PM	
<b>Session III</b>	NABL accreditation – role of open source software technologies	02PM-03PM	<b>Dr Shailesh Patel</b>
<b>Session IV</b>	Poster Presentation/Oral Presentation and TEA	03PM-4.30PM	
<b>Session V</b>	Brain Storming discussion on challenges in NABL accreditation in Government Teaching Hospitals	4.30PM-5.30PM	<b>Dr S.Ghosh, Dr Shilpa Jain &amp; Dr. S. M. Patel</b>
	Valedictory function	5.30PM-6.00PM	
<b>Approved 3 Credit Hours from MCI</b>			

## SPEAKER'S LECTURE

### Postgraduate curricular reforms, scope and opportunity – an NABL perspective

“Curriculum is in the air. No matter what the problem in medical education , curriculum is looked as the solution” Davidoff 1996

#### Objectives

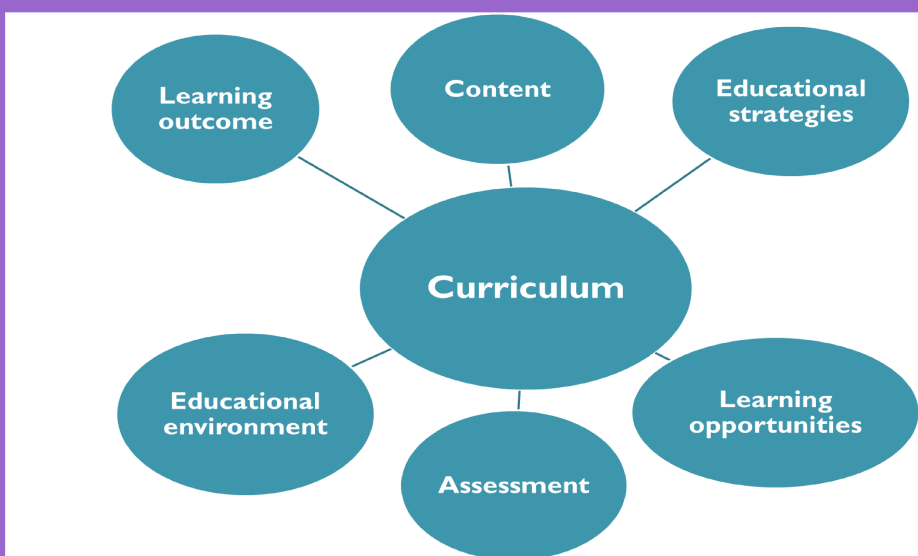
To sensitize :

About need to change post graduate curriculum.

Why and what changes are required ?

How the changes can be done ?

What will be its impact on the quality of laboratory medicine practice ?



#### Curriculum planning

##### Stages of curriculum planning

- Identifying the need
- Establishing learning outcome
- Assessment planning
- Deciding the syllabus
- Deciding the teaching methods
- Preparing the assessment

##### Need assessment

- Decline of small labs.
- Growth of large laboratory conglomerates with centralized testing.
- Advent of managed health care.
- Increasing public expectation.

- Demand of accountability .

### **Learning outcome**

- Competent in:  
Monitoring all work performed in the laboratory to determine that clinically relevant information is being generated.
- Addressing any complaint, request or suggestion from staff and/or users of laboratory services.
- Ensuring that processes needed for the quality management system are established, implemented, and maintained.
- Providing effective leadership of the medical laboratory service.
- Implementing a safe laboratory environment in compliance with good practice and applicable requirements.
- Liaising with clinical and technical staff, and contacting patients.

### **Deciding the syllabus**

- Syllabus should include :  
Accreditation process  
ISO15189  
NABL 112  
Training of internal audit  
CLSI guidelines  
Accreditation process in other countries

### **How to teach**

- Integrated theory lectures e.g.  
Accreditation process an overview  
Managerial requirements of ISO 15189  
Technical requirement of ISO 15189  
Document control in NABL
- Training for internal audit of ISO 15189 is given by Quality council of India  
**[www.stqc.gov.in/](http://www.stqc.gov.in/)**  
**<http://www.bis.org.in/trg/OpenProg.pdf>**  
**St. Johns Medical college Bangalore email : [leadinf@gmail.com](mailto:leadinf@gmail.com)**





Working in NABL accredited lab (posting in other colleges etc.)

- In house training
- Dissertations based on NABL
  - Establishment of laboratory critical value reporting at clinical biochemistry laboratory of New civil hospital Surat
  - Turnaround time for common clinical chemistry examination and clinicians' perception of its adequacy
  - Development and implementation of autoverification algorithm for observed values of examinations in Clinical Chemistry
  - XML schema for writing IS/ISO 15189 & NABL compliant laboratory makeup language (CLP-ML) for SOPs of clinical laboratory examinations.

#### Topics for seminars

EQAS terminology

Internal QC- CLSI Guidelines

Process of method validation

Post exposure management in needle prick injury.

Policy for the use of NABL logo (NABL-113)

## Standard books

1. Basic Quality Assurance and Quality Control in the Clinical Laboratory  
*Author : A. Wayne Bruce*
2. Total Quality Management in the Clinical Laboratory  
*Author: Dough Hutchinson*
3. Basic Quality Management Systems  
*Author : James Westgard*
4. Laboratory Total Quality Management for Practitioners and Students of Medical Laboratory Science  
*Authors: Erhabor Osaro, Adias Teddy Charles*

## Clinical and laboratory standard institute website

[www.clsi.org/edu](http://www.clsi.org/edu)



## Assessment planning

The knowledge and skills about NABL can be assessed in both theory and practical examination. A full question or part of a question.

### Some sample theory questions

Non-conformance and root cause analysis in clinical biochemistry  
Laboratory reporting in clinical laboratory with reference to ISO 15189

### Some sample theory questions

Root cause analysis of nonconformance as a laboratory quality improvement tool.  
Challenges to NABL accreditation in a large public hospital.

### Some sample theory questions

Difference between ISO 15189:2007 and ISO 15189:2012.  
CLSI specifications for reagent grade water and diagram of a prototype water plant for production of

reagent grade water

### **Some practical exercises**

Perform partial internal audit of your lab for clause 5.5 of ISO15189:20012

Using high and low glucose serum pool verify linearity of glucose reagent used in your laboratory using 11 points dilution scheme described in CLIS document EP-6A

### **Some practical exercises**

Review the examination procedure(SOP) given to you. Identify where does it not follow ISO 15189 guidelines for documentation examination procedures. Print the corrected SOP.

### **Some practical exercises**

Review records of NC given to you and find common causes for non-conformance and its root cause analysis

### **Some practical exercises**

Observe the laboratory waste management activity. Find out where there are deficiencies and prepare a report on corrective actions possible.

### **Opportunities**

With corporatization of health care there is focus on accredited of labs.

There is growing need of Laboratory professionals with NABL experience.

### **Opportunities**

Corporate labs are now employing separate managers for all the sections of labs

Dr. Shanthi Naidu : Care Hyderabad

Dr. Barnali Das :Kokilaben hospital

Dr. Suhasini D : Apollo hospital Hyderabad

### **Summary**

Accreditation is here to stay.

Growing need of laboratory experts in corporate sector

Knowledge of NABL will add another feather in one's cap

NABL should be included in postgraduate curriculum

## NABL ACCREDITATION PROCESS :AN OVERVIEW



**Dr. Pramod Ingale**

**Professor & Head**

Dept. Of Biochemistry,  
LTM Medical College, Sion, Mumbai-22

**Lab Director**

PreventiNe Life care Laboratories

Navi Mumbai

Technical Assessor

NABL

We all strive hard to maintain highest standards of our laboratory results, within the available resources, in terms of manpower, equipments, reagents etc.

&

We all feel that our lab results are the best.

**In short- We certify our own work.**

### **Types of Certification :**

#### **First party Certification:**

Laboratory belongs to user, who is satisfied.

#### **Second party Certification :**

Laboratory does not belong to user but user using his own means certifies the laboratory.

#### **Third party Certification :**

Certifying/Accreditation body for laboratories, is neither the owner nor the laboratory nor is the user.

### **Accreditation**

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

In India this authoritative body is NABL.

### **National Accreditation Board for testing & Calibration Laboratories ( NABL )**

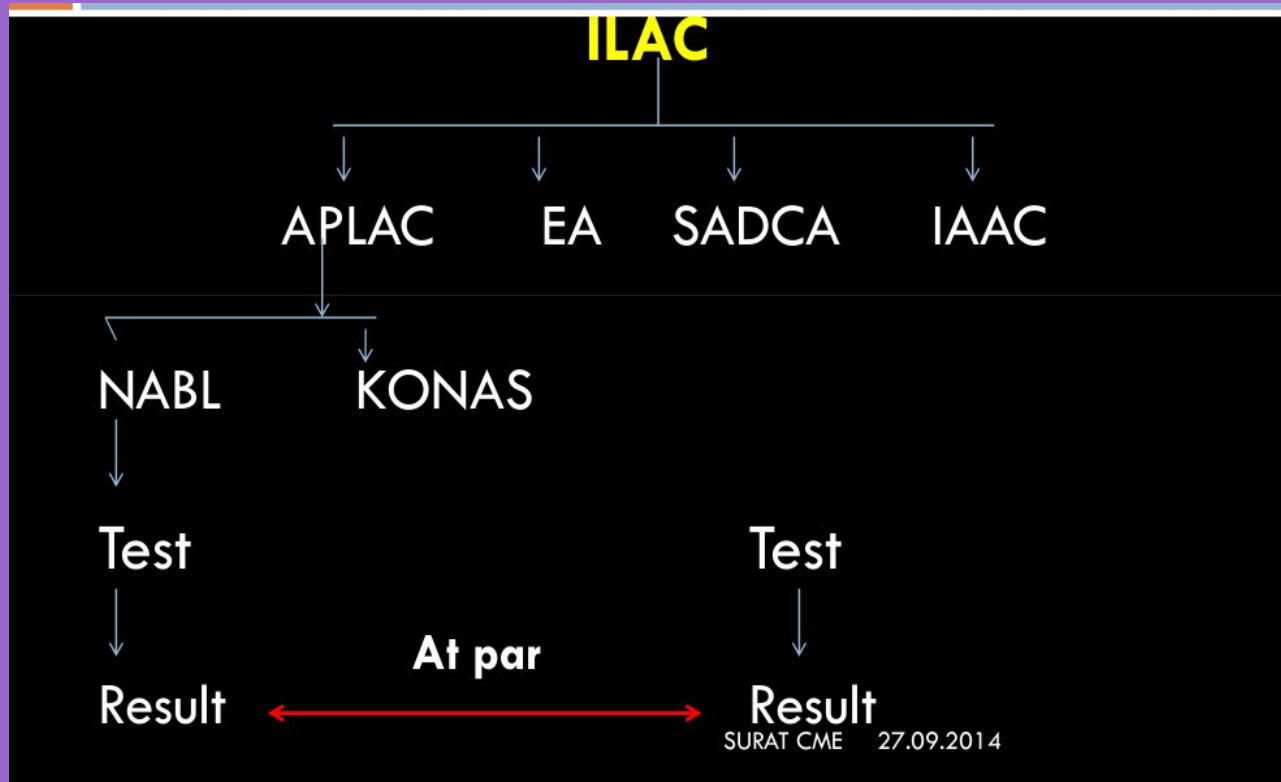
Deals with Testing & calibration Laboratories.

