UNIVERSITÄTS KLINIKUM jena | Placenta-Labor

Klinik für Geburtsmedizin
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Treatment contract for examination of uterine cells

Additional analysis on existing tissue

To be filled in by patient

I have been informed in detail about the analysis of uterine natural killer cells (uNK) and/or plasma cells (PZ) from an existing endometrial biopsy. The analysis only makes sense within a maximum period of 3 months after the biopsy and reflects the condition of the uterine lining (endometrium) at that time.
I have been informed that an analysis of the cytotoxic activity of the uNK cells (CD16+) can only be carried out in conjunction with a previous analysis of uterine natural killer cells (CD56+) and can only be interpreted diagnostically in the range of 100 to 400 uNK cells/mm².
I agree that the analysis will be carried out by the Placenta Lab of the Clinic for Obstetrics at the Jena University Hospital and that the costs will be charged to me as a self-payer service. I have been informed that patient confidentiality and data protection as required by law will be respected.

First name: _____

Last name: _____

Date of birth: |__|__|.|__|__|.|__|__|__|__|

Address: _____
Street, House number

_____
Postcode, City

Patient sticker

Initial analysis Number: *eg P/2023/1234* Date: |__|__|.|__|__|.|__|__|__|__|

I commission the Placenta Lab on the basis of the German GOÄ ("*Gebührenordnung für Ärzte*") to perform the following analysis on private invoice. A detailed list of the services is available on our website www.uniklinikum-jena.de/geburtsmedizin/EndometriumDiagnostik. ***If I, the patient, do not receive any or no reimbursement of the invoiced fees from my health insurance, I am obliged to bear these costs myself.***

Additional analysis on existing tissue:

☐	Cytotoxic activity of uterine NK cells (CD16+) *	**48,96 €**
☐	Analysis of the number of uterine natural killer cells (CD56+)	**97,92 or 48,96 € ****
☐	Analysis of the number of uterine plasma cells (CD138+)	**97,92 or 48,96 € ****

*Additional analysis of cytotoxic-active CD16+ cells with prior analysis of CD56+ uNK cells and detection of 100-400 uNK cells/mm²

** Price depends on the extension of an initial examination order (€ 97.92) or a control examination order (€ 48.96)

Right to object: I have the right, at any time to file an objection to specific decisions or measures concerning the processing or use of personal data relating to me (Article 21 DSGVO, §36 BDSG-new). Such processing or use of my personal data will be subsequently and indefinitely discontinued. The objection is effective upon receipt in the Placenta Lab.

I expressly declare that I have understood the meaning and content of this consent.

_____ _____
Place, Date of Signature Signature of patient

Information for patients according to the European General Data Protection Regulation (GDPR)

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data, on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

You are hereby informed of your rights as set out in the GDPR (Article 12 et seq. GDPR):

Legal basis: In the case of clinical trials, the legal basis for the processing of your personal data is your voluntary written consent in accordance with the GDPR and the Declaration of Helsinki (Declaration of the World Medical Association on the Ethical Principles for Medical Research Involving Human Subjects) and the Guideline for Good Clinical Practice. In the case of drug studies, the German Medicines Act is also the legal basis. The revised Federal Data Protection Act (BDSG-neu) comes into force in Germany at the same time as the GDPR.

Person responsible for data processing: The project manager named in the clarification in each case is responsible for data processing within the scope of research projects (hereinafter referred to as clinical studies). In matters of data protection, this person reports to the person in charge of data protection at the UKJ.

Right to information: You have the right to information about the personal data concerning you that is collected, processed or, if applicable, transferred to third parties in the context of the clinical trial (handing over a copy) (Article 15 DSGVO, §§34 and 57 BDSG-neu).

Right to rectification: You have the right to have inaccurate personal data concerning you rectified (Articles 16 and 19 DSGVO, Section 58 BDSG-neu).

Right to erasure: You have the right to erasure of personal data concerning you, e.g. if this data is no longer necessary for the purpose for which it was collected (Articles 17 and 19 DSGVO, §§ 35 and 58 BDSG-neu). However, you must be aware that the collected data may not be completely deleted or even allowed to be deleted due to other applicable regulations (ICH- GCP guideline).

Right to restriction of processing: Under certain conditions, you have the right to request the restriction of the processing of personal data, i.e. the data may only be stored, not processed. You must request this. To do so, please contact the responsible project manager (named in the declaration of consent) or the UKJ data protection officer (Articles 18 and 19 DSGVO, Section 58 BDSG-neu).

Right to data portability: You have the right to obtain the personal data relating to you that you have provided to the Clinical Study Manager. This allows you to request that this data be transferred either to you or, where technically possible, to another body designated by you (Article 20 GDPR).

Right of objection: You have the right to object at any time to specific decisions or measures concerning the processing of personal data relating to you (Art. 21 DSGVO, § 36 BDSG-neu). Such processing will then no longer take place.

Consent to the processing of personal data and right to withdraw this consent: The processing of your personal data is only lawful with your consent (Article 6 DSGVO, Section 51 BDSG- new). You have the right to revoke your consent to the processing of personal data at any time. However, the data collected up to this point may be processed by the bodies named in the patient information and consent form for the clinical trial (Article 7, Paragraph 3 DSGVO, Section 51 Paragraph 3 BDSG-neu).

If you would like to make use of one of these rights, please contact the UKJ's data protection officer. You also have the **right to lodge a complaint with a supervisory authority if** you believe that the processing of personal data concerning you violates the GDPR:

Data protection: Contact details of the data protection officer at the UKJ
Bachstraße 18, 07743 Jena
Phone: 03641 9 325624/ Fax: 03641 9 399925
E-mail: datenschutzbeauftragter@med.uni-jena.de