

**The Appendix is an integral part of
Certificate of Accreditation No. 291/2024 of 13/06/2024**

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

Zdravotní ústav se sídlem v Ústí nad Labem

CAB Number 8065, Department of Laboratory Immunology of the Centre for Immunology and
Microbiology
Na Kabátě 229, 400 11 Ústí nad Labem

Medical laboratory locations:

1. **Workplace Ústí nad Labem** Na Kabátě 229, 400 11 Ústí nad Labem
2. **Workplace Praha** Dittrichova 329/17, 120 00 Praha 2

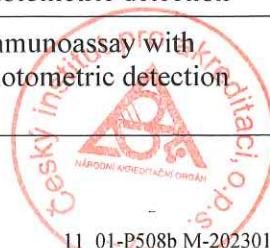
The laboratory applies a flexible approach to the scope of accreditation.

*The current "List of activities within the flexible scope" is available on the website
<https://www.zuusti.cz/laboratorni-imunologie-usti-nad-labem/>.*

1. Workplace Ústí nad Labem

Examinations:

| Ordinal Number | Analyte/ parameter/diagnostics | Principle of examination | Identification of procedure/equipment | Examined material | Degrees of freedom ¹ |
|------------------------------------|---|---|--|----------------------|---------------------------------------|
| 801 – Clinical Biochemistry | | | | | |
| 1. | Albumin | Absorption spectrophotometry | Commercial procedure | Serum, plasma | A, B |
| 2. | Total protein | Absorption spectrophotometry | Commercial procedure | Body fluids | A, B, D |
| 3. | Albumin | Immunonephelometry | Commercial procedure | Cerebrospinal fluid | A, B |
| 802 – Medical Microbiology | | | | | |
| 1. | Antibodies against infectious agents | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 2. | Antigens of infectious agents | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 3. | HIV markers | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B |
| 4. | Antigens of infectious agents | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 5. | Post-vaccination antibodies | Immunoassay with photometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 6. | Antibodies against <i>Borrelia burgdorferi</i> s.l. | Immunoassay with photometric detection | Commercial procedure | Serum, plasma | A, B |



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| Ordinal Number | Analyte/ parameter/diagnostics | Principle of examination | Identification of procedure/equipment | Examined material | Degrees of freedom ¹ |
|--|---|---|--|--|---------------------------------------|
| 7. | Antibodies against <i>Treponema pallidum</i> | Immunoassay with photometric detection | Commercial procedure | Serum, plasma | A, B |
| 8. | Antibodies against <i>Treponema pallidum</i> | Indirect immunofluorescence | Commercial procedure | Serum, plasma | A, B |
| 9. | Antibodies against Tick-borne Encephalitis virus | Immunoassay with photometric detection | Commercial procedure | Serum, plasma | A, B |
| 10. | Antibodies against pertussis toxin | Immunoassay with photometric detection | Commercial procedure | Serum, plasma | A, B |
| 11. | Antibodies against infectious agents | Immunoblotting | Commercial procedure | Serum, plasma | A, B, C |
| 12. | Intrathecal antibody synthesis against infectious agents | Immunoassay with photometric detection | Commercial procedure | Serum, plasma, cerebrospinal fluid | A, B, C |
| 813 - Allergology and Immunology Laboratory | | | | | |
| 1. | Immunoglobulins | Immunoturbidimetry | Commercial procedure | Serum, plasma | A, B, C |
| 2. | Specific proteins | Immunoturbidimetry | Commercial procedure | Serum, plasma | A, B, C |
| 3. | Rheumatoid factor | Immunoturbidimetry | Commercial procedure | Serum, plasma | A, B |
| 4. | Antistreptolysin O (ASLO) | Immunonephelometry | Commercial procedure | Serum, plasma | A, B |
| 5. | IgG subclasses | Immunonephelometry | Commercial procedure | Serum, plasma | A, B |
| 6. | Immunoglobulins | Immunonephelometry | Commercial procedure | Cerebrospinal fluid | A, B |
| 7. | Albumin quotient and intrathecal synthesis of total immunoglobulins | Calculation | Commercial procedure | Serum, plasma, cerebrospinal fluid | A, B |
| 8. | Detection and typing of paraprotein | Electrophoresis and immunofixation | Commercial procedure | Serum, plasma, urine | A, B |
| 9. | Oligoclonal IgG | Isoelectric focusing | Commercial procedure | Serum, cerebrospinal fluid | A, B |
| 10. | Total IgE | Fluorescence immunoassay | Commercial procedure | Serum, plasma | A, B |

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| Ordinal Number | Analyte/ parameter/diagnostics | Principle of examination | Identification of procedure/equipment | Examined material | Degrees of freedom ¹ |
|--|--|---|--|------------------------------------|---------------------------------------|
| 11. | Specific IgE | Fluorescence immunoassay | Commercial procedure | Serum, plasma | A, B |
| 12. | Immunophenotyping of cell populations | Flow cytometry | Commercial procedure | Blood | A, B, C |
| 13. | INF γ after T cells stimulation by <i>Mycobacterium tuberculosis</i> antigens | Immunoassay with photometric detection | Commercial procedure | Plasma | A, B |
| 14. | Autoantibodies | Indirect immunofluorescence | Commercial procedure | Serum, plasma | A, B, C |
| 15. | Neuronal autoantibodies | Indirect immunofluorescence | Commercial procedure | Serum, plasma, cerebrospinal fluid | A, B, C |
| 16. | Autoimmune encephalitis-associated antibodies | Indirect immunofluorescence | Commercial procedure | Serum, plasma, cerebrospinal fluid | A, B, C |
| 17. | Autoantibodies | Fluorescence immunoassay | Commercial procedure | Serum, plasma | A, B, C |
| 18. | Autoantibodies | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 19. | Autoantibodies | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 20. | Autoantibodies | Immunoassay with photometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 21. | Autoantibodies | Immunoblotting | Commercial procedure | Serum, plasma | A, B, C |
| 22. | Neuronal autoantibodies | Immunoblotting | Commercial procedure | Serum, plasma | A, B, C |
| 815 - Nuclear Medicine Laboratory | | | | | |
| 1. | Prostate-specific antigen - total (PSA) | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B |



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2. **Workplace Praha**

Examinations:

| Ordinal Number | Analyte/parameter/diagnostics | Principle of examination | Identification of procedure/equipment | Examined material | Degrees of freedom ¹ |
|--|--------------------------------------|---|---------------------------------------|-------------------|---------------------------------|
| 802 – Medical Microbiology | | | | | |
| 1. | Antibodies against infectious agents | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B, C |
| 2. | HIV markers | Immunoassay with luminometric detection | Commercial procedure | Serum, plasma | A, B |
| 813 - Allergology and Immunology Laboratory | | | | | |
| 1. | Immunoglobulins | Immunonephelometry | Commercial procedure | Serum, plasma | A, B, C |
| 2. | C-reactive protein (CRP) | Immunonephelometry | Commercial procedure | Serum, plasma | A, B |
| 3. | Total IgE | Fluorescence immunoassay | Commercial procedure | Serum, plasma | A, B |
| 4. | Specific IgE | Fluorescence immunoassay | Commercial procedure | Serum, plasma | A, B |
| 5. | Autoantibodies | Indirect immunofluorescence | Commercial procedure | Serum, plasma | A, B, C |
| 6. | Calprotectin | Fluorescence immunoassay | Commercial procedure | Stool | A, B |

Explanatory notes:

¹ Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination / sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself."