Global Scenario of Accreditation

### Development of Laboratory Accreditation

War time test house scheme	Australia	1943
NATA	Australia	1946
Telarc	New Zealand	1973
STP	Denmark	1973
NVLAP	USA	1976
ILAC – International Conference		1977
A2LA	USA	1978
ISO/IEC Guide 25 - Requirements for Competence		1978
RNE	France	1979
CSCP	Canada	1980
NCTCF	India	1981
NABL	India	1992
NAMAS	UK	1981
HOKLAS	Hong Kong	1985
EA - European Co-operation		1987
APLAC - Asia Pacific Co-operation		1992

## Global perspective



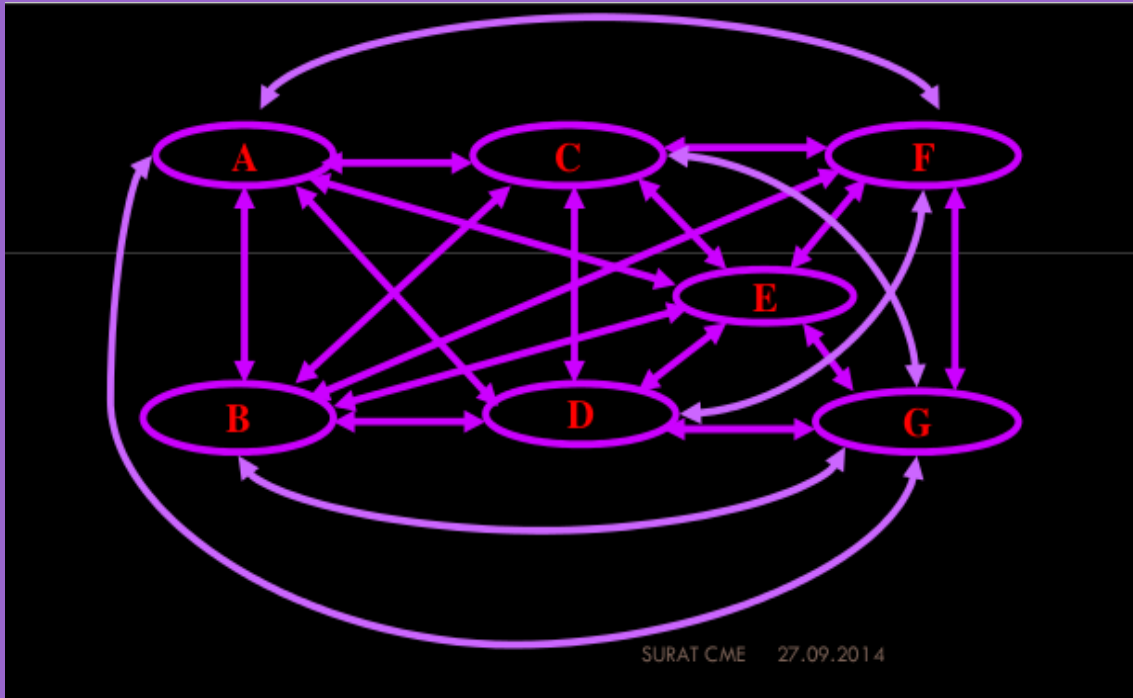
**ILAC:** International Lab. accreditation cooperation, Started in 1977, has 135 accreditation bodies covering 88 different economies. Currently 35,000 accredited labs under ILAC.

**APLAC:** Asia Pacific Lab. Accreditation Cooperation  
To develop the principles and practice of laboratory accreditation  
To harmonize procedures and criteria for accreditation  
To assist in the development of new programmes  
To facilitate mutual recognition of members' programmes  
To reduce technical barriers in trade  
To improve international acceptability of test results

**EA:** European Cooperation for Accreditation.

**IAAC:** Inter-American Accreditation Cooperation.

## Bilateral Mechanism MRA



## A Typical Accreditation Body

Statutory body

May be established by Act of Parliament (NABL has been established by the Cabinet)

User and/or government funded, "not for profit"

General third-party accreditation body

Internationally recognized through MRAs

Functions:

To promote the development and maintenance of good practice in testing and measuring  
Has MRA- Mutual Recognition Agreement, valid for 4 years.

APLAC assesses activities of NABL every 4 years.

2000 & 2004 - Testing & Calibration Laboratories

2008 & 2012 - Testing & Calibration Laboratories & Medical Laboratories.

In India accreditation process started in 1981.

Till date > 461 Medical laboratories accredited .

Functions

Works directly under APLAC

**NABL Accreditates For:**

Testing Laboratories	Calibration Laboratories
Biological Chemical Electrical Electronics Fluid-Flow Mechanical Non-Destructive Testing etc. Clinical Forensic	Electro-Technical Mechanical Radiological Thermal & Optical Fluid-Flow etc

**Benefits of Accreditation**

National & International recognition.

Public & Industry acceptance.

Assurance to clients of GLP.

Provides Global equivalence.

Provides comparability in measurements.

Decision makers can rely on test results.

Improves staff motivation.

Ensures better support in the event of legal challenge.

Saves money by getting it right at first time.

**Accreditation Process**

**Key reference documents**

**ISO15189:2012-** Medical laboratories- Requirements for quality & competence.

**NABL 112-** Specific criteria's for Medical testing laboratories

**NABL 153-** Application form for Medical testing laboratories

**NABL 160-** Guide Preparing a quality manual

**About ISO 15189**

ISO- International Organisation for Standardization

Worldwide federation of ISO Member bodies- ( National standards bodies)

This document is prepared by technical committee formed by representatives of ISO member bodies.ISO collaborates closely with IEC – International Electrotechnical commission on all matters of electrotechnical standardization.

**ISO 15189:2012**



Medical laboratories- Requirements for quality & competence.

2 main clauses

Clause 4.0- Management requirements

Clause 5.0- Technical requirements

#### **Clause 4.0**

**4.1-** Organization & Management Responsibility

**4.2-** Quality Management System

**4.3-** Document Control

**4.4-** Service Agreements

**4.5-** Examination by referral laboratories

**4.6-** External services and supplies

**4.7-** Advisory services

**4.8-** Resolution of Complaints

**4.9-** Identification and Control of Nonconformities

**4.10-** Corrective Action

**4.11-** Preventive Action

**4.12-** Continual improvement

**4.13-** Control Of Records

**4.14-** Evaluation And audits

**4.15-** Management Review

#### **Clause 5.0**

**5.1-** Personnel

**5.2-** Accommodation And Environmental Conditions

**5.3-** Laboratory Equipment, Reagents & Consumables

**5.4-** Pre-Examination Processes

**5.5-** Examination Processes

**5.6-** Ensuring Quality of Examination Results

**5.7-** Post-examination Processes

**5.8-** Reporting of Results

**5.9-** Release Of Reports

**5.10-** Laboratory Information Management

#### **Pre-requisites for Laboratory**

Laboratory or the organisation of which it is part shall be legally registered so that it can be held responsible for the testing and / or calibration activities it carries out.

Laboratory should have adequate facilities and technically competent qualified staff to carry out the testing and / or calibration for which it wish to seek accreditation.

Laboratory must comply with all the requirements as laid down in the Standard ISO 15189, relevant Specific Criteria and other NABL documents.

Ensure all test equipment in the laboratory are properly calibrated and have traceability to National / International standards.

Laboratory must have completed one Internal Audit covering all clauses of ISO 15189 and a Management Review.

Laboratory must have satisfactorily participated in at least one Proficiency Testing Program conducted by NABL or other reputed national or international organizations in accordance with the international standard ISO 17043.

**Documents required:**

Quality Manual  
Quality system documents/procedures  
SOPs  
Records, forms, formats etc.

**Procedure for NABL Accreditation**

**Application for Accreditation**

Laboratory shall apply to NABL in the prescribed Application Form (NABL 153) along with laboratory's Quality Manual in accordance with ISO 15189 and applicable application fees.

**Acknowledgement and Scrutiny of Application**

NABL Secretariat on receipt of laboratory's application after scrutiny for its completeness in all respects will issue an acknowledgement and a unique customer registration number to the laboratory.

**Adequacy of Quality Manual**

NABL will appoint a Lead Assessor to study in detail the information provided by the laboratory in its application and verify the compliance of laboratory's Quality Manual in accordance with ISO 15189 and NABL Specific Criteria.

Lead Assessor Selection is based on:

Technical Expertise  
Availability  
Preferable from Near by Place

**Adequacy of Quality Manual**

Documents Provided to Lead Assessor:

Applications  
Quality Manual

Lead Assessor submits the Adequacy Report to NABL indicating the inadequacies, if any. Laboratory is then required to take necessary corrective action(s) within specified time and submit report to NABL.

**Pre-assessment**

In case no inadequacies are pointed out in the Adequacy Report or after satisfactory corrective action by the laboratory, a Pre-assessment Visit of the laboratory is organized by NABL.

