**Organizer:** HLA Department

 Institute of Hematology and Blood Transfusion

 U Nemocnice 2094/1, 128 20 Prague 2

 Czech Republic

**Guarantor:** MSc. Milena Vraná phone number: +420 221 977 430 e-mail: milena.vrana@uhkt.cz

**Administrator:** Petra Mazanová phone number: +420 221 977 660 e-mail: ept-hla@uhkt.cz

**Offered variants of PT:**

1. **Alleles of DQ loci associated with coeliac disease (**DQA1\*02, \*03, \*05; DQB1\*02, \*03:02)

 (5 samples in the first round + 5 samples in the second round)

1. **B\*27 (association with Morbus Bechterev and other rheumatoid autoimmune diseases)**

(5 samples / 10 samples on request)

1. **DQB1\*06:02 (association with narcolepsy)**

(5 samples / 10 samples on request)

1. **DRB1 epitopes (association with rheumatoid arthritis)**

(5 samples)

**Prices:**

|  |  |
| --- | --- |
| **variants** | **price** |
| DQ alleles associated with CD – one round | **2 500 CZK ≅ 100 €** |
| DQ alleles associated with CD – two rounds | **4 000 CZK ≅ 160 €** |
| DQ alleles associated with CD – adding the second round afteran unsuccessful participation in the first round | **2 000 CZK ≅ 80 €** |
| B\*27 | **2 500 CZK ≅ 100 €** |
| DQB1\*06:02 | **2 500 CZK ≅ 100 €** |
| DRB1 epitopes | **2 500 CZK ≅ 100 €** |
| DQ alleles associated with CD (one round) + B\*27 + DQB1\*06:02 | **5 000 CZK ≅ 200 €** |

**Bank account:** 314 380 21 / 0710

 IBAN: CZ46 0710 0000 0000 3143 8021

 SWIFT/BIC: CNBACZPP

 CIN: 00023736

 VAT ID/TIN: CZ00023736

 (an invoice based on the application form will be sent to the participant’s address)

**Important dates**: 8th April 2025 deadline for registration

April 2025 distribution of samples for DQ alleles associated with CD (the first round) + B\*27 + DQB1\*06:02 + DRB1 epitopes

31st May 2025 deadline for submitting results

June 2025 evaluation of results and issuance of certificates by the organizer

31st August 2025 deadline for registration for DQ alleles associated with CD (the second round)

September 2025 distribution of samples for DQ alleles associated with CD (the second round)

31st October 2025 deadline for submitting results

December 2025 issuance of certificates and the final report

**Evaluation of the results:**

**B\*27 a DQB1\*06:02:**

Correct evaluation of the presence/absence of a given allelic group/allele in each sample.

**DRB1 epitopes:**

Correct evaluation of the presence/absence of the predisposing/protective epitopes in each sample.

**Coeliac disease:**

**Correct detection of all alleles/allelic groups associated with a risk of coeliac disease**

* DQA1\*02, \*03, \*05; DQB1\*02, \*03:02
* Correct detection of one allele/allelic group = 1 point, incorrect detection or absence of one allele/allelic group = -1 point
* Incorrect detection of an allele from a correct allelic group = -0,5 point (except for DQB1\*03:02 and other DQB1\*03 alleles, where the mistake causes a change in interpretation)

**Marking a serological equivalent** according to the consensus of laboratories from 16. 2. 2015, i. e. positivity/negativity of DQ2 (DQ2.5, DQ2.2) and DQ8

**Interpretation of results related to the risk of coeliac disease**

* In case of positive results, it is necessary to mention a notification of low specificity of the examination (if this information is a part of your standard documentation, please make a note under the results table)

**Final evaluation**

* Genotype: successful attendance 90-100 %

unsuccessful attendance < 90 %

* Interpretation: successful attendance = all results included in the correct risk category of coeliac disease:

HLA genotype is associated with a risk of coeliac disease

HLA genotype is associated with a low risk of coeliac disease

HLA genotype is not associated with a risk of coeliac disease

 (please use a formulation, which you normally write in your reports)

**Commitment of the PT organizer:**

The PT organizer commits to carry out the organization of the PT "Determination of HLA alleles associated with diseases" on the dates specified in this application.

