**Introduction of importance of calibration in your IVF lab**

Quality management in the IVF laboratory underpins a successful clinic. Managing the quality of laboratory processes leads to improved results and a greater confidence for clinicians and patients.

As a result of this global expansion boosted with cutting edge technologies, quality management and risk management are becoming increasingly important for running IVF clinics, and consequently they are fast becoming “prime debatable topics”.

IVF Centers to operate, according to ICMR guidelines reflect modern awareness of our professional – and commercial – environment, and should be embraced by all IVF Centers that truly care for their patients.

To maintain ambient quality there are certain vital parameters like Particle count, Filter integrity Test, Air Velocity, Temperature, Humidity and CO2 for incubators which need to be kept under a constant check as they can harm the gametes and embryos, ultimately compromising the results.

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**What is calibration?**

Calibration is the comparison of an instrument's actual measurement performance to a standard of known accuracy. Calibration performed on an instrument can document the deviation of a measurement from the known standard, or it can include adjusting the instrument's measurement capability to improve measurement accuracy. International committees define standards for calibration.

The most basic requirement of a calibration is proof of traceability. Traceability is defined as an unbroken chain of comparisons, all having stated uncertainties, between your measurement and some national or internationally accepted standard.

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**Hygiene Monitoring**

A powerful tool for implementing and managing your hygiene monitoring program. 3M™ Clean-Trace™ NG Luminometer is used with the Clean-Trace ATP surface test and water tests to determine the level of contamination in a sample, results are available in seconds. It has all the features to maximize its value to your business.

**Benefits:**
- Helps reduce risk of cross contamination due to poor cleaning.
- Provides a tool to allow you to track and improve your hygiene performance.
- Adds value to your results by allowing you to generate powerful management reports for continuous improvement.
- Helps protect your reputation.

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**Meeting Standards**

Calibrate your instruments to meet the latest international standards and you can be assured that your data and instruments are more readily accepted locally as well as globally. Our services are designed to ensure that your equipments fulfill the requirements of an ideal IVF lab.
Particle Count

Particle Counts are an extremely important consideration when designing an IVF lab. Gametes & embryos should be handled in a class 100 hood and the lab should be preferably of class 1000.

Particle count is probably one of the best tests to verify your system cleanliness. While it is an excellent method for determining the number and size of particles being generated, particle count won’t tell you what the particles are but will help you to know how favorable your lab is for the growth of an embryo.

The major problem with particles is that they originate from some sources like paint chips, dirt, and fecal matter. So, these particles are an amalgamation of chemicals and/or bacteria, and severely compromise the lab results.

Filter Integrity Test

HEPA filters (HIGH EFFICIENCY PARTICULATE AIR filters) are made of 100% glass microfiber. These filters block particles of 0.3microns and above at a minimum efficiency of 99.97%.

Air which exits out of a HEPA filter is Class 100. HEPA filters are used in applications where a dust free and a sterile environment is needed.

As HEPA filters remove sub-micron particles and the HEPA filter being delicate, it can get damaged even while storing. To ensure that the HEPA filters installed in the equipment like AHU/labguard/laminar/ air purifiers etc are not damaged, certain tests need to be done. They are Air velocity checking, HEPA filter Pressure drop test & HEPA filter Integrity Test (PAO Test)

HEPA filter Integrity test procedure: the filter is challenged with known aerosolized particles of 0.3micron and larger (PAO) on the upstream side and checked downstream using a Photometer Probe. If there is a leak in the filter, the particles are sensed by the scanner of the Photometer and displayed as leak on the LED screen. If the leak is more that 0.03%, the filter is supposed to have failed and needs replacement on attention.

Temperature

A very “critical” parameter in embryo culture and it needs “precise” monitoring. Fluctuations in temperature even by a fraction of a degree can result in numerous culture suboptimal embryo formation or/and at times a stage referred to as “developmental arrest”.

All “temperature related gadgets/equipments” like incubators, Test tube warmers, Heating tables, Heating Plates etc. should be precisely maintained at the “ideal” required level. Failure to do so will end up in a disaster.

Measurement of CO₂ Gases

The main equipment which “cultures” the embryos, the “INCUBATOR”, hence rightly called as the heart of the IVF lab would be optimally productive if the circulating/infused CO₂ gas is of the ideal proportion or what we refer to it as “%”. An ideal culture environment created by precise temperature, accurate “%” of CO₂ gas and ambient humidity helps in maintaining optimum “pH” of the media resulting in uncompromised embryo growth. This makes routine CO₂ check of your incubator, a mandatory exercise.

Recommended Calibration Intervals

The accuracy of the electronic components used in all instruments drifts over time. The effects of time in service as well as environmental conditions add to this drift. At some point, the drift causes the instrument’s uncertainty to become undefined, meaning the manufacturer no longer can predict the uncertainty and guarantee measurement results. Hence a routine/periodic check needs to be carried out after a fix time slot preferably six months.
We Make Life Easier for You by:

- On site calibrations.
- Calibrating most types and brands of instruments.
- Calibrating all parameters critically related to instruments and lab.
- Keeping track of re-calibration dates, so we can call ahead of time, and schedule convenient and timely re-calibrations.
- Critical information about your equipment is stored in our databases, hence your data is well managed.
- Calibration certificates produced by the laboratory are in accordance to ISO requirements.

Shivani’s Expertise will Optimize Performance of your Equipment

Expert preventive maintenance of your equipment extends its useful life and help you to achieve a good results. As the original designer and manufacturer of the equipment, shivani has the expertise to make the necessary adjustments or repairs so that your instruments performance is up to the mark.

Quality

- Backed by a large engineering department and skilled scientific team.
- All measurements are traceable to National Accreditation Board for Testing and Calibration Laboratories (NABL) standards.
- All staff are factory trained.
- All methods are documented.
- New generation instruments used for calibration.

On-site Calibration Services Include

- Filter Integrity Test
- Particle count Test
- Hygiene Test
- CO₂ gas calibration for ivf incubators only
- Temperature calibration

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