Pre-assessment is conducted by the Lead assessor at the laboratory location.

It is conducted to check the preparedness of the laboratory to undergo Final Assessment. have better understanding of documentation and operations of the laboratory.

familiarize with the facilities, sites/ location, circumstances and to have better knowledge of operations; make the methodology to be adopted for the assessment ascertain number of assessor / man-days required for Final Assessment and to review the Scope of Accreditation.

### **Pre-assessment**

Lead Assessor shall submit the Pre-assessment Report to NABL/laboratory.

Laboratory is then required to take necessary corrective action(s) on the inadequacies as observed during Pre-assessment, if any, within specified time and submit a corrective action report to NABL.

### **Final Assessment**

In case no inadequacies are pointed out in the Pre-assessment Report or after satisfactory corrective action by the laboratory, Final Assessment of the laboratory is organized by NABL.

Final -Assessment is conducted by the Lead Assessor and Technical Assessors to cover the entire scope of accreditation.

### **Final Assessment**

#### **Assessment team reviews:**

Compliance to ISO 15189, relevant NABL Specific Criteria and other NABL policy documents.

Technical Competence of the laboratory to perform specific tests and/or calibrations.

Lead Assessor shall submit the detailed Final Assessment Report along with the recommendations of the Assessment Team to NABL, providing a copy of the assessment summary and the non-conformance(s) raised to the laboratory.

Laboratory is then required to take necessary corrective action(s) on the inadequacies (Non-conformances) as observed during Final Assessment, if any, within specified time and submit a corrective action report to NABL.

### **Scrutiny of report by NABL Secretariat**

After satisfactory corrective action by the laboratory and closure of non-conformance(s) raised by the assessment team, NABL Secretariat scrutinizes the assessment report and place the report before Accreditation Committee for examination

### **NABL Accreditation Committee**

NABL Accreditation Committee examines the assessment report, corrective actions taken and additional information as sought from the laboratory.

Accreditation Committee shall then give appropriate recommendations for grant of accreditation or otherwise to the Chairman - NABL.

### **Approval of Accreditation from Chairman - NABL**

Approval is sought from Chairman NABL for grant of Accreditation or otherwise based on

## Accreditation Committee's Recommendation

### **Issue of Accreditation Certificate**

On approval from Chairman-NABL for grant of Accreditation, NABL will issue an Accreditation Certificate to a laboratory having unique number for each field of testing or calibration and having specified validity period along with detailed Scope of Accreditation. Accreditation Certificate to a laboratory is initially issued for a period of 2 years.

### **Surveillance**

NABL conducts Annual surveillance of an Accredited Laboratory in its first accreditation cycle, to ensure that the laboratory continues to comply with the requirements of the standard ISO 15189 and NABL.

Surveillance is conducted by an assessment team which submits its detailed report to NABL. Laboratory shall take necessary corrective action(s) on the non-conformances observed, if any, during Surveillance within specified time and submit a corrective action report to NABL.

### **Re-assessment**

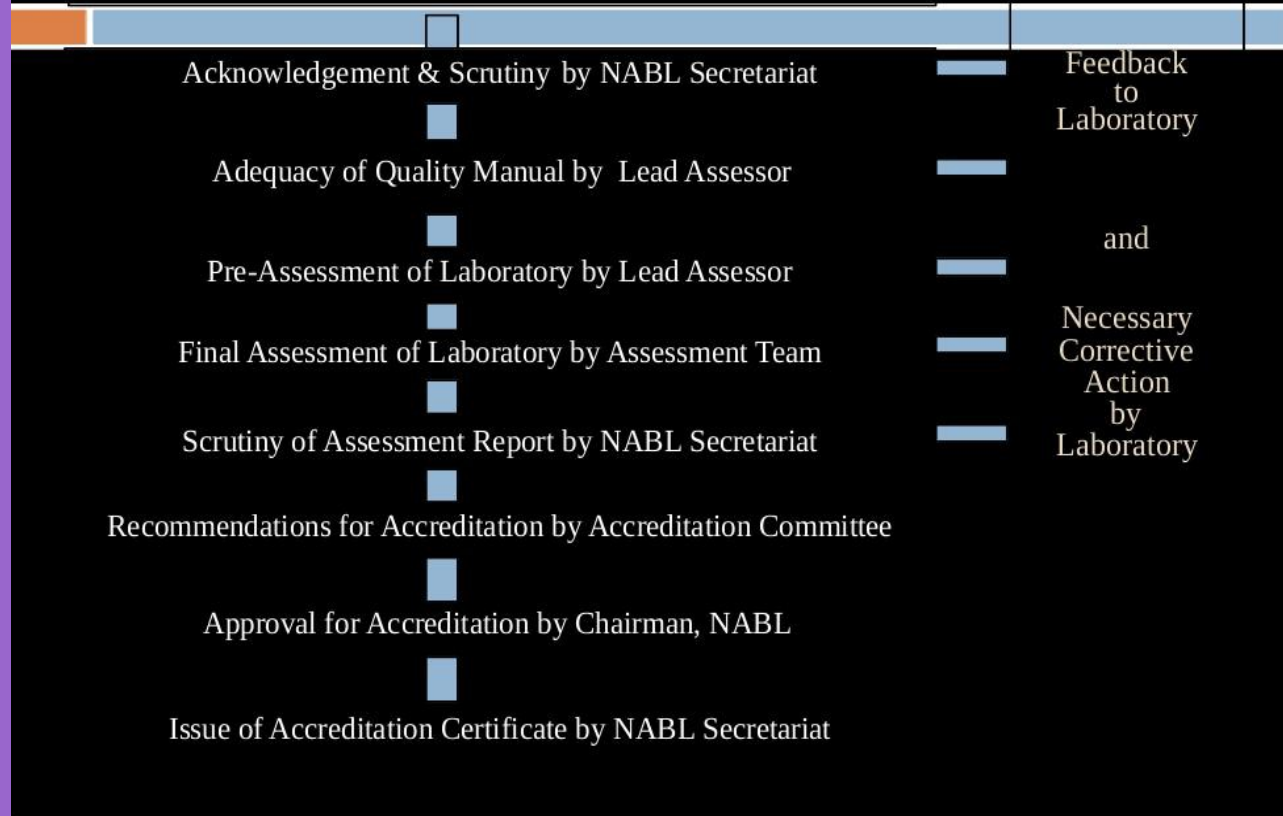
Accredited laboratories shall apply for renewal of accreditation in the prescribed application form, at least 6 months prior to the expiry of validity of its accreditation so that the process of re-assessment is completed before the certificate expires.

The process for Re-assessment is similar to that of the initial assessment.

When the laboratory is recommended for renewal of accreditation, NABL will re-issue the Accreditation Certificate to the laboratory.

# Accreditation Procedure

Application for Accreditation by Laboratory



### Authorised signatories- NABL 112

J	MBBS with three years experience in medical laboratory	Routine Clinical Biochemistry, routine Haematology, routine Microbiology and Serology, and Clinical Pathology.
K	M.Sc. in Medical Biochemistry with 5 years experience or M.Sc. in Biochemistry with 7 years experience in Medical laboratory	Clinical Biochemistry, Clinical Pathology, routine Haematology, routine Microbiology and Serology.

*a recognized medical institution/ university, along with at least 5 years of post-Ph.D. experience in the relevant subject area in a medical diagnostic laboratory.*

### How to become an NABL Assessor

Advertisement for assessors training on NABL website.

Apply with biodata.

Good laboratory experience is required.

If selected, then you have to undergo 5 days residential training followed by examination.

First assignment is an observership, after which you work as technical assessor.

Adequate experience & competence required for appointment as Lead assessor .

With further experience you can become member of Technical or expert committee, who are advisers to NABL.

### For further details

<http://www.nabl-india.org/>



- Home
- About NABL
- Training
- Publications
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- Proficiency Testing
- Log In

About NABL

- ◆ Vision and Mission
- ◆ Introduction
- ◆ Organisational Structure
- ◆ Accreditation Schemes
- ◆ International Recognition
- ◆ Careers
- ◆ List of Contact Personnel

Our Vision

To be the world's leading accreditation body and to enhance stake holder's confidence in its services.

Our Mission

To Strengthen the accreditation system accepted across the globe by providing high quality, value driven services, fostering APLAC/ILAC MRA, empanning competent assessors, creating awareness among the stake holders, initiating new programs supporting activities and pursuing organisational excellence.

About Accreditation

- ◆ Why Laboratory Accreditation ?
- ◆ Benefits of Accreditation
- ◆ Scope of Accreditation
- ◆ FAQ

About NABL



National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act. [Read More...](#)

EVENTS

**Revised Fee Structure of NABL for the Year 2013-2014**

**Info wrt changed version of ISO 15189 for Accreditation of Medical Laboratories**

**Dismissal of Complaint as well as Appeal of ACCAB under the Competition Act**

Secretariat-

NABL House  
Plot No. 45,  
Sector 44,  
Gurgaon - 122002,  
...



Locate us

News & Announcements



# Oral Presentation



## **Analysis of an I/D polymorphism in ACE gene and the risk of diabetic nephropathy in type 1 diabetes mellitus patients.**

### **Name of Authors:**

Deepak Parchwani, Dharmik Patel, Amit Maheshwari, Darshan Patel, Digisha Patel

### **Address of Principal author:**

Dr. Deepak Parchwani, H/No: B-10, G.K. General Hospital, GAIMS, Bhuj

### **Aims:**

To assess the presence of Angiotensin-Converting Enzyme (ACE) gene polymorphism [insertion/deletion (I/D)] in type 1 diabetes mellitus (T1DM) patients with nephropathy and to determine the effects of the three ACE polymorphic variants in intron 16 for a possible role in modulating diabetic nephropathy (DN) in T1DM patients from Kutch region, Gujarat.

