Result of the non-invasive prenatal examination

PraenaTest®

2014-06-11*

LifeCodexx AG | Jakob-Stadler-Platz 7 | 78467 Konstanz, Germany

Dr. med. Martin Musterarzt
Musterklinik
Musterallee 13
10365 Musterstadt

Title, last name, first name of patient	
Dr. Musterfrau, Martina	
Singleton or multiple pregnancy	**Date of birth**
Singleton pregnancy	1971-11-08*
Test option	**Express service**
Test option 3	no

Sample received on	Bar code no.	Lab ID	QC	cffDNA content
2013-06-05*	99999999	LCB99999	approved	9.07 %

Chromosome	z-score	Result	Interpretation
Chromosome 21	6.3	**Outside of the normal range**	Evidence of fetal trisomy 21
Chromosome 18	0.7	Within the normal range	No evidence of fetal trisomy 18
Chromosome 13	1.0	Within the normal range	No evidence of fetal trisomy 13
Sex chromosomes		Within the normal range	No evidence of gonosomal aneuploidy

Based on this positive test result, we wish to highlight the need for genetic counseling and its significance with regard to the implications for the patient who underwent the examination and her family. According to recommendations from international professional associations, further medical clarification, usually in the form of invasive diagnostics, is urgently recommended to validate the test result. We request a response in the event of inconsistent results.

If medical reasons which necessitate a more detailed PraenaTest® analysis should arise during the course of the pregnancy, you may request a more extensive bioinformatic data analysis without the need for another blood sample using a separate form (available at www.lifecodexx.com)

Fetal sex

Male

In Germany, the fetal sex may only be disclosed to the pregnant woman with her consent after the twelfth week of pregnancy has passed, as per section 15 para. 1 German Genetic Diagnostics Act [GenDG]. Please be aware of the need to comply with corresponding national regulations in other countries.

Examination method and analysis result: The PraenaTest® for the determination of fetal trisomies 21, 18 and 13 as well as gonosomal aneuploidy is based on *next generation sequencing* and a z-score calculation following DNA isolation from maternal plasma. The bioinformatic PraenaTest® DAP.plus analysis software used as part of the PraenaTest® is CE marked. LifeCodexx AG would like to point out that 100% accuracy (referred to as sensitivity and specificity) cannot be expected during use of the PraenaTest® in practice. In general, no statements regarding structural chromosomal changes, mosaics or polyploidy can be made with the PraenaTest®. More information on the appraisal of results and accuracy of the PraenaTest®, the limits of the examination as well as fetal sex determination can be found at www.lifecodexx.com.

Konstanz, 2014-06-11*

Dr. Wera Hofmann
CSO

Dr. Sebastian Grömminger
QMB

Dr. Michael Lutz
CEO

LifeCodexx AG Jakob-Stadler-Platz 7; 78467 Konstanz, Germany, Tel. +49(0) 7531-9769460, Fax +49 (0) 7531-9769480, info@lifecodexx.com
Chairman: Dr. Michael Lutz I Freiburg im Breisgau District Court, Commercial registry 701989 I Registered office: Konstanz I VAT ID no. DE 258862614
* YYYY-MM-DD