Quality Assessment and Standardization

Executive Committee – 20.November, 2021
Established subcommittees under QAS Committee

• Allergen Standardization - Stefan Vieths – Germany
• Autoantibodies in Rheumatic and Related Diseases – Edward Chan - USA
• Complement – Michael Kirschfink – Germany
• Leukocytes – Pablo Engel – Spain
• Big data in Immunology – Jamie Scott – USA
• Cytokines – Menu Wadha (NIBSC - London) ➔ in negotiation
Expansion in the scope of QAS Committee

New Subcommittees to be developed

- Serology in infectious diseases
- Autoantibodies in autoimmune liver diseases
- Autoantibodies in autoimmune endocrine diseases
- Autoantibodies in autoimmune neurological diseases
- Autoantibodies in autoimmune dermatologic diseases
- HLA determination
- Immunological tests in Inborn Errors of Immunity
• Research Topic in Frontiers in Immunology
• Allergen Subcommittee
• Autoantibody Standardization Subcommittee
• Big-Data for Immunology Subcommittee
• Complement Subcommittee
• Cytokine Subcommittee
• Leukocyte Subcommittee
Contemporary Challenges in Immunologic Testing in Clinical and Research Laboratories

12th International Workshop on Autoantibodies and Autoimmunity (IWAA)

Topic editors
Luis Andrade, K. Michael Pollard, Allan Wiik, Edward Chan
Contemporary Challenges in Immunologic Testing in Clinical and Research Laboratories

Topic editors
Luis Andrade, Edward Chan, Pablo Engel, Michael Kirschfink, Stefan Vieths
Contemporary Challenges in Immunologic Testing in Clinical and Research Laboratories

Impact increase rate - November 19, 2021

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Contemporary Challenges in Immunologic Testing in Clinical and Research Laboratories

Impact up to November 19, 2021
Contemporary Challenges in Immunologic Testing in Clinical and Research Laboratories

Impact up to November 19, 2021

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- Canada: 1,823

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- pubmed.ncbi.nlm.nih.gov: 1,191
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- t.co: 583
Report progress 2020/2021

• Research Topic in Frontiers in Immunology

• **Allergen Subcommittee**

• Autoantibody Standardization Subcommittee

• Big-Data for Immunology Subcommittee

• Complement Subcommittee

• Cytokine Subcommittee

• Leukocyte Subcommittee
The General Text for the European Pharmacopoeia (Ph. Eur.) describing the Bet v 1-specific ELISA (2.7.36 Assay of Bet v 1 allergen)

The corresponding text for the Phl p 5-specific ELISA is currently in final reconciliation with the Allergen Working Party at the EDQM

A new project was initiated to prepare a second batch of the two respective CRS (Bet v1 and Phl p5)

Report progress 2020/2021

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The total number of reference sera available from ASC now is 23, distributed worldwide free of charge (https://asc.dental.ufl.edu/reference-sera/).

Three new reference sera were added in 2021, containing autoantibodies directed against multiple nuclear dots, GW bodies, and NuMA protein, respectively.

Three other reference sera are in the process of validation, containing antibodies to sp100, mitotic spindles, and nuclear envelope protein gp210, respectively.
Autoantibody Standardizing Subcommittee - 2021

Edward Chan, USA

**International Consensus on ANA Patterns - ICAP**

- Promotes the harmonization and standardization in the indirect immunofluorescence assay on HEp-2 cells (HEp-2 