**Methodology:** A total of 280 T1DM patients with proliferative diabetic retinopathy were included and were examined using a case control approach. All recruited individuals were carefully phenotyped {using Albumin Excretion Rate (AER)} and genotyping was performed using polymerase chain reaction and alleles were visualized on 1% agarose gels after ethidium bromide staining under UV light as a 190 bp fragment in the absence of an insertion and a 490 bp fragment in the presence of the insertion (genotypes described as II-490 bp, ID-490+190 bp, and DD-190 bp). Of the patients, 138 had nephropathy (AER > 30 mg/day) and were considered as cases; all others (n:142) were normoalbuminuric (AER < 30 mg/day) and were treated as controls. The distribution of alleles in studied groups was tested for fitting to the Hardy-Weinberg equilibrium and to assess the correlation between I/D polymorphism and DN both univariate (chi-squared and t-test) and multivariate (multivariate binary logistic regression with adjusted odds ratios) analyses were applied. P<0.05 was considered statistically significant.

### **Results:**

Genotype frequencies in all groups were in accordance with the Hardy-Weinberg equilibrium. Genotypic distribution was significantly different between cases and controls (p<0.01). Multivariate logistic regression analysis (using age and sex as clinically significant variables and creatinine, HbA1c and systolic/diastolic BP as statistically significant variables) revealed that, D/D variant had an independent and strongest influence on the micro-albumin excretion (p<0.01) and the risk of nephropathy was 2.1 times more in patients homozygous for the allele than that of II genotype. However, it did not independently change the odds of having macroalbuminuria versus microalbuminuria. Analysis of the association under various genetic models revealed that ACE I/D polymorphic variant contribute to DN susceptibility under recessive mode only.

### **Conclusion:**

Genetic variation at the ACE locus as D/D variant in intron 16, contribute to an increased risk of nephropathy in T1DM patients, but not extent of DN severity (as the allelic or genotypic distribution was comparable between the two DN groups). Thus this polymorphism might be considered as a potential genetic susceptibility locus (genetic marker) for susceptibility to DN among patients with type 1 diabetes.

## Ambiguity in ISO 15189:2012

### **Name of Authors :**

Dr. Manisha P. Kapadia (3<sup>rd</sup> year resident Biochemistry), Dr. S.M. Patel (Prof. And head department of biochemistry)

### **Affiliation :**

Department of biochemistry, Govt. Medical College, Surat

### **Introduction :**

For NABL accreditation, laboratory must follow ISO 15189 2012 requirements. So, we need to understand each clause so that all requirements are fulfilled. But there are certain clauses which are not clearly explained.

### **Objective and methodology :**

To study ISO 15189 2012 and then make note of points which are difficult to understand

### **Results and Conclusions:**

Following are the points unclear in ISO 15189 2012:

1. Legally responsible: the laboratory needs to be legally identifiable as Described in ISO 15189 2007 , it is now changed to legally responsible in ISO 15189 2012. What is the difference in 2 terms and what is the significance of such change.
2. Quality indicators and Quality objectives : The two terms are very overlapping . Difference is not very well understood.
3. Service agreement : In ISO 15189 2007 , title was "Review of Contract" is changed to "Service agreements". The significance for change of term to agreement is not very understood. Also what kind of agreement we need to do with our users.
4. Risk management : Though literal meaning is clear but what specifically risk management activities means is not well understood.
4. Sample transportation: Is ward sample collection under NABL assessed activity.\
5. Is signature mandatory in report? : Signature importance in report is not mentioned in ISO 15189 2012 .
6. Critical value reporting for OPD samples : How it is useful??

## **Non-conformance Analysis at Biochemistry New Civil Hospital Surat Laboratory Services.**

**Author:**

Dr Sarita Mangukiya(Senior Resident), Dr. S M. Patel (Prof& Head), Biochemistry Department, Government Medical College, Surat.

**Introduction:**

IS/ISO: 15189 & NABL-112 require policy and procedures for Identification, Control, correction, Prevention of Non-Conformance (NCs). A Laboratory must have system to Record & analyze NCs.

**Method & material:**

The clinical biochemistry laboratory of NCHS recorded 517 NCs during period from Aug-2011 to Aug-2014. The Data retrieved from LIS & NCs were analyzed for Various Sources of NCs, Apparent Causes of NCs, NCs related to major Process of ISO 15189,2012.

**Result:**

Analysis of NCs according to Various sources,77.8% NCs are related to Internal Quality control Process. 51% & 26% NCs related to Examination Process & Quality control Process of ISO 15189,2012 respectively. In RCA of NCs, major causes were Quality of equipment & reagent were found defective (30%), improper method selection (23%), staff did not follow procedure even after training (19%).

**Discussion:**

Major NCs were related to Internal Quality Control & examination process. They can be solved by Improvement in quality of analyzer & reagents, written procedure & training, continual monitoring & improvement.

**Conclusion:**

Such study should help in Identification of defects in processes, Prevention of recurring failure, Identification of permanent solutions.

# Effect of implementing methodological root cause analysis on EQAS performance.

## **Name of Authors :**

Dr. Ashishkumar Agravatt, Dr. H.B.Sirajwala, Dr. Shilpa Jain

## **Affiliation :**

Department of biochemistry, Medical College, Baroda, Vadodara

## **Introduction :**

While participating in External Quality Assurance Scheme, we find the the performance of certain parameters is out of acceptable criteria time & again. There is in general ambiguity regarding corrective actions to be taken in such circumstances .There is a need for documented stepwise methodological plan for corrective actions to be taken when any parameter is out of acceptable criteria

## **Objective :**

- To collect proficiency testing data of various analytes tested in our laboratory.
- To perform and document methodological root cause analysis of outliers, take corrective actions and monitor its effectiveness

## **Methodology :**

Clinical Chemistry laboratory of S.S. G. Hospital & Medical College, Baroda participates in EQAS of Randox Laboratories Ltd ( RIQAS ) every month . RIQAS results of various analytes are monitored in term of standard deviation index (SDI) , target score ( TS ) and percentage deviation ( DEV ).Taking into consideration the common causes for variation in results including technical errors,method errors,material errors,clerical errors etc, we devised a checklist for root cause analysis.Root cause analysis of discordant results were performed as per this checklist and corrective actions were taken.

## **Results :**

In present study , we were able to find many variables which caused discordant results but usually remained unnoticed earlier. We found significant improvement in our RIQAS results after implementing documented methodological root cause analysis of outliers.

## **Conclusion :**

Participation in EQAS helps a laboratory in quality assurance but many times cause of discordant is not identified and so improvement is not possible. A thorough knowledge of possible causes of discordant results and carrying out methodological root cause analysis with an extensive checklist helps in identifying cause of discordant result and thus take corrective action and thereby improve performance.

## **Effect of SDS and albumin blank on Jaffe's Creatinine Assay.**

### **Name of Authors :**

Dr. Herat D. Soni (3<sup>rd</sup> year resident Biochemistry), Dr. S.M. Patel (Prof. & head, department of biochemistry)

### **Affiliation :**

Department of biochemistry, Govt. Medical College, Surat

### **Introduction :**

On observing EQC results of creatinine for year 2013 , it was found that creatinine results given by our lab are 0.2 to 0.3 mg/ dl higher than the EQC target values. As we know that protein interferes with Creatinine assay, an experiment is conducted in which Sodium Dodecyl Sulphate(SDS) is used in reagent 1 (NaOH) of creatinine and 5% albumin is used as blank

### **Methodology :**

- 2 Reagents are prepared : R1 with 1g/L SDS and R1 without SDS .
- Calibration done of these two reagents with Randox calibrators:  
R1 with SDS and 5% albumin as blank and  
R1 without SDS and DI water as blank.
- Data of calibration sorted and a calibration curve is plotted with absorbance on X axis and creatinine in mg/dl on Y axis
- 360 patients samples were run with both the methods and difference and proportion bias is calculated for the results with both methods .

### **Results and Conclusions:**

1. SDS and Protein Blanking improves linearity of three point creatinine calibration.
2. The pattern of decrease in creatinine values with SDS and protein blanking suggest that serum protein causes systemic bias in creatinine measurement in the range of 0.2 mg/dl.

## **To compare serum total cholesterol and fasting blood glucose levels in the patients with Acrochordon (skin tags) with healthy controls.**

### **Name of authors:**

Dr.Kinjal P. Patel, Dr. Vishwal Patel, Dr.Mayur Makadia, Dr.N Haridas

### **Address of principal authors:**

Pramukhswami Medical College And Sri Krishna Hospital, Karamsad

### **Aims and objectives:**

- To compare serum total cholesterol and fasting blood glucose levels in the patients with Acrochordon (skin tags) with healthy controls.
- To investigate correlation between number of the skin tags and level of serum total cholesterol and blood glucose levels.

### **Methodology:**

The present study is conducted in the department of biochemistry of Pramukhswami Medical College,Karamsad. It is a case control study.

The patients and healthy controls are recruited from the Sri Krishna Hospital, Karamsad.

Patients are subjected to thorough personal history taking including smoking, diabetes, hypertension,and family history of skin tags.

### **Sample collection:**

5 ml.of fasting venous samples are collected from the participants in plain and fluoride tubes.

Method of tests:

- (1) All the tests are performed by fully automated COBAS INTEGRA - 400 plus analyzer.
- (2) Serum total cholesterol:colorimetric assay with CHOD-POD method.
- (3) Plasma glucose:HEXOKINASE method.

### **Results:**

The BMI of the patients ranged from 28 to 35 Kg/m<sup>2</sup> and there was a statistically significant difference between BMI of the patients and controls( $r=0.85, P < 0.05$ ). The number of skin tags ranged from 5 to 20. skin tags were detected on the neck in 75% patients,in axillae in 10% patients,on both neck and axillae in 15% patients.

Skin tags patients showed significantly higher cholesterol and fasting blood glucose compared to controls.

the number of skin tags was positively correlated with plasma fasting blood glucose and cholesterol. ( $r=0.89, r=0.74$ , respectively,  $P\text{-value}<0.05$ )

### **Conclusion:**

- The higher levels of fasting blood glucose and total cholesterol in the skin tags patients may be causative factors for the development of skin tags.
- There are also significant correlations between number of the skin tags with fasting blood glucose and cholesterol.

# Performance check of newly installed fully automated biochemistry analyzer in Clinical Chemistry Laboratory of S.S.G.Hospital, Baroda.

