Early
Prenatal Diagnosis –

New Advances in
Early Pregnancy Care

The FMF-Germany Certification Process for Laboratories

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Information on

The FMF-Germany Certification Process for Laboratories

In an effort to provide first-trimester screening in Germany with as much diagnostic certainty and reliability as the FMF London, a group of medical laboratories in Germany have adopted proven practices from this UK-based institution in order to apply them to their own work, namely the implementation of controls as well as to the introduction of standardised requirements in regard to biochemical analysis and ensuing risk calculation. With regard to the performance of first-trimester screening, an additional set of defined uniform regulations is agreed on a voluntary basis. These regulations are derived from the scientific results available and are specified in a standardised format in the “Declaration of Conformity”. The fulfilment of such voluntary self-obligations is reviewed in regular intervals by the FMF-Germany – in close cooperation with UK-NEQAS – a British quality control organisation for medical laboratories – and with the FMF in the United Kingdom.

Thanks to their close cooperation, prenatal diagnosticians and laboratories are in a position to create more quality and value to the benefit of women and their children in terms of individual treatment than any of them could ever provide alone. The joint quality assurance for the entire procedure and the reduction of invasive diagnostic interventions are primary goals of the FMF.

Certification for Laboratories
Prerequisites:

1. Accreditation of the medical laboratory by an accreditation body recognised in Germany.
2. Compliance with all regulations, and pledge to submit a specific declaration of conformity to the FMF-Germany, the content of which has been defined by the FMF-Germany and which must be obtained therefrom.
3. The laboratories obtain certification from the FMF-Germany by signing the above-mentioned "Declaration of Conformity".
4. By doing so, they undertake to use the FMF-certified measurement procedures only and to undergo regular external quality controls performed by the FMF-Germany. This involves regular participation in the UK-NEQAS interlaboratory trials and a regular submission of the risk data obtained by them to the FMF-Germany for the purpose of quality review. They also oblige themselves to pass on risk calculation results solely to likewise certified gynaecologists.
5. A transitional period existed until 31st December 2002: Prior to the expiry of this period, gynaecologists who had so far only completed the theoretical part of the examination were allowed to receive risk calculation results. However, this permission was accompanied by the reminder that they should obtain full certification in the shortest possible time. Since the expiry of this period, each of the certified laboratories has been under the obligation to pass on FMF-certified results to fully certified gynaecologists only.
6. All certified laboratories in Germany must incorporate the additional regulations for FMF certification into their existing accreditation system.

The license is awarded by the FMF-Germany

The certification remains in force for a period of twelve months each. In order to maintain the quality standard, every certified laboratory undertakes to participate in an ongoing quality assurance programme and to undergo regular AUDITS. This quality assurance programme provides for a regular submission of data obtained to the FMF-Germany. There, the data will be reviewed, whereupon the submitter will be awarded recertification for another twelve months, provided that all submitted values have been found to be acceptable. The risk calculation software is accessible for a period of twelve months each, and the software becomes inactive in the case of non-recertification.