# FMF-Deutschland

Section: Laboratory Diagnostics
Dr. Dr. H. Wagner

## PRENATAL INVESTIGATION IN THE FIRST TRIMESTER

## RECOMMENDATIONS AND COMPLIANCE FOR LABORATORY GLP

### D e c l a r a t i o n  o f  C o n f o r m i t y

*We, the laboratory*

*full name of the lab:* ……...
*complete adress:* ……...
*:* ……...
*Telephone No:* ……...
*Fax No:* ……...
*e-mail adress:* ……...
*Responsible contact person:* ……

*declare the following in order to achieve the certification by the FMF, London*:

1. We are CPA (UK) Ltd accredited or accredited by an equivalent country standard.

2. We intend to have a workload exceeding 1000 screens per year.

3. We participate in the UKNEQAS scheme for 1st Trimester Down's Syndrome Screening. Our participant No. is ....

4. We will demonstrate that our performance in the UKNEQAS scheme is acceptable i.e. that our analytical Bias from the Method Mean for Free Beta hCG and PAPP-A does not deviate by more than +/- 10% on an ongoing basis.

5. We perform all Prenatal Risk Calculations only using Fetal Medicine approved software which uses the Fetal Medicine Foundation risk algorithm.

6. We ensure that we take nuchal translucency measurements only from Fetal Medicine Foundation accredited Sonographers or Obstetricians/Gynaecologists.

7. We ensure that if we receive samples as whole blood that they are received within 48 hours of collection. If samples are received as serum this must be within 72 hours of collection. Use of material outside of these limitations could result in invalid Free Beta hCG results being produced.

8. We only analyse samples when the referring centre has provided a minimum data set with the request. Samples will only be analysed when the gestation is between the limits 11 week 0 days to 13 weeks 6 days.

   The minimum data set includes:

   Forename & Surname
   Gynaecologist & Referral centre address
   Patient Date of Birth
   Previous history of T21/T18/T13
   Maternal weight
   Date of NT & CRL
   NT measurement
   CRL Measurement
   Multiple Pregnancy Status
   Date of Blood Sample
   Specimen reference number

   Optional items are Smoking status and ethnic origin

9. We ensure that we use the KRYPTOR® instrument and KRYPTOR® reagents for Free Beta hCG and PAPP-A or any other instruments and reagents for the same markers provided that such instruments and reagents are approved by the FMF UK for the purpose of prenatal screening in the 1st trimester. Such assay systems must have demonstrable proven clinical performance for this use.

10. We perform Internal Quality Control procedures with each batch of samples analysed – or on a daily basis. Three level QC will be performed for the analytes Free Beta hCG and PAPP-A.

11. We commit on demonstrating the following between day CVs.

| | Free Beta - hCG | | PAPP-A | |
|---|---|---|---|---|
| | Conc (ng/ml) | CV (%) | Conc (U/l) | CV (%) |
| Level 1 | 85 | 3.0 | 0.30 | 4.0 |
| Level 2 | 20 | 3.0 | 1.50 | 4.0 |
| Level 3 | 8 | 3.5 | 4.0 | 3.5 |

12. We will also give consideration to monitoring the variability of the risk derived from a fixed maternal age, fixed gestational age and fixed NT using results from the Level 1 control. At a target risk of 1 in 250 a 10% CV of the risk should be achievable.

13. We will take part in the annual Fetal Medicine Foundation audit of screening centres.

14. We will make best efforts to follow up the outcome of all pregnancies screened or at least those identified with a risk of 1 in 300 or greater.

15. We will monitor the overall median MoM for Free Beta hCG and PAPP-A on a monthly basis. This should be within the limits 1.00 +/- 10%.

16. We will monitor the individual completed weekly medians on a 3 monthly basis to ensure they do not deviate from the expected values by more than +/- 10%.

17. The percentage of total screened cases identified with a risk of 1 in 300 or greater will be monitored on a monthly basis. Depending upon the age of the population being screened this should not be greater than 6% and less than 3%.

……
Laboratory (stamp)

…… ……
Location / Date Signature