## Authors:

Dr. Lipi Patel, Dr. Shubhra Jandial, Dr. Shilpa Jain

## Affiliation:

Department of biochemistry, Medical College, Baroda.

## Introduction:

As per good laboratory practice, any instrument which is installed in the laboratory must be checked for performance before it is put into routine use for patients' sample testing. Performance qualification of instrument should meet the standards laid by the laboratory. Performance check include within-run and between-run imprecision, inaccuracy, total error, stability check and linearity check. So, after the installation of fully automated biochemistry analyzer cobas c311, its Performance check was done to validate it for use in laboratory.

## Objectives:

To check within-run imprecision, between-run imprecision and linearity.

To calculate the inaccuracy and total error.

To validate the analyzer for testing of patients' samples.

## Material and Method:

Performance check was done for 12 analytes including glucose, urea, creatinine, total bilirubin, direct bilirubin, cholesterol, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatases, total protein, albumin and uric acid. For each parameter, quality control sample was tested 20 times repeatedly and again everyday for 20 days. Serial dilution of high concentration samples or standards was done and tested for linearity check. From these data, we calculated within-run and between-run imprecision, inaccuracy, total error, stability check and linearity check using MS office excel worksheet.

## Result:

The results showed within-run and between-run imprecision, inaccuracy and total error within acceptable limits for all tested analytes. Linearity was also appropriate as per our laboratory SOPs.

## Conclusion:

Tested analyzer was found to have satisfactory accuracy, precision, stability and linearity and thus could be put into routine use in the laboratory

# Effect of Pre-donation motivation sessions on Voluntary Blood Donation Experience.

**Author :**

Dr Ankit G Patel

**Co-Authors :**

Dr. Mustafa Ranapurwala, Dr. Kirti Rathod, Dr. Monica Gupta, Dr. Menka Shah.

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central diagnostic centre(cdl), Pramukh Swami Medical College & Shree Krishna Hospita, gokalnagar, Karamsad-388325, Gujarat

**Introduction:**

Pre donation motivation is effective Tool to Improve Knowledge, Attitude and Behavior Regarding Blood Donation.

**Aim and objectives:**

The aim of this study was to assess the impact of motivation on the blood donation experience of a voluntary blood donor.

**Method and Material:**

All blood donation camps organized by A.D. Gorwala Blood Bank in Anand district in between July 2013- July 2014 were included in our study. From total 88 camps, camps with pre donation motivation were 44 and camps without pre donation motivation were 44.

**Results :**

In the 44 camps with pre donation motivation, we achieved 85% of the total target set in such camps with an average adverse donor reaction rate of 0.97% observed. In the 44 camps without pre donation motivation, 58% of the target was achieved with an average adverse donor reaction rate of 3.14% observed.

**Conclusion:**

Pre donation motivation sessions not only motivate for voluntary donation but also enhance the donor experience by decreasing the adverse donor reactions.



## Alpha – 1 antitrypsin in smokers and non smokers patients of chronic obstructive pulmonary disease

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**Abstract**

**Aim:**

The aim of the present study is to correlate and compare alpha-1 antitrypsin level in smoker and non smoker chronic obstructive pulmonary disease patients. Material and Methods: A comparative study was carried out in 200 subjects, more than 40 years of age and having chronic obstructive pulmonary disease for more than 1 year with history of smoking at least 20 cigarette per day (Group A) and without history of smoking (Group B). Pulmonary function tests were used to diagnose the disease as per the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification. Alpha-1 antitrypsin level was done by turbidimetry method on fully auto analyzer I-Lab 650 (Instrumentation Laboratory USA) at Clinical Biochemistry Section, Laboratory Services Sir Takhtsinhji Hospital, Bhavnagar. Statistical analysis was done by using unpaired t-test and Pearson's correlation coefficient. Results: Results of present study shows that alpha-1 antitrypsin level was decreased in smoker chronic obstructive pulmonary disease patients ( $150.83 \pm 18.853$ ) when compared to non smoker ( $183.97 \pm 29.383$ ). There was statistically significant difference in alpha-1 antitrypsin level between the two groups with 'p' value of  $<0.0001$ . Pearson's correlation test show negative correlation between smoker and non-smoker chronic obstructive pulmonary disease patients. Conclusion: The values of serum alpha-1 antitrypsin level were more significantly decreased in smokers indicating an important role of smoking in pathogenesis of chronic obstructive pulmonary disease. Alpha-1 antitrypsin can act as predictor for future development of chronic obstructive pulmonary disease in smokers and in non smokers.

**Keywords:**

Alpha-1 antitrypsin, Chronic Obstructive Pulmonary Disease (COPD), Forced Expiratory Volume (FEV), Global Initiative for Chronic Obstructive Lung Disease (GOLD)

## Study of post-prandial triglyceride levels in patients of type-2 diabetes mellitus

**Author:**

Gangwani Sagar Jagdish\* , Khubchandani Asha Sailesh\*\* , Parmar Vijaysinh\* , Shah Parin\* \* Residents, Department of Biochemistry, B.J. Medical College, Ahmedabad \*\*Associate Professor, Department of Biochemistry, B.J. Medical College, Ahmedabad

**Aim-** To study the postprandial Triglyceride levels in Patients of Type-2 Diabetes Mellitus.

**Method:-** a cross sectional study(from 1st february'2014 to 31st august'2014) of 40 diagnosed cases of type-2 diabetes mellitus with age more than 30 years is done to measure their serum glucose, triglyceride, total cholesterol and hdl-cholesterol in fasting and postprandial states. The method of estimation used for Serum Glucose is GOD/POD method, for Serum Triglyceride is GPO method, for Serum Total Cholesterol is Cholesterol esterase method and for Serum HDL is Direct method.

**Result:-** the fasting levels of serum triglyceride were in the normal range in all the patients with mean±sd of 93.2±20.3 mg/dl. Post prandial Triglyceride levels were measured at 2 hrs, 4hrs, 6hrs and 8hrs. Post prandial Hypertriglyceridemia was observed in all the patients and the peak was observed at 6hrs postprandially.

**Conclusion:-** there is a significant postprandial hypertriglyceridemia and delay in postprandial triglyceride clearance following a fatty meal in patients with type-2 diabetes mellitus. Persistent postprandial hypertriglyceridemia may result in proatherogenic environment leading to atherosclerosis.

**Keywords:-** type-2 diabetes mellitus, atherosclerosis.

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# Poster Presentation

## A comparison of EGFR based on S. creatinine value estimated with different methods.

### **Author:**

Dr. Dhara Kanani<sup>1</sup>, Dr. Vaidehi Patel<sup>1</sup>, Dr. Amit Trivedi<sup>2</sup>, Dr. Kiran Chauhan<sup>3</sup>Dr. N.Haridas<sup>4</sup>

1. 3rd year resident, biochemistry, psmc, Karamsad.

2. Assistant professor department of biochemistry, psmc, Karamsad.

3. Associate professor, GMERS medical college, Gandhinagar

4. Professor & Head of department of biochemistry, psmc, Karamsad.

### **Introduction**

Chronic kidney disease (CKD) is increasingly recognized as a global public health problem and highest rates of reported incident of end stage kidney diseases (ESRD). It is necessary for early diagnosis of CKD to decrease the risk of ESRD and cardio vascular diseases (CVD).

The accurate estimation of the glomerular filtration rate (GFR) is essential for the evaluation of patients with chronic kidney disease (CKD). The present study is a comparison of 3 methods (Jaffe kinetic method, Jaffe compensated method and enzymatic method) of creatinine estimation to know that which method is better for MDRD (Modification Of Diet in Renal Disease) formula based estimated GFR method.

### **Aim**

Evaluate the degree of variability in the estimated GFR using MDRD equation by different methods of creatinine estimation.

### **Methodology**

In this study 120 Patients with age between 18 to 60 years and total bilirubin >2mg/dl were categorized into 5 stages of CKD. The serum samples from these patients were used to estimate serum creatinine by jaffe kinetic method, jaffe compensated method and enzymatic method to find out the differences among the estimated GFR and their chronic kidney disease stages assignments were also studied.

### **Results**

Here we have taken enzymatic Method of Cobas Integra 400 plus as standard method and by taking eGFR < 60 mL/min/1.73 m<sup>2</sup>, only 27.5 % were found normal and 72.5 % have renal failure with different stages.

However with compensated Jaffe's kinetic on Cobas Integra 400 plus and Jaffe's kinetic on semi-automated methods show 65 % and 49.4 % have kidney failure respectively. That means in the case of patients with high total bilirubin, if eGFR derived from serum creatinine using compensated Jaffe's kinetic method diagnosed 7.0 % false negative with Jaffe's kinetic on semi-automated method diagnosed 20.0 % false negative.

### **Conclusion**

It can be concluded that in patients with high bilirubin level, the CKD status of the patients may be missed out if we use conventional picric acid Jaffe's kinetic method for the estimation of creatinine as high bilirubin level interfere with creatinine estimation and give false negative result by 20%.

If we use compensated picric acid Jaffe's kinetic method for the estimation of creatinine in similar type of patients with high bilirubin the false negative results are only 7%.

From this it can be concluded that to measure eGFR in CKD patients with high bilirubin content the method of creatinine estimation should preferably enzymatic jaffe kinetic method and not other two methods.

# Effect of Progressive Muscle Relaxation on pulse rate and blood pressure of medical students.

## Author :

Dr Payal Dangar\*, Dr Dharitri Parmar\*\*

\*Resident, \*\*Professor and Head, Department of Physiology, Government Medical college, Surat.

## Introduction:

In the present lifestyle, stress and anxiety have become part of everyone's day to day life. Stress experiences often lead to various chronic health conditions like hypertension, coronary heart diseases and psychiatric disorders. Students are more prone to anxiety and often display characteristic symptoms of anxiety. Studies have been done in past to achieve relaxation using various techniques. In this study we have studied effects of progressive muscle relaxation on pulse rate and blood pressure in medical students.

## Aims & objectives:

To study effects of progressive muscle relaxation technique on pulse rate and blood pressure.

