**Organizer:** HLA Department

Institute of Hematology and Blood Transfusion

U Nemocnice 2094/1, 128 20 Prague 2

Czech Republic

**Guarantee**: MSc. Milena Vraná phone number: +420 221 977 484, e-mail: milena.vrana@uhkt..cz

**Administrator:** MSc. Barbora Kinská phone number: +420 221 977 144, e-mail: barbora.kinska@uhkt.cz

**Offered variants of PT:**

1. **Alleles of DQ loci alleles associated with coeliac disease (**DQA1\*02, \*03, \*05, DQB1\*02, DQB1\*03:02)
2. samples in the first part + 5 samples in the second part)

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

1. samples/ 10 samples on request)

 **3 DQB1\*06:02 (association with narcolepsy)**

(2 samples/ 10 samples on request)

**Price:**  DQ alleles associated with CD – one series **1 600,- CZK ≅ 64,- Euro**

 DQ alleles associated with CD – two series **2 200,- CZK ≅ 88,- Euro**

DQ alleles associated with CD – adding the second

 series after unsuccessful participation in the first series **1 000,- CZK ≅ 40,- Euro**

 B\*27 **1 200,- CZK ≅ 48,- Euro**

 DQB1\*06:02 **850,- CZK ≅ 34,- Euro**

 DQ alleles associated with CD (one series) +

 + B\*27 + DQB1\*06:02 **3 250, - CZK ≅ 129,- Euro**

**Bank account:** 31438021/0710

 IBAN: CZ4607100000000031438021

 SWIFT: CNBACZPP

 IČO: 00023736

 DIČ: CZ00023736 (VAT)

(An invoice based on the application form will be sent to the participant´s address)

**Terms**: 15. 4. 2021 deadline for registration

April 2021 samples distribution for DQ alleles associated with CD (the first series) + B\*27 +

 + DQB1\*06:02

31. 5. 2021 deadline for results submission

June 2021 release of the final report and certificate

31. 8. 2021 deadline for registration for DQ alleles associated with CD (the second series)

September 2021 samples distribution for DQ alleles associated with CD (the second series)

31. 10. 2021 deadline for results submission

December 2021 release of the final report and certificate

**Results evaluation:**

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

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

**Coeliac disease:**

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

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

**Marking serological equivalent** according to the consensus of laboratories from 16.2.2015, which means positivity/negativity of DQ2 (DQ2.5, DQ2.2) and DQ8 respectively

**Interpretation of results related to the risk of CD**

* 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 a table)

**Final evaluation**

* Genotype successful attendance 91 – 100 %

unsuccessful attendance ≤ 90 %

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

 HLA genotype is associated with a risk of celiac disease

 HLA genotype is associated with a low risk of celiac disease

 HLA genotype is not associated with a risk of celiac disease

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

**Commitment of PT organizer:**

The terms given in this application form are guaranteed by organizer.

All the results sent by participating laboratories are considered to be 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 it´s 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 signed testing micro tubes. Each micro tube contains 50 μl of DNA of known concentration. Simultaneously with the samples the PT organizer will send electronically the result form.

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

This commitment is guaranteed by the guarantee of the PT.

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

The PT participant will realize the payment mentioned in this form based on the invoice from the organizer.

The DNA samples can be used by 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 using the form provided by the organizer in complete and readable form and results simultaneously send in form of reports used in the routine practice. The results must be delivered to the organizer on time by e-mail (e-mail address: milena.vrana@uhkt.cz) or by regular mail.

The results and their evaluation made by PT organizer according to criteria in this application form are considered to be correct. A complaint against this fact can be sent by PT participant by regular or electronic mail milena.vrana@uhkt.cz or barbora.kinska@uhkt.cz) not 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 participants.**Participant of PT**

|  |  |
| --- | --- |
| Name of the laboratory |  |
| Address of the laboratory |  |
| IBAN, SWIFT number (IČO) |  |
| VAT number (DIČ) |  |
| Contact person:(title) name, surname |  |
| Contact telephone number |  |
| Contact e-mail address |  |
| Authorized person:(title) name, surname |  |
| Contact telephone number |  |
| Contact e-mail address |  |
| **PT variant** | Price | Choose variant (mark off yes / no) |
| (DRB1), DQA1, DQB1 – one part | 1 600,- CZK / 64,- Euro | □ yes □ no |
| (DRB1), DQA1, DQB1 – two parts | 2 200,- CZK / 88,- Euro | □ yes □ no |
| (DRB1), DQA1, DQB1 – adding the second part due to not be succesful in the first part | 1 000,- CZK / 40,- Euro | □ yes □ no |
| B\*27 Note | 1 200,- CZK / 48,- Euro | □ yes □ no |
| DQB1\*06:02 Note | 850,- CZK / 34,- Euro | □ yes □ no |
| (DRB1), DQA1, DQB1 (one part) + B\*27 + DQB1\*06:02 | 3 250,- CZK / 129,- Euro  | □ yes □ no |

Note If you enter "YES", 3 or 2 samples will be automatically sent to you. If you want to send 10 samples, please state "YES / 10 SAMPLES", the price remains the same.

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

 Signature of the contact person

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

 Signature of the authorized person