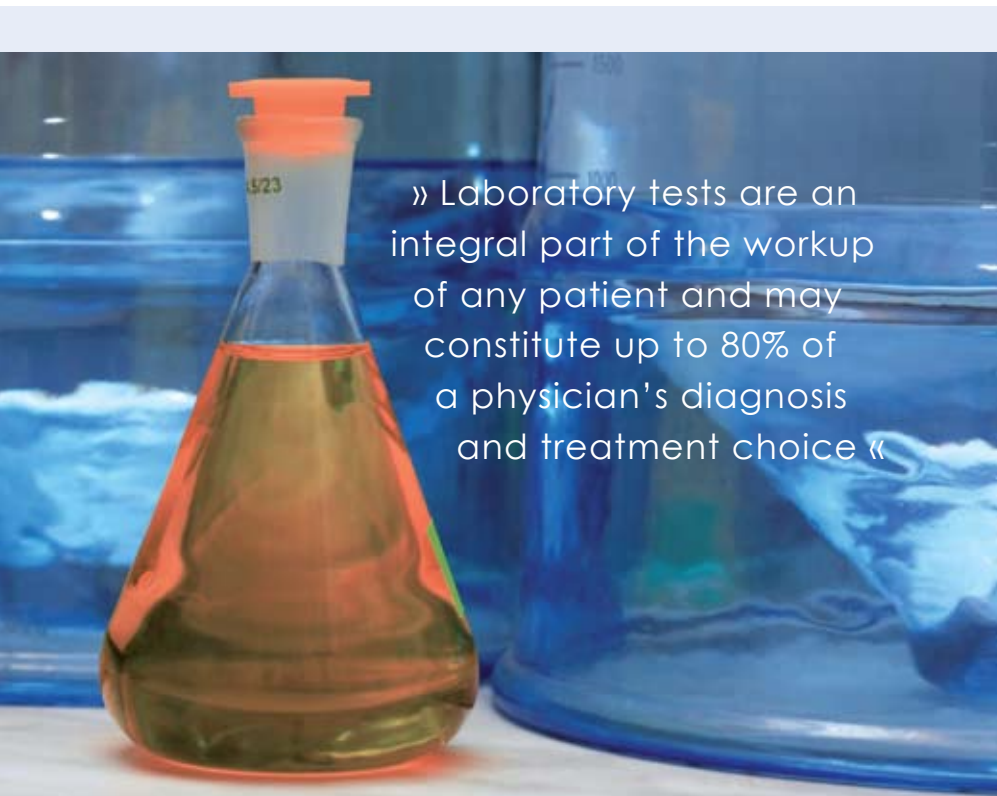


Dubai heralds a **new era** of quality healthcare provision

Meeting the challenge

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FOLLOWING ON FROM a speech given by His Royal Highness Sheikh Mohammed bin Rashid Al Maktoum, UAE Vice President and Prime Minister, and Ruler of Dubai in April of last year, where he outlined the core objectives of his strategy aimed to improve the life of all those living in the Emirate of Dubai, the Government of Dubai is moving forward in strengthening its medical services and healthcare provisions. The Department of Health and Medical Sciences (DOHMS) and Dubai Health Authority (DHA) have correctly identified the fact that first world medicine today is built on a strong diagnostic infrastructure represented by Standardised Pathology Services. This fact allows their medical establishments to diagnose and treat disease several steps closer to its point or origin (pathogenesis).

If you imagine that a dangerous disease will take ten steps in its whole life cycle i.e. be-

tween pathogenesis and death, then on average first world medicine with its standardised pathology services tends to meet the disease at step three. This is where treatment methodologies and solutions can have a greater chance of effecting cure. On the other hand, third world medicine with largely unregulated, non-standardised laboratories tends to meet

the same disease at step seven or eight, when most of the disease's life cycle has already been complete and most treatment modalities do not yield satisfactory results. In other words it is the pathology services who determine if the disease you meet is still a tiny cub or has developed into a roaring lion before management can begin.

From the 1st of September 2008, all laboratories in Dubai will be obliged to adhere to strict new standards and guidelines published by the DOHMS earlier last year. No one should underestimate the boldness of this essential move. It is bold because there will always be strong and powerful groups with vested interest, who would like to maintain the status quo. In the fullness of time, I have no doubt that this step will be seen as the turning point in improving all medical practice in the country.