## Materials & methods:

30 healthy medical students from govt medical college, surat were taken for the study. They practiced 20 minutes progressive muscle relaxation. Pulse rate and blood pressure were measured immediately before and after relaxation technique. They continue practice of progressive muscle relaxation for 3 weeks. On day 21, again pulse rate and blood pressure was measured immediately before and after relaxation technique.

## Results:

A significant reduction in mean post training pulse rate ( $p < 0.001$ ) and systolic blood pressure ( $p < 0.001$ ) was observed. From the mean values diastolic blood pressure was reduced but statistical analysis reveal no significant reduction ( $p = 0.213$ ) in diastolic blood pressure.

## Conclusion:

We can conclude that progressive muscle relaxation is efficient in reducing pulse rate and blood pressure of medical students.

## To evaluate reliability of Friedwald's formula for LDL- cholesterol estimation.

### Name of Authors:

Dr. Pratik Raghavani, Dr. Hiren Rana, Dr. N.R. Malukar.

### Affiliation:

Dept. Of Biochemistry. Medical College Baroda.

### Aims and Objectives:

1. To estimate serum LDL cholesterol (LDL-c) by Direct Enzymatic colorimetric method.
2. To calculate serum LDL-C by Friedwald's formula.
3. To compare results obtained by direct method and by calculation and to evaluate reliability of formula in different Triglyceride (TG) ranges.

### Methodology:

Study was carried out on 175 samples received in Clinical Chemistry Laboratory for Lipid Profile measurement during the period of January 2014 to April 2014. Samples were divided in 3 groups according to serum TG levels.

Group A: TG < 200 mg/dl (no.=100 )

Group B: TG between 200 to 400 mg/dl (no.= 45)

Group C: TG > 400 mg/dl (no.= 30)

In all the groups LDL-c was measured by direct method and as well as by Friedwald's formula. Mean and SD were calculated and correlation coefficients were found between LDL-c obtained by direct method and by Friedwald's formula in all 3 groups.

### Results:

We found no significant difference in LDL-c levels, obtained by two methods, in Group A ( $p=0.5935$ ,  $SE=5.143$ ), but in Group B and C, there was significant difference ( $p<0.05$ ,  $SE=9.614$  and  $p< 0.001$ ,  $SE=14.34$  respectively). Positive correlations were found between direct and calculated LDL-c values in all the three groups.

### Conclusion:

Friedwald's formula calculation may be reliable for estimation of LDL-c for TG < 200 mg/dl but not for TG > 200mg/dl. If TG is more than 200 mg/dl, direct estimation of LDL-c must be performed as calculated values are lower than measured values.

## Effects of TSH level on HbA1C in Nondiabetic Subjects With Subclinical Hypothyroidism.

Dr. Vishwal Patel, Dr. Mayur Makadia, Dr. Kinjal Patel, Dr. Hitesh Shah, Dr. N Haridas.

### Methodology:

30 cases of Subclinical Hypothyroidism were chosen. Subclinical Hypothyroidism was established on the basis of Serum TSH level.

Inclusion Criteria: Age Group 15-75 years  
Exclusion Criteria: Pediatric age group  
Renal Disorders  
Hepatic Disorders  
Diabetes Mellitus  
Clinically Established Hypothyroidism

Controls: 30 age and sex matched healthy individuals were included in the study.

### Method of Analysis :

3 ml of venous blood sample was drawn for each plain & EDTA vacutue from Cases and Controls. Serum was separated & tested for TSH. TSH was measured by Electrochemiluminescence Immunoassay method on Roche Hitachi Cobas e411 auto analyser. Whole Blood from EDTA vacutue was tested for HbA1C. It was measured by Immunoturbidimetry IFCC Method on Roche Cobas Integra 400 Plus.

The results of cases & controls were compared by Student 't' test. A p value of <0.05 was considered significant and value of <0.01 was considered highly significant.

### Results:

When the Cases and Controls were compared, HbA1C was significantly elevated in non diabetic subclinical hypothyroid patients compared to the controls. The mean of HbA1C in cases was  $6.30 \pm 0.14$  while in Controls it was  $5.41 \pm 0.33$ , p value < 0.01. The mean of TSH in cases was  $6.78 \pm 2.38$  while in Controls it was  $2.21 \pm 1.15$ , p value <0.01.

### Conclusion:

We found that A1C levels were significantly higher in patients of non diabetic subclinical hypothyroidism compared with controls.

# Antisense technology & its therapeutic potentials.

## **Name of Authors:**

Dr. Hinal Shah, Miss Payal Patel, Dr. Shilpa Jain.

## **Affiliation:**

Department of Biochemistry, Medical College, Baroda.

## **Aims:**

- i. To identify various molecules that can silence genes by antisense mechanisms.
- ii. To find the potential areas of therapeutic applications of antisense therapy.

## **Methodology:**

Review of recently published articles in the field of RNA interference, gene silencing & antisense therapy.

Observation:

Antisense technology is being routinely used for laboratory research & has a great potential in therapeutic field.

Types of antisense strategies- antisense oligonucleotides, ribozymes & RNA interference.

- Scope of antisense therapy- viral infections, neurodegenerative diseases, septic shock, macular degeneration and cancer.
- Advantages-
  - Specific silencing of gene with expected biological outcome
  - Endogenous biological pathways, thus allowing for the development of safe and efficacious drugs
  - It is ancient natural, robust pathway of gene silencing.
- Limitations-
  - Minimal stability
  - Problems in delivery to the target
  - Off-targeted effects due to sequence complementarity with other than target mRNA
  - Can trigger immune response
- Current scenario:-

Phase II & III trials have been started for Age-related Macular Degeneration, viral infections like viral hepatitis, Herpes Simplex, HIV, respiratory syncytial virus, cancers, etc.

## **Conclusion:**

Despite its limitations, the clinical development has been initiated & appears promising. Phase II & III clinical trials are going on & soon antisense technologies might be launched for therapeutic use. The ability to use synthetic agents to control gene expression would have a transformative impact on the treatment of many diseases.



## To study specimen stability for certain biochemical parameters

Dr.Vaidehi Patel<sup>1</sup>,Dr.Dhara Kanani<sup>1</sup>,Dr.Amit Trivedi<sup>2</sup>,Dr.Kiran Chauhan<sup>3</sup>,Dr.N.Haridas <sup>4</sup>

1.Third year resident ,biochemistry department ,PSMC ,Karamsad .

2.Assistant professor ,Biochemistry, PSMC, Karamsad .

3.Associate professor,GMERS medical college,Gandhinagar.

4.Head of the department of Biochemistry ,PSMC ,Karamsad.

### **Aim**

A number of factors, primarily preanalytic and analytical or normal biological variations affect the accuracy of test results. Preanalytical factors such sample collection and handling, diet, exercise and drugs can all impact a test result. The aim of this study is to study specimen stability for certain biochemical parameters and to provide the evidence on how the quality of a test parameter varies with time in primary collection (without separation of serum from clot) and secondary collection tube (with separated serum from cell contact) under the influence of storage.

### **Methodology**

Patient's blood were collected in primary collection (without separation of serum from clot) tube and within two hours of collection serum were separated in secondary collection(with separated serum from cell contact) tubes. The primary and secondary tubes were stored at 4 to 8° C. The set of tests were done from primary and secondary collection tubes at 0,24 and 48 hrs.

Following tests were performed. Electrolytes: Sodium, Potassium, Ionized calcium, Chloride; Metabolites: Glucose, Creatinine, Urea, Uric acid, Total Protein, Albumin, Total Bilirubin; Lipids: Total Cholesterol, Triglycerides, HDL-Cholesterol; Enzymes: Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Alkaline Phosphatase (ALP).

Statistically significant changes were determined by two tailed paired sample Student's t test (p = 0.05)All statistical analyses were performed using SPSS for Windows, version 13.0 (SPSS Inc.,Chicago, IL, USA).

### **Results**

All analytes values for primary and secondary tube at 24 and 48 hours are within significant change limit except potassium and ionized calcium. From mean values at different time point shows upward trend in serum Total Cholesterol and Triglyceride and downward trend in HDL-Cholesterol. Positive % bias is maximum in potassium in primary tube after 48 hours . Similar negative % bias is maximum in plasma Glucose in primary tube after 48 hours also . But major difference between this two is due to storage temperature; sample were stored at 2 to 8 ° C so hemolysis increases and glucose utilization decreases because of this maximum decrease in glucose were 4.13 % only. Effect of time of storage of primary and secondary tube on test results revealed significant difference in mean values of all analytes between 0.5 hours and 24 hours as well as 0.5 hours and 48 hours values, with or without serum-clot separation except for urea analyte.

### **Conclusion**

Only a few routine analytes e.g. serum potassium and plasma glucose required stringent control before serum-clot separation.

Most routine tests can tolerate fairly long delays in transportation without changes in analyte content. And when considering analytical variation result can be given as long as 48 hours when stored at 2 to 8 ° C even without serum-clot separation.

## **Gamna Gandy bodies of spleen : Autopsy finding in four cases of different etiology.**

**Name :**

Dr. Amit .R.Bhut (second year resident, Dept. of pathology,GMC, Surat)

Underguidance of : Dr. R. N. Hathila (Additional Professor)

Dr. Hemali Tailor (Assistant prof.)

Dr. Prashant patel ( Assistant prof.)

**Introduction**

Gamna Gandy (G-G) bodies of the spleen which are mainly found in patients with portal hypertension, represent the end result of hemorrhages in the splenic follicles or adjacent trabeculae. It is defined as spheroidal yellow –brown foci consisting of dense fibrous tissue and collagenous fibers encrusted with iron pigments and calcium salts. It was first described in 1921 in association with sickle cell disease and other pathological process such as hemolytic anaemia, congestive splenomegaly, acquired haemosiderosis, hemolytic anemia and paroxysmal nocturnal haematuria etc.

We are presenting four cases of Gamna Gandy bodies of spleen with different etiologies.

**Method:**

Gamna gandy bodies demonstrated by haematoxylin and eosin stain on paraffin embedded block.

**Conclusion:**

Patients with sickle cell anaemia, portal hypertension, undergoing recurrent sequestration crisis develops splenic inclusions known as G-G bodies.

