

“Guidelines for Pathology Laboratories in Goa”
As Drafted By the Goa Medical Council

Preamble:

It has been observed for some time now, that pathology laboratories are operating without any controls, supervision or checks. The matter has come before the Supreme Court in numerous cases, and figured in various complaints of negligence, prompting the Goa Medical Council to take suo motto action to rectify the problem.

The Goa Medical Council, at its meeting on the 7th February 2014, has produced guidelines for pathology laboratories in the state of Goa. These guidelines are the result of a series of meetings of a committee of the Council specially appointed for the purpose. This Committee was chaired by Dr. Dhanesh T. Volvoikar, Vice President, Goa Medical Council with the following members:-

Dr. Rajendra M. Tamba - Chairman, Disciplinary Committee, Goa Medical Council

Dr. R. G. Wiseman Pinto – Professor & HOD, Department of Pathology, Goa Medical College, Bambolim Goa.

Dr. Suresh Mandrekar– Assistant Professor, Department of Pathology, Goa Medical College, Bambolim Goa.

Dr. Govind G. Kamat– Special Invitee/ Member, Goa Medical Council

Dr. Babita Angle– Special Invitee, Practitioner Pathologists

Director, Directorate of Health Services

President, Indian Medical Association

President, The General Practitioners Association

The Committee met on 23-08-2012, 09-10-2012 & 21-06-2013. Relevant stakeholders such as representatives of practicing pathologists in Goa, the D.H.S. Director, the Dean, Goa Medical College were also consulted. These guidelines have now been presented to the government for formal

ratification, and as per the decision of the Council taken at its meeting on the 7th February, will come into effect immediately.

**Guidelines for Investigation Laboratories in the State of Goa as approved by
Goa Medical Council**

- I) For the purpose of these guidelines “**Laboratory**” means a clinical establishment which deals with collection, processing and analysis of various specimens namely blood, urine, stool, sputum, semen, body fluids – i.e. CSF, Pleural, Pericardial, ascitic/ peritoneal etc., tissue and other types of biopsy and cytology specimens.
- II) DEFINITIONS:
- a) Registered Medical Practitioner (R.M.P.): means Registered Medical Practitioner who has medical qualification (i.e. MBBS or equivalent) as included in the Schedule of Indian Medical Council Act, 1956 and registered with Medical Council of India/State Medical Council.
- b) Laboratory: as defined in I.
- c) Post graduate degree/diploma holder in any branch of Laboratory medicine: are doctors registered with MCI/State Medical Council with recognized postgraduate degree/diploma in any branch of laboratory medicine namely Pathology, Pathology & Bacteriology, Microbiology, Biochemistry, Clinical Haematology, Clinical Pathology, Laboratory medicine (or equivalent).
- d) M.C.I.: Medical Council of India.
- III) For the purpose of regulations, the **laboratories may be sub-divided as follows:**
- a) Standalone laboratories.
 - b) Laboratories attached to Hospitals and Nursing homes.
 - c) Physicians’ office side lab.

- d) Labs/ Centers conducting fitness check for overseas recruitments,for factory workers, occupational health services etc.
- e) Collection Centers
- f) Laboratory in Govt.Institutions:

IV) Requisite qualifications and experience to run a pathology laboratory in the State of Goa and authorization to sign laboratory reports.

a) For Standalone laboratories i.e. laboratories which are run independently and are not apart of any nursing home/ hospital.

R. M. P. with:

1. Post-Graduate degree/ diploma in any branch of laboratory medicine from a recognized University.
2. Failing above (iv/a/1) report can be signed by registered medical practitioner. (Refer Para. V for details)

b) For Laboratories attached to Hospitals and Nursing Homes.

R. M. P. with:

1. Post graduate degree/ diploma in any branch of laboratory medicine namely Pathology, Pathology and Bacteriology, Microbiology, Biochemistry, Clinical Pathology, Laboratory Medicine from a recognized University.
2. Failing above (iv/b/1), report can be signed by registered medical practitioner. (Refer Para. V for details)
3. For Emergency services like Blood gases, Electrolyte etc. done at odd hours (outside office hours), basic doctor with MBBS or equivalent should be the signatory

for reports (Registered Medical Practitioner). This report should be ratified by in charge authorized doctor of that laboratory next day.

c) Physician's office side labs which deals with routine basic tests & which are being used for their own clinical practice shall be the responsibility of the concerned physician(Registered Medical Practitioner) who shall be duly registered with the Medical Council, to run a lab and sign report.