One of the difficulties the Government faces in making fundamental changes in healthcare is that the general public is not really an active participant in the debate. The public's view of medicine today is based on seemingly mysterious and often incomprehensible phenomena; few are capable of understanding the complexities of modern medical management and are unaware of the processes on which their healthcare is based. In many ways they feel as if they are held hostage in their reliance on the limited information they have regarding the safety, efficacy and quality of the healthcare provisions or what standards are applied and followed.

Laboratory tests are an integral part of the workup of any patient and may constitute up to 80% of a physician's diagnosis and treatment choice. In clinical practice, one of the difficulties doctors and patients face is in determining if laboratory critical data is of the quality needed. Keeping in mind that, based on the data laboratories provide, major healthcare

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decisions are made. It is not difficult to extrapolate that a major portion of society's confidence in its healthcare establishments will largely be determined on the strength and accuracy of its pathology services.

For this reason the public must be assured that it is being given sound information by Government regulatory agencies and profes-



sional regulatory bodies as they are inherently incapable of confirming this alone. This information must be transparent and not influenced by economic or political pressure, and is free from conflict of interest, a fact that must not only be strictly observed, but must also be seen and perceived to be observed in order to maintain public confidence.

Today's medical laboratory is challenged to provide accurate, precise, and high-quality data for patient care at a reasonable cost. Laboratory directors and managers must make appropriate decisions in selection of instrumentation, and once that decision has been made, they must then adequately and efficiently verify and maintain performance.

A laboratory may be defined as a facility where tests are done on clinical specimens in order to get information about the health of a patient. It must offer appropriate containment where the laboratory use of hazardous biological material and chemicals can occur safely. It is a workplace where strict health and safety guidelines must be followed to ensure the safety of its work force and the general public alike. Indeed, some may go as far as using the word Laboratory synonymously with Containment. This fact is now taken seriously by DHA and accordingly any Medical laboratory that fails to demonstrate level containment II (Biosafety level II), will no longer be allowed to practice within the Emirate.

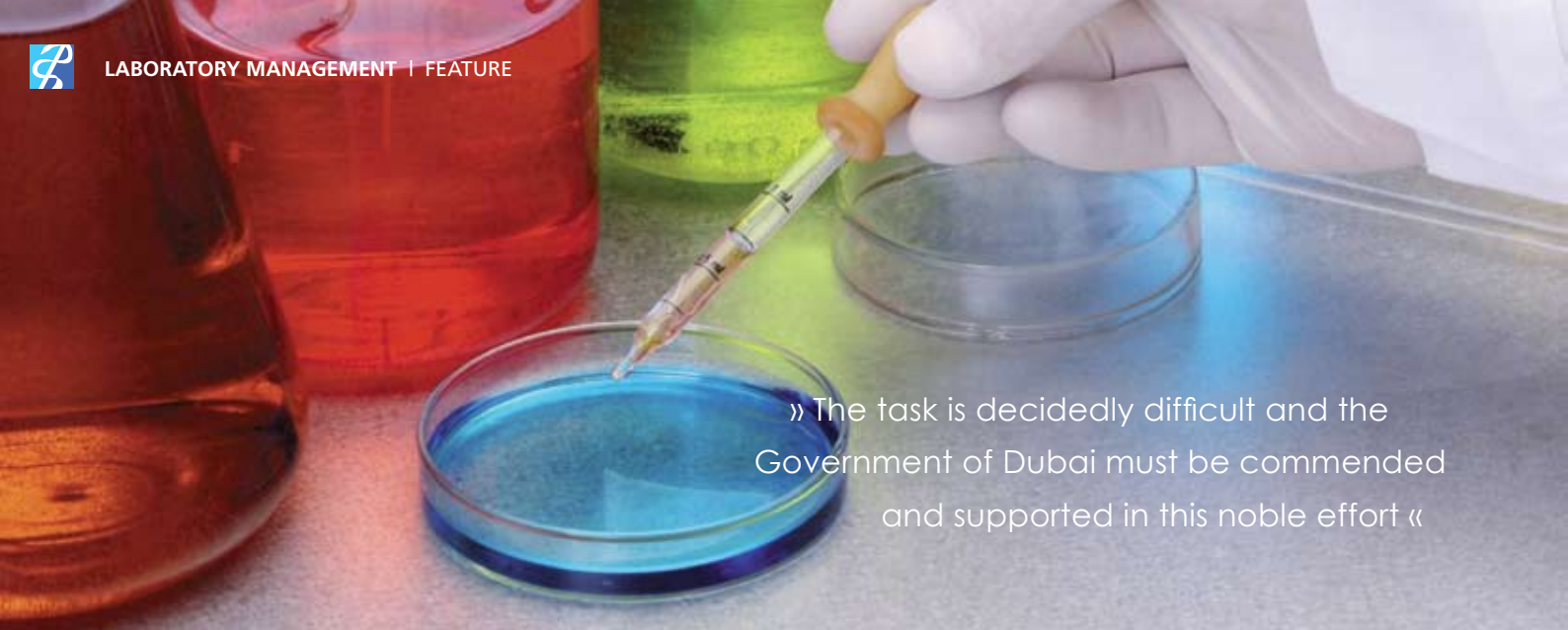
It is imperative that laboratories follow the fundamentals of quality provision insisted on by international accreditation bodies where they must:

- Operate a quality management system to integrate the organisation, procedures, processes and resources.
- Set quality objectives and plans in order to implement this quality policy.
- Ensure that all personnel are familiar with this quality policy to ensure customer satisfaction.
- Commit to health, safety and welfare of its entire staff.
- Ensure that all visitors to the laboratory will be treated with respect and all due consideration will be given to their safety while on site.
- Uphold professional values and is committed to good professional practice and conduct.
- Improve staff recruitment, training, development and retention at all levels to provide a full and effective service to its customers
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service
- The use of standard operating procedures, instructions and forms that will ensure the highest achievable quality service is provided.
- The reporting of assessment results in ways which are timely, confidential, accurate and reliable.
- The assessment of customer satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

Credibility of medical laboratories is paramount to the health and safety of the patients relying on the testing services provided by these labs. The international standard in use today for the accreditation of medical laboratories is ISO 15189, which stipulates particular requirements for quality and competence. »

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The new regulations in Dubai insist that all laboratories will have to be certified by an International Accreditation Board within three years of their inception. These Boards will oversee that the laboratory is:

- competent to perform specific medical laboratory tests on samples from humans in the specialties and subspecialties, listed on its Scope of Accreditation;
- its management system addresses and conforms to all elements of ISO 15189, and is documented per ISO 15189 and is fully operational; and
- it is operating the Pre-analytical, Analytical and Post-analytical systems in accordance with its management system.

Accreditation Boards will request copies of quality documentation and representative test specific technical Standard Operative Procedures (SOPs) in order to prepare for the assessment.

The quality manual and related documentation must be reviewed by the assessment team before the assessment can begin. This review is done ideally before the assessment is scheduled. Upon review of submitted documentation, the assessor(s) will provide the document review results to the laboratory in writing, and may ask the laboratory to implement corrective action to fill any documentation gaps required by ISO 15189 before scheduling the assessment.

A pre-assessment visit may be requested by the laboratory or suggested by the assessor as an option at to enhance the success of the full assessment.

The full assessment generally involves:

- An entry briefing with laboratory management;
- Interviews with technical staff; (including health care providers outside the laboratory in hospital based laboratories)
- Demonstration of selected tests including, as applicable, tests; including tests performed at other sites within the scope of the accreditation.

- Examination of equipment and calibration records; test records, supplies and reagents
- Audit of the management system to verify that it is fully operational and that it conforms to all sections of ISO 15189, including documentation;
- Review of training records and competency assessments
- A written report of assessor findings; and
- An exit briefing including the specific written identification of any deficiencies.

While the laboratory is expected to meet every individual requirement, the assessor also seeks to determine the laboratory's overall compli-

ance. The assessors use an outcome-oriented approach that emphasizes the provisions that have a direct impact on the laboratory's overall test performance. The bottom line: Is the laboratory producing quality results (accurately, reliably, and timely)?

All these provisions that will be enacted from the 1st of September this year are designed to bring pathology practice in Dubai into the 21st Century and enhance patient safety and well being. Once again the eyes of the region will be fixed on Dubai to see the outcome of this bold strategy. The task is decidedly difficult and the Government of Dubai must be commended and supported in this noble effort. ■

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