**Keywords:**

Gamna Gandy body, sickle cell anaemia, congestive splenomegaly.

## A case series of liver FNAC under USG guidance.

### Name:

Dr.Heta Modi(second year resident,Dept. of Pathology,G.M.C.Surat)

Under guidance of: Dr. Pinal Shah, Dr.V.M.Bhagat

### Introduction:

- The liver is a common site of hematogenous metastasis from gastrointestinal malignancies as well as extra intestinal cancers. Among primary, Hepatocellular carcinoma (HCC) is the most common.
- The FNAC is an important useful diagnostic tool in combination with USG to make a clear difference between primary and metastatic carcinoma. On the basis of this management of these lesions differ.

### Aims & objectives:

To differentiate between primary and metastatic carcinoma of liver on the basis of cytological features.

### Methods:

Under USG guidance FNAC was performed with the use of 22-23 gauge spinal needle after satisfactory coagulation profile. Material aspirated on FNAC was spread on slides. Slides were stained with Hematoxylin&Eosin, MGG and PAP method after fixation.

### Results:

Age group: 50-70 years

Clinical history: Abdominal lump & heaviness

USG:Space occupying lesion of liver.

### Diagnosis:

50yr/Female	Well differentiated Hepatocellular Carcinoma
52yr/Male	Hepatocellular Carcinoma
60yr/female	Metastatic Adenocarcinoma
50yr/Female	Metastatic Adenocarcinoma
68yr/Male	Metastatic Renal cell Carcinoma
60yr/Female	Metastatic Carcinoma most probably from carcinoma with neuroendocrine differentiation

### Keywords:

FNAC, Hepatocellular Carcinoma. Metastatic carcinoma.

## **A case report of Multiple Myeloma diagnosed on Bone Marrow Examination in an elderly male.**

**Name:**

Dr. Juhi D. Mahadik (2nd year resident, Dept. of Pathology, GMC, Surat)  
Under Guidance of : Dr. Sharmishtha M. Patel (Asst. Professor, Dept. of Pathology)

**Aims and objectives:**

Multiple Myeloma has been recognized since Ancient Times. The first well-documented case was reported in 1844 by Samuel Solly. The most commonly recognized case is that of Thomas Alexander McBean, a highly respectable tradesman from London in 1850. Multiple myeloma is a debilitating malignancy of the elderly that is part of a spectrum of diseases ranging from Monoclonal Gammopathy of Unknown Significance (MGUS) to Plasma Cell Leukemia. It is characterized by a proliferation of malignant plasma cells and a subsequent overabundance of monoclonal paraprotein (M protein). The presentation of Multiple Myeloma can range from asymptomatic to severely symptomatic with anemia, leucopenia, bleeding, infection, renal failure, pathologic fractures, spinal cord compression and secondary amyloidosis as major manifestations. Recognition of this clinical entity by appropriate investigations (including bone marrow examination) is essential to lessen the morbidity resulting from the disease, which as of now, has no cure.

**Methodology:**

Slides prepared from bone marrow aspiration and biopsy, after staining with Giemsa and hematoxylin eosin stains respectively, were examined microscopically for the presence of abnormal plasma cells and immunohistochemistry was performed for confirmation.

**Results:**

Aspiration showed presence of 38% plasma cells (both mature and immature) with biopsy showing focal nodular as well as interstitial infiltrate of mature and immature plasma cells.

**Conclusion:**

Complain of bone pain and weakness in an elderly patient with lytic lesions in axial skeleton and presence of > 30% plasma cells in bone marrow point towards a diagnosis of Multiple Myeloma.

**Keywords:**

plasma cells, monoclonal paraprotein, immunohistochemistry

## Solid – Pseudopapillary Neoplasm of Pancreas : An Unusual Case

### Author:

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### Keywords :

Papillary cystic tumour, pseudo rosette , Vimentin

### Introduction:

solid –pseudopapillary neoplasm of pancreas is an unusual neoplasm which is often included in the “cystic” group of exocrine tumours of the pancreas. It occurs predominantly in adolescent girls and young women with a median age of 26 yrs.

### Case Report:

A female aged 13 yrs presented with painful abdominal mass. Imaging techniques ,CT scan showed 11.4x 9.6x7.4cm in tail area of the pancreas. We received a mass measuring 10x8x7cm, weighing 320 gm, grossly mass was solid and cystic with areas of haemorrhage . Microscopic examination revealed cells arranged in sheets, cords and trabeculae of uniform round cells , cytoplasm was eosinophilic to vacuolated . solid portion was characterised by rich and delicate vascular network . Pseudo rosette and pseudo papillary patterns also seen. Surprisingly invasion is also common in these tumours and we also observed invasion in our case. Immunohistochemistry also was performed on sections , giving positive results for Vimentin and Neuron specific enolase .

**Conclusion:** The treatment is surgical and over all prognosis is excellent . Approximately 15% of reported cases in other studies have resulted in local recurrence and/ or liver metastasis. Therefore this tumour be regarded as carcinoma of low malignant potential and follow up of the patient is advised .

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## Evaluation of anti- TPO and TSH in diabetes mellitus.

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Altered thyroid hormones have been described in patients with Diabetes mellitus especially those with poor glycemic control. Both thyroid disease & diabetes mellitus both are autoimmune disorders. Anti TPO (antibody) supposed to increase in autoimmune disorders. TSH is measured conventionally to evaluate thyroid dysfunction. Considering these facts we want to evaluate subclinical thyroid dysfunction in Diabetes Mellitus by measuring Serum TSH & anti TPO for screening.

To study for this we have measured T.S.H and Anti TPO from 100 confirmed diabetes mellitus patients and 100 non-diabetic controls as well. Both TSH & Anti-TPO were measured by highly sensitive Chemiluminescence Microparticle Immunoassay (CMIA) method in Abbott Architect system. We have observed that serum anti-TPO was positive for 18 cases and was negative for all the controls. Serum TSH was abnormal in 50% of positive Anti-TPO cases.

So we conclude that although serum TSH is more sensitive in detecting thyroid abnormalities in diabetes, the presence of positive serum anti-TPO antibodies may be an earlier marker for thyroid disease. Therefore patient with positive antibodies should be monitored for serum TSH at yearly intervals.

## Computer related health problems among IT professionals

**Author:**

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**Background:**

The world is getting cyber-centric but with technological advancement the medical experts are learning the whole new genre of occupational health issues and here, it is computer related health problems. The problems may seem to be coming slowly, they require attention to prevent unwanted consequences that otherwise could become major problems.

**Objectives:**

- (1) To study the prevalence of computer related health problems (visual and musculoskeletal) among information technology professionals.
- (2) To correlate the problems with time (in hours and in years) that they spent in this organizations.

**Methodology:** The present study was a cross-sectional analysis done among 152 Information Technology Professionals working in Ahmedabad city.

More than half of IT Professionals mentioned to have different kind of computer related health problems. Time spent and years spent in this profession is significantly correlate with various computer related problems among them.

**Conclusion:** The problems of eye and musculoskeletal system were the common health problems of the computer users. Regular exercise, health checks and good ergonomics may contribute to reduced problem and improved productivity of computer users.

**Key words:**

IT Professionals, health problem, vision problem, musculoskeletal problem. Dr Sajid sayad

## Leptin diet in obesity control

### Leptin – king of hormone

**Author:**

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**Objective:**

Understanding the Physiology of Leptin, Role of Leptin in Weight Management and Leptin Diet

**Introduction:**

Secreted from adipocytes as a hormone, leptin sends signal to the brain indicating how much of fat is present in the body, thereby limiting the amount of fat deposition. Absence of Leptin was found in some strain of Obese mouse and when externally injected they became Non-Obese, then on it was considered to be a Major Hormone, playing its role in Body Weight

**Concept:**

leptin is considered to be playing key role in obesity. By understanding Leptin Physiology and proper diet patten according to Leptin levels in blood, its possible to control and maintain the Body Weight.

**Conclusion:**

Leptin is truly considered as a King of hormones or the Commander in Chief of the Body, as it Governs many important Hormones as well as Functions of the Body.



## Quality Assurance in Point of care testing (POCT)

### **Name of Authors:**

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### **Affiliation:**

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### **Introduction:**

Past decade has witnessed an increasing trend of use of Point of care testing (POCT). Although POCT provides rapid test results and the opportunity for faster medical decisions, the unique risk of errors with POCT raises concern over the quality and reliability of test results. To ensure quality results in POCT, there is a need for documented procedures or guidelines, in compliance with evidence based laboratory medicine, governing use of POCT.

### **Aim:**

To find documented procedures or guidelines governing use of POCT for Quality assurance in Point of care testing.

### **Methods:**

We studied various guidelines available in this field including  
American Association for clinical chemistry guidelines: managing risk at the POCT(July 2014)  
The clinical biochemist reviews; volume 31: August 2010  
Biochemia Medica 2010;20(2):200-6.  
Clinical Laboratory Improvement Advisory Committee: summary report of meeting (Feb. 2008)  
Document ISO 22870:2006  
Clinical and Laboratory Standard Institute guidelines  
National Academy of Clinical Biochemistry guidelines

### **Observation:**

POCT use can provide quality results if proper quality assurance is maintained in areas of training, quality control and external quality assurance. Wherever POCT is done, there must be a team of qualified laboratory personnel who prepare documented procedures and guidelines in compliance with evidence based laboratory medicine and ensure proper implementation.

### **Conclusion:**

Quick, reliable, accurate and precise results can be obtained by POCT. It decreases pre analytical and post analytical errors. Although used by personnel near patient, central laboratory should be actively involved in maintaining quality as per standard protocol laid based on Evidence based laboratory medicine.

## Autopsy Case Presentation as Fatal Myocardial Sarcoidosis

### Author:

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### Introduction:

Sarcoidosis is a systemic disease of unknown cause characterized by non-caseating granuloma in many tissues & organs. It can represent many clinical patterns or discovered unexpectedly on routine chest film. Prevalence is higher in women than in male, younger than 40 year of age, but varies widely in different countries & population.