d) For Labs/ Centers conducting fitness check for overseas recruitments, for factory workers, occupational health services etc.1) R. M. P. with Post graduate degree/diploma or recognized certificate course like AFIH which deals with investigation, examination and certification for above mentioned purpose and curriculum of said courses include lab investigation.

e) Collection Centers:

1. Independent collection centers dealing with collection of patients samples should have trained technical personal who shall work under the supervision of Registered Medical Practitioner.
2. All collection centers should be under registered medical practitioner and his/her degree certificate, registration with medical council and other certificates as per land of law has to be displayed in the premises.
3. Registered Medical practitioner under whose name these centers are working will be fully responsible for all the affairs of the collection centre.

f) In Government Institutions:

- i) Medical Colleges:

1) Registered Medical Practitioner with post graduate degree/diploma in Laboratory Medicine.

4. In Emergency situation and after office hours: Registered Medical Practitioner. (Refer Para V) This doctor can be Resident doctor/ Houseman, etc. The report should be ratified by in charge authorized doctor of that laboratory next day.

ii) District Hospital:

1) Registered medical practitioner with post graduate degree/diploma in any branch of Laboratory Medicine.

2) Failing above (iv/f/i/1) Registered Medical Practitioner. (Refer Para V)

3) In emergency situations Registered Medical Practitioner in absence of Post graduate degree/diploma holder in Laboratory Medicine.

iii) Peripheral Hospitals/ Health Centers like Primary Health Center/Urban Health Center/ Rural Health Centre/ Rural Medical Dispensary/Mobile Clinic/Sub Center/ Sub District Hospitals/ other Govt. Health Centers or small Hospitals. The report should be ratified by in charge authorized doctor of that laboratory next day.

1) Minimum Registered Medical Practitioner.

V) REQUISITE KNOWLEDGE AND EXPERTISE FOR SIGNING REPORT:

Signatory for any of the Laboratory reports has to be minimum Registered Medical Practitioner who has registered qualification as included in the schedule of MCI Act 1956, i.e. MBBS or equivalent. Those doctors who do not have any of the post graduate qualification in Laboratory Medicine but their undergraduate curriculum has covered all basic investigation can sign Laboratory report within the level of his/her competence and should have full knowledge of the investigation carried out and will be fully responsible for same. These signatory with a basic degree like MBBS or equivalent qualification recognized by MCI as per MCI Act 1956, should restrict themselves in

signing basic laboratory report and as far as possible should not sign highly specialized reports like histopathology etc. which require expert person with appropriate training and post graduate qualification in concern subject. A basic graduate doctor who takes responsibility of signing this report can get their knowledge and expertise updated with refresher courses or refresher training in larger laboratory run by a qualified post graduates like pathologist.

Specialized investigations like histopathology, blood culture etc. should be signed by postgraduate degree/diploma in concerned specialty like pathology, microbiology, Biochemistry, Clinical Hematology etc. who has requisite training, knowledge & required qualification about the concern subject and curriculum of that particular post graduate qualification and covers corresponding investigation.

VI) Requisite for complete authentic report.

- 1) Every report has to be signed by authorized doctor as stated in Para IV & V.
- 2) Report must have complete Name of signing doctor, his/her qualification, Registration Number of Medical Council along with other information like date, address, and Email address if available. License Number from Govt. authority as per the law of land should be displayed on the report.

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Input/Reference:

- 1) MCI vide letter No MCI/211(2) (51) 2011 Ethical 64036 dated 11/8/11 regarding guidelines for running the individual lab has stated as under:- Pathology laboratory can only be opened by trained Registered Medical Practitioner, who has registered qualification as included in the schedule of Indian Medical Council Act 1956.

Pathology laboratories as such do not come under the preview of MCI, however the pathological report has to be signed by the registered doctor.

- 3) As per discussion in the meetings of committee appointed by Goa Medical Council to frame these guidelines.
- 4) As per discussions in executivecommittee meetingof this council.

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CAUTION FOR R. M. P's WHO TREAT PATIENTS BASED ON LAB REPORT:

Clinicians should not treat patients based on unauthorized report. They will be fully liable for their act and disciplinary action can be taken as per Goa Medical Council Act.

Reports signed by Laboratory technicians are unauthorized report and cannot be used in modern medical practice to treat patients. Authorized and authentic report is one which will full form all the criteria laid down in this guideline.
