Quality Control – Critical in Assisted Reproductive Technology

Vitrolife uses Vaisala's carbon dioxide meters to monitor CO_2 concentration in incubators as a part of its quality control and customer service programs.

Assisted reproductive technology (ART) is continually improving to offer successful treatment of human infertility with the most desired outcome – a healthy baby. Success rates in ART depend on many factors, including the quality of products used, making quality control a top priority for manufacturers of ART products.

One such company, Vitrolife, is a global leader in the preparation, cultivation, and storage of human cells, tissues, and organs. In its ART business area, Vitrolife designs and produces nutrient solutions used by in vitro fertilization (IVF) clinics worldwide for the handling, culturing, and storing of human embryos.

These nutrient solutions – called IVF media – contain amino acids, vitamins, and other additives designed for each phase of ART. To ensure the quality of its IVF media products and to assist its fertility clinic customers in the field, Vitrolife has chosen Vaisala's handheld CO_2 meters to measure CO_2 concentration in incubators. The CO_2 concentration is critical since it has direct effect on one of the most important sources of environmental stress to human embryos: pH fluctuation.

Minimizing Stress on Embryos by Maintaining Specified pH

Incubators simulate one important function of a human body – providing a constant environment.

"Incubators are vital to the overall success of IVF. They create the optimal, constant environment for embryo cultures," explained Michael Baird, Vitrolife Embryologist, adding, "Fluctuation causes stress and IVF labs want the least stress."

Near the top of the list of stress factors are unwanted fluctuations in pH. These fluctuations can be caused by incubators not maintaining the specified environment, exposure to external variables when opening the incubator doors, and by the biological processes of the cells.

CO_2 is used to regulate the pH level, thus pH is measured and maintained by monitoring and adjusting the concentration of CO_2. CO_2 and pH have an inverse relationship; as the concentration of CO_2 increases, pH level decreases. According to Baird, IVF media are "designed and buffered to maintain specific pH at specific CO_2 levels where CO_2 dissolves in and out of the media to maintain the correct pH."

Upgrading CO_2 Measurement Technology

Maintaining constant, specified pH is critical to Vitrolife's s strict quality control program. At its production facility in Colorado, Vitrolife tests the quality of its IVF media in its mouse embryo assay (MEA) lab before the product is shipped to customers.

The MEA lab measurement practices include monitoring the incubators' digital displays and independent verification with portable measurement devices. Like many bioassay and IVF labs, the MEA lab had used blood gas analyzers that report chemical absorption rates of a fluid that is selective of CO_2 absorption to meet their independent measurement requirements, but was dissatisfied with the level of accuracy and unreliability due to user variability.

According to Vitrolife MEA Laboratory Manager Brett Glazar, "The standard was using fluid-based gas analyzers, but the readings were not specific enough at plus or minus a half of a percent. And we had repeatability issues. Two operators using the same device on the same incubators could produce completely different readings. Overall, the devices were not accurate enough for us."

Vitrolife sought to lower the error by improving accuracy and repeatability. They selected Vaisala CARBOCAP® Handheld Carbon Dioxide Meter GM70 because – according to Baird – it was the "most accurate, consistent, and easy to use". After implementation, Glazar reported that the accuracy and automatic calculations of variables of the GM70 provided the "tighter range and higher repeatability" needed to meet their quality control standards.

Expanded Use at Customer Sites

Vitrolife's successful use of the GM70s in their own MEA lab led to their use during customer site visits. ART product suppliers like Vitrolife are often called on to help diagnose the source of the problem if embryo cultivation rates do not meet the IVF clinic's standards. As part of his diagnostics, Baird measures CO_2 concentrations using the GM70 to make sure the incubators are operating within specification.

Baird observes that while IVF labs check CO_2 daily, many labs still rely on the less accurate, fluid-based gas analyzers. "Once we started using GM70s on service calls to double check their CO_2 levels, we were surprised to see how inaccurate many of their readings were."

Baird attributed common sources of inaccuracies to the lab's use of older equipment, ranging from function loss of older digital displays on the incubators to outdated measurement technology that can be resolved with an upgrade plan for lab equipment.

Repeatable Measurements Advancing Reproductive Technology

The GM70 uses infrared (IR) technology that is more accurate, stable, and repeatable than fluid-based gas analyzers. It does not require any calculations for pressure and temperature compensation. The temperature and pressure of the environment at the measurement point can be easily set using the graphical GM70 interface. Compensations are made internally and the instrument displays the corrected measurement.

Advances in the design and quality of ART products are improving the treatment of human infertility. Vitrolife's experience shows how accurate, stable, and repeatable measurements can enable tighter control and less fluctuation of a critical environmental variable such as pH, in both a production environment and in IVF incubators.

Vaisala's handheld carbon dioxide meter GM70 uses infrared technology that is more accurate, stable, and repeatable than fluid-based gas analyzers.

Vitrolife AB

Vitrolife designs and manufactures systems for the preparing, cultivating and storing human cells, tissues and organs outside the body. The company was developing in vitro fertilization (IVF) media in Sweden in the early 1990s. By the end of the decade, it offered a full line of IVF-media products and lung preservation solutions and changed its name from Scandinavian IVF Science to Vitrolife.

The 2000s have seen Vitro-life expand its product portfolio in its three core business areas: providing nutrient solutions for embryo cultures used to treat human infertility, solutions and systems for transporting organs for transplantation, and media for stem cell development for therapeutic use.

Vitrolife serves a global market with production facilities in Sweden and the United States with subsidiaries in Australia, France, Italy, China and Japan.

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