

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**RAJYA SABHA
STARRED QUESTION NO.22
TO BE ANSWERED ON THE 20TH JULY, 2021**

**GUIDELINES ISSUED BY NABL REGARDING PATHOLOGICAL
LABORATORIES**

22 # DR. KIRODI LAL MEENA:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether it is a fact that paramedics are running pathological laboratories, if so, the number of such laboratories, State-wise
- (b) whether it is also a fact that according to an order by the Hon'ble Supreme Court, the pathology degree holders recognised by Medical Council of India can only run a pathological laboratory, if so, the details thereof and
- (c) the details of guidelines issued in this regard by National Accreditation Board for Testing and Calibration Laboratories (NABL) which provides recognition to the medical laboratories related to testing and calibration?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI MANSUKH MANDAVIYA)**

- (a) to (c):** A Statement is laid on the table of the House.

**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO. 22* FOR 20TH JULY, 2021**

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(a) & (b): As per Constitutional provisions, 'Health' is a State subject. The States/Union Territories (UT) are primarily responsible for implementing guidelines/protocols for Medical Diagnostic / Pathological Laboratories in their States as per the applicable provisions of law in the respective State / UT. Union Ministry of Health & Family Welfare do not maintain details in this regard.

The [Hon'ble Supreme Court of India, on 12.12.2017](#), disposed a Special Leave petition no. 28529/2010 (North Gujarat Unit of Association of Self Employed Owners (Paramedical) of Private Pathology Laboratories of Gujarat versus North Gujarat Pathologists Association & Ors.), wherein, the Hon'ble Apex Court held that

"The stand of the Medical Council of India that Laboratory Report can be counter signed only by a registered medical practitioner with a post graduate qualification in pathology is correct."

Further, the Board of Governors in supersession of Medical Council of India (MCI) in their speaking order dated 3 April 2019 , inter-alia, clarified

"5., the Registered Medical practitioner shall sign / countersign the Laboratory Reports in their respective field of specialization / subject. That is to say that a Pathologist shall sign / countersign a Pathological Report, a Microbiologist shall sign / countersign a Microbiological Report and a Biochemist shall sign / countersign a Biochemical Report, so on and so forth.

8.Thus, any ambiguity arising out of the order dated 12.12.2017 of the Hon'ble Supreme Court stood dispelled with effect from the date of the notification of the Ministry of Health and Family Welfare, Government of India, i.e. 21.05.2018.

The notification dated 21 May 2018 (http://clinicalestablishments.gov.in/Writ_ReadData/4161.pdf), by Ministry of Health and Family Welfare, Government of India, referred above, is in respect of Minimum standards for Medical Diagnostic Laboratories (or pathological laboratories) for grant of registration under Clinical Establishments (Registration and Regulation) Act, 2010 in the States/UTs wherever the Act is applicable. This was further amended in 2020 (<http://clinicalestablishments.gov.in/WriteReadData/551.pdf>) following directions of Hon'ble High Court of Delhi and Hon'ble High Court of Rajasthan and after hearing various professional laboratory associations in compliance thereof. As a result, non-medical laboratory professionals with specified qualifications have also been permitted to sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of laboratory results. Such test reports must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.

(c) National Accreditation Board for Testing and Calibration Laboratories (NABL) have published guidance document NABL 112 "Specific Criteria for Accreditation of Medical Laboratories" for use of its accredited laboratories. This guidance document is available on its website www.nabl-india.org. The "accreditation" is however, a voluntary process and not a pre-requisite for registration of Medical Diagnostic/ Pathological Laboratories under the Clinical Establishments (Registration and Regulation) Act, 2010.