All the results sent by participating laboratories are considered as confidential. PT organizer commits to confidentiality in areas that could harm the laboratory. In the overview report the laboratories are labelled by codes. The identification of the specific laboratory is known only to its contact person.

Based on the sent application form the PT organizer is obliged to send to all participants anonymous DNA samples of the requested variant of the PT in labeled microtubes. Each microtube contains 50 μl of DNA of a known concentration. Simultaneously with the samples the PT organizer will send electronically a form or a link to a web interface for recording the results.

HLA of all samples were previously determined by PT organizer by the routine practice according to standard operation procedures (PCR-SSP and NGS according to NRL\_05\_SOP\_14\_02). The testing was performed using CE certified diagnostics, using results evaluation according to the recent HLA database: IMGT/HLA (http://www.ebi.ac.uk/imgt/hla/).

This commitment is guaranteed by the guarantor of the PT.

**PT participant agrees with the following conditions by submitting this application form:**

The PT participant will pay the organizer the amount stated in this application form according to the selected variant based on the invoice issued by the PT organizer.

The DNA samples can be used by the participant only for the purpose of this PT.

The participants must use the methods routinely applied for patient samples testing. All results must be reported in a complete and readable way using the form or the web interface provided by the organizer. The results must be delivered to the organizer on time by e-mail (e-mail address: ept-hla@uhkt.cz) or through the web interface.

The results and their evaluation made by the PT organizer according to the criteria stated in this application form are considered to be correct. A complaint against this fact can be sent by the PT participant by regular or electronic mail (milena.vrana@uhkt.cz or ept-hla@uhkt.cz) no later than ten days after the final report and certificate delivery.

The contact person written in this application form guarantees the compliance of the conditions by the participant.

**Participant of PT**

|  |  |
| --- | --- |
| Name of the laboratory |  |
| Address of the laboratory |  |
| IBAN, SWIFT number |  |
| VAT ID / TIN (DIČ) |  |
| Contact person:(title) name, surname |  |
| Contact telephone number |  |
| Contact e-mail address |  |
| Authorized person:(title) name, surname |  |
| Contact e-mail address |  |
| **PT variant** | **Price** | **Choose a variant(mark off YES / NO)** |
| DQ alleles associated with CD – one round | 2 500 CZK ≅ 100 € | [ ]  YES [ ]  NO |
| DQ alleles associated with CD – two rounds | 4 000 CZK ≅ 160 € | [ ]  YES [ ]  NO |
| DQ alleles associated with CD – adding the second round after an unsuccessful participation in the first round | 2 000 CZK ≅ 80 € | [ ]  YES [ ]  NO |
| B\*27Note | 2 500 CZK ≅ 100 € | [ ]  YES [ ]  NO |
| DQB1\*06:02Note | 2 500 CZK ≅ 100 € | [ ]  YES [ ]  NO |
| DRB1 epitopes | 2 500 CZK ≅ 100 € | [ ]  YES [ ]  NO |
| DQ alleles associated with CD (one round) + B\*27 + DQB1\*06:02 | 5 000 CZK ≅ 200 € | [ ]  YES [ ]  NO |
| Surcharge for transport outside the Czech Republic | 1 000 CZK ≅ 40 € | [ ]  YES [ ]  NO |
| Surcharge for transport outside the European Union | 1 500 CZK ≅ 60 € | [ ]  YES [ ]  NO |

Note If you enter "YES", we will automatically send you 5 samples. If you would like to receive 10 samples, please state "YES/10 SAMPLES", the price remains the same.

In date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of the contact person

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of the authorized person