

## Accreditation of Diagnostic Laboratories – Dr. Th. Dhabali Singh MD

Medical laboratories are an important component of healthcare system. The diagnosis and treatment of a patient depends on the test results, and an incorrect test result can have serious consequences by way of wrong diagnosis. Needless to say, accuracy of test results are important, each and every time, the tests are conducted. Laboratory medicine is the backbone in medical treatment, diagnosis and prevention and, laboratory diagnostics influence 70 – 80% of hospital health care decisions.

### SCENARIO OF DIAGNOSTIC LABORATORIES IN INDIA

The exact number of pathology and diagnostic labs are not known but it is estimated that there are about 1,00,000 of them in India. Out of these, 80% are supposedly small, 18% are medium and only 2% of them are large sized. Even though we have been seeing the emergence of big corporate labs in the past few years, these constitute only a small percentage and a vast majority of the labs are in unorganised sector. Accreditation of clinical laboratories is not mandatory in India. In fact, there are no guidelines or laws governing diagnostic laboratories. There is no standard practice for conducting diagnostic tests or storage facilities. In the absence of a benchmark, even the rates of tests vary from one laboratory to another.

### IMPORTANCE OF ACCREDITATION

Accreditation is a way to demonstrate the competence of medical laboratories and ensure the delivery of timely, accurate and reliable results. Medical laboratory services encompass arrangements for test requisitions, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent result validation, interpretation, reporting and advice. The services should meet the needs of all patients, physicians and clinical personnel responsible for patient care and any other interested parties. Laboratory accreditation provides formal recognition of competent laboratories. Accreditation offers incentives of increased customer confidence, better control of laboratory operations, and greater access for their services.

### ACCREDITATION IN INDIA

As mentioned, accreditation is not mandatory for clinical laboratories in India. The **National Accreditation Board for Testing and Calibration Laboratories (NABL)** is an autonomous body under the Department of Science and Technology, Government of India and is the sole government-authorised accreditation body for laboratories. NABL offers accreditation to testing, calibration and clinical laboratories and its activities include surveillance and re-assessment visits, proficiency testing programmes and the withdrawal, suspension or reduction in scope of accreditation. In an effort to draw on established quality assurance programs and ensure validity of laboratory test results across national borders. NABL has adopted the International Criteria for laboratory accreditation set by the International Organization of Standardization (ISO). It has also entered into a mutual recognition

arrangement with Asia Pacific Laboratory Accreditation Cooperation (APLAC) and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) arrangement.

## **NABL ACCREDITATION AND ISO 15189**

For accreditation by NABL, the medical laboratories are assessed in accordance with ISO 151889: 2007 standards. ISO 15189 covers the essential elements for medical laboratories to demonstrate the quality and competence of their services, as well as to consistently deliver technically valid test results. The standard, which has been developed with strong involvement from the medical, scientific and clinical community, is for the use of medical laboratories in developing their management systems and maintaining their own competence. Specialist scientific and clinical assessors, with expertise in the relevant discipline of practice, conduct a thorough evaluation of all factors in the laboratory that affect the production of test data, including:

- technical competence of staff
- validity and appropriateness of test methods, including pre- and post-analytical elements
- sample quality, including patient identification, handling and transportation
- a review of the history relating to previous patient results and any known clinical diagnoses
- procedures relating to the use of “referral laboratories” such as specialised testing centres for specific diseases
- traceability of measurements and calibrations to relevant standards
- suitability, calibration and maintenance of test equipment
- testing environment
- quality assurance of test data
- acceptable turnaround time
- application of appropriate ethical values.

## **PRESENT STATUS**

Of the estimated 1,00,000 pathology and diagnostic labs in India, only about 370 of them are accredited by NABL. This is less than 1% of the total number of diagnostics laboratories in the country. The absence of strict regulatory environment has led to the mushrooming of large number of small laboratories with limited facilities. The diagnostics landscape is expected to change in the coming years with registration and quality compliance mandatory for laboratories and diagnostic centres under the National Clinical Establishment Act, 2010. However, looking at the small percentage of accredited labs in the entire country, we still have miles to go.

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