

A Global Commitment to Quality

SHENZHEN, CHINA, November 14, 2022 /EINPresswire.com/ -- if you are having a clinical test, it is important to know that the laboratory meets government standards and has been certified to a universally accepted standard, and that your clinical sample and any accompanying data will be handled securely and safely and only used for the purposes you have agreed to.

BGI Australia's recent accreditation to perform clinical whole exome sequencing (cWES), an important test for identifying possible disease-causing genetic changes, was the culmination of a two-year process to meet the rigorous standards set by the accreditation body, the National Association of Testing Organizations of Australia (NATA).

This is the latest addition to the more than 100 international quality system accreditation certificates that BGI Group holds worldwide that meet international requirements and are designed to reassure customers about BGI's laboratory quality management and efforts in data security, personal privacy, environmental protection and the like.

"It is the mission and vision of BGI to benefit mankind through genetic technology, and quality is the lifeline that BGI firmly adheres to," says Dr. Fu Wei, BGI Genomics Director of Quality Management.

Bodies such as ISO develop internationally recognized standards and quality systems. It is then the role of reputable, third-party accreditation bodies such as NATA to accredit organizations to these and other standards that have been government-endorsed, and then to perform regular checks to ensure the standards are being maintained. Where they are not, accreditation can be withdrawn.

Across BGI Group some international qualifications of quality management systems in place are as follows:

1. Medical Laboratories Qualifications

There are two main international quality systems for medical laboratories.

One is the College of American Pathologists (CAP) whose accreditation is considered to be the 'gold standard' for medical laboratory quality systems. BGI's laboratory in Hong Kong has obtained this accreditation.

The other is the ISO system. For example, ISO 15189 is used internationally to regulate the management and technical requirements for the quality and capability of medical laboratories. BGI Group's laboratories in Denmark and Australia have obtained the ISO 15189 qualification, while the UK laboratory is in the final process of applying.

To ensure the test reliability, BGI laboratories undertake method validation by conducting clinical samples testing to produce hundreds of data results to guarantee accuracy, precision and so on.

2. Medical Devices Qualifications

ISO 13485 is a quality management system applicable to medical devices and their design, production, storage, distribution and installation. For BGI, this includes IVD (in vitro diagnostic) products covering fertility, oncology and infectious diseases, such as thalassemia genetic testing kits, solid tumor testing kits, and the coronavirus viral antigen detection kits.

BGI Group labs have passed ISO 13485 certification in six cities in China and overseas in Singapore, Denmark, Latvia, Ethiopia and elsewhere.

3. Data and Personal Privacy

Personal privacy protection is of critical importance. The EU has the GDPR (General Data Protection Regulation) which means the protection of personal information in the EU is extremely high. The BS10012 Personal Information Management issued by the British Standards Institute includes reference to GDPR, providing a good framework for personal information protection in data governance.

BGI has obtained BS 10012 certification in Hong Kong and Denmark and is actively pursuing applications for information security and personal privacy related qualification in many other places.

Multiple branches of BGI Group in China have also obtained ISO 27001 Certification, which is one of the most common information security management systems at present.

While these are some of the international qualification systems BGI has obtained, there are also many more including ones for environment, health and safety such as ISO 9001, ISO 14001, and ISO 45001 which many subsidiaries of BGI have obtained. In addition, BGI meets all local regulations around quality management and data protection in the countries where it operates.

As BGI Group CEO, Dr. Yin Ye, notes: "As the world's leading life sciences organization, BGI Group's leadership in the industry is inseparable from a commitment to quality management. BGI has taken the lead in attaining quality system certifications and is actively participating in setting up industry standards, social organization standards, and even international standards."

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