### Case report :

In Autopsy we received a case of 27 year male with history of chest pain, breathlessness & sudden death. Grossly heart weight was 450 gram with cardiomegaly & greyish white area in left ventricular wall. Other organs unremarkable. Microscopically heart shows many non caseating granuloma along with giant cell, presence of chronic inflammatory infiltrate and foci of necrosis of muscle fibers. Lung also shows non-caseating epithelioid cell granuloma with schammann body & asteroid body. Liver shows similar finding. AFB & PAS stain were negative. Our probable diagnosis was sarcoidosis.

Etiology of sarcoidosis remains unknown but evidence suggests its disordered immune regulation in genetically predisposed individual expose to certain environmental agents like rickettsia & mycobacteria.

Other diseases, including mycobacterial or fungal infections & berylliosis also producing non-caseating granuloma so histological diagnosis of sarcoidosis one of exclusion.

### Conclusion :

Sarcoidosis is an incidental finding at autopsy and it is one of the cause of myocarditis which leads to lethal ventricular arrhythmias accounts for most of sudden cardiac death in young individual.

### Keywords:

Sarcoidosis, Granuloma, Asteroid bodies, Schumann bodies

## Effect of different types of music on exercise performance in normal individual

### Author:

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While exercising, people seem to enjoy listening to music believing that it relaxes them or helps give the necessary rhythm for exercise. But is music really beneficial ? In view of different people listening to different types of music, this study was intended to assess effect of different types of music on exercise performance. 30 healthy male college students in the age group of 18 to 25 years were made to walk on the treadmill 3 times at one week interval: without music (A), with slow music (B), with fast music (C). Duration of exercise and rate of perceived exertion were recorded at the end of each session. The results showed an increase in the duration of exercise in Group B and Group C as compared to Group A and the increase was more in Group C as compared to Group B. It was observed that level of RPE was the same at the end of every exercise session. The reason for increase in exercise duration with music could be because of various factors like dissociation, arousal, motivation, etc. It can be thus suggested that exercises can be performed for longer duration with music than without music and the effect is more with fast music than with slow music. Also with music, the same level of exertion is perceived though the walking duration is considerably increased.

## Eosinophil count in petrol pump Workers in and around The surat city

### **Author:**

Dr. Hardik Mistry, 1st year Resident, Department of Physiology, GMC, Surat.

### **Background:**

Benzene exposure is one of the main health concerns for high risk occupations like petrol pump workers. But there is little knowledge about the effect of benzene metabolites on blood parameters.

### **Aims & Objective:**

The objective of this study is to find out the effect of benzene exposure on hematological parameter especially eosinophil count on petrol pumps workers.

### **Materials and Methods:**

Fifty four (54) petrol pump workers between age group of 20-60 years were included in this study and categorized into 04 groups according to duration of exposure. The data collected are represented as mean  $\pm$  SD. These changes were statistically significant ( $<0.05$ ) when we compared eosinophil count in study group and control group, when duration of exposure is less than 10 years.

### **Results:**

When we compared eosinophil count in subjects exposed to more than 15 years the count was significantly ( $<0.05$ ) decreases. The count decreases as the duration of exposure increases.

### **Conclusion:**

Long term exposure to benzene may cause bone marrow suppression leads to decreased eosinophil count.

### **Key Words:**

Eosinophil Count; Benzene; Petrol Pump Workers; Hematotoxicity

## Laboratory Turnaround time evaluation of OPD Samples

### **Name of Authors :**

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### **Introduction :**

Turnaround time (TAT) : reliable indicator of laboratory effectiveness. Aim is to evaluate TAT and appraise the contribution of the different phases of analysis towards the same.

### **Methodology :**

The study was conducted at Clinical biochemistry department of NCHSLS to evaluate the TAT for the OPD samples for 14 days and Blood specimens were collected at a centralized collection center by laboratory personnel.

Following Time period were noted and Average of all time periods and % of Total time vs all segments were calculated:

1. Sample Collection
2. Sample Receiving
3. Centrifugation and Aliquoting
4. Analyzing
5. Report dispatch

### **Conclusion :**

- Generally analytical phase is bestowed with the responsibility of ensuring speedier reporting.
- But the study shows that, pre- and post-analytical phases needs to be streamlined to improve TAT in scenario where the Patients receive the reports as and when they turn up for subsequent health check ups.
- Major time lapses were noted in sample transport time and report dispatch time due to the lack of automated facilities for sample transport and report dispatch.

## Liver enzymes-an over view

Dr.Shaesta samol, 2 nd year resident in department of physiology, GMCS

### Liver Function Test

- A liver function test is actually a series of blood tests designed to measure the levels of various substances in the blood. Together, these tests provide with a helpful overview of how well your liver is working. These tests measure the levels of four key liver enzymes, as well as total protein, cholesterol, bilirubin and albumin. The enzymes measured include aspartate aminotransferase (AST) previously called as SGOT, alanine aminotransferase (ALT) previously called as SGOT, gamma-glutamyl transferase (GGT) and alkaline phosphatase (ALP). Elevated liver enzymes usually indicate an injury or inflammation of the liver. However, the range of causes of an abnormally high level of liver enzymes is extremely wide, and such a result from a liver function test is not necessarily indicative of serious illness.

### Function of Liver Enzymes

- AST and ALT are enzymes produced in the liver to assist in the production of proteins and the metabolism of amino acids. When the liver is damaged or inflamed, these enzymes leak into the bloodstream. GGT and ALP are known as cholestatic enzymes, and elevated levels of these enzymes usually indicate a problem with the bile ducts that transport bile from the liver to the gall bladder and the intestines. The term "cholestasis" is used to describe a partial or full blockage of the bile ducts,

### Elevated AST & ALT

- Elevated levels of AST and ALT can signal a variety of conditions, ranging from inflammation caused by certain drugs and herbs to cirrhosis or liver cancer. Other causes include obesity; nonalcoholic fatty liver disease; hepatitis; chronic alcohol abuse; reactions to over-the counter (OTC) pain medications, such as acetaminophen; celiac disease; cytomegalovirus infection; dermatomyositis; Wilson's disease; hemochromatosis; and mononucleosis. Normal readings for AST range from 0 to 40 IU/L (international units per liter), while normal ALT levels run from 0 to 45 IU/L.

### Elevated GGT & ALP

- High levels of GGT and ALP may be signs of diverse conditions, such as bile duct blockage, gallstones, alcoholic liver disease, nonalcoholic fatty liver disease, primary sclerosing cholangitis, liver tumors, drug-induced liver disease and primary biliary cirrhosis. Normal levels of GGT range from 3 to 60 IU/L, while normal ALP readings usually fall somewhere between 35 and 115 IU/L.

## Number Of Data Points For Calculating SD And Mean: How Much Enough Is Enough???

### **Authors:**

Dr. Khushbu S. Soni (2nd Year Resident Biochemistry), Dr.Rohan Rana (1st Year Resident Biochemistry), Dr.S.M.Patel ( Prof. & Head of Department Of Biochemistry),Dr.Manisha Baraiya(Assi.prof.),Govt.Medical College,Surat.

### **Aims:**

Measurement of SD of rejection rate with different set of 20 datapoints of QC data.

### **Methods:**

Collect 220 data points for Normal and Abnormal QC sera for Urea,Calculate Mean and SD for each consecutive 20 data points (11 sets),For each set of Mean and SD measure 2(2S) and 1(3S) rejection rate for all 220 data points,Measure CV% of variation in rejection rate.

**Results:** Total 220 data points were observed in 11 set at Biochemistry laboratory of New civil hospital Surat. Coefficient of Variation in rejection rate based on 20 days average and SD, is as much as 70%.

### **Conclusions:**

Laboratory must calculate SD and average from larger data to decrease false rejection rate. No efforts are made by this study to find optimum data points required.

## Root cause analysis and Prevention of needle stick injury

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**Co-Author :**

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**Introduction:**

Needle stick injury contributes to significant risk of transmission of infections like Hepatitis, HIV, etc and avoidance of practices like recapping of needle prevents the risk significantly.

**Case:**

There was a needle stick injury to a resident during collecting a sample using vacutainer while recapping the needle. She was brought to ART center where first dose of PEP given and necessary investigations done.

**Root cause analysis:**

during removing needle from the holder, there is need to unturn needle with recapping. And this recapping is a source of injury.

**Prevention:**

1. Use of Specialized Holder with release catch allow removal of needle from its holder without recapping.
2. Use of vacutainer needle with protective cap is useful when specialized needle holders are not available.



## Estimation of serum Vitamin D3 level in patients with Subclinical Hypothyroidism.

### Authors:

Dr. Mayur Makadia, Dr. Kinjal Patel, Dr. Vishwal Patel, Dr. Hitesh Shah, Dr. N Haridas.

### Methodology:

30 cases of Subclinical Hypothyroidism were chosen from routine health check-up scheme. Subclinical Hypothyroidism was established on the basis of Serum TSH level (TSH>4.2 but, <10 mU/L).

Inclusion Criteria: Age Group 25-70 years

Exclusion Criteria: Paediatric age group  
Renal Disorders  
Hepatic Disorders  
Patient with Vitamin D supplements  
Clinically Established Hypothyroidism

Controls:30 age and sex matched healthy individuals were included in the study.

**Method of Analysis** : 3 ml of venous blood sample was drawn for plain vacutte from Cases and controls. Serum was separated at 3000 rpm for 15 mins & tested for TSH & Vitamin D3. TSH & Vitamin D3 was measured by Electrochemiluminescence Immunoassay method on Roche Hitachi Cobas e411 fully automated analyser.

The results of cases & controls were compared by Paired Student 't' test. And p value of <0.05 was considered significant and value of <0.01 was considered highly significant.

**Results:** When the Cases and Controls were compared, Vitamin D3 was significantly low in subclinical hypothyroid patients compared to the controls. The mean of Vitamin D3 in cases was  $32.0 \pm 11.5$  while in Controls it was  $65.51 \pm 11.37$ , p value < 0.01. The mean of TSH in cases was  $5.65 \pm 1.30$  while in Controls it was  $2.07 \pm 0.64$ , p value <0.01.

**Conclusion:** We found that serum Vitamin D3 levels were significantly lower in patients of subclinical hypothyroidism compared with control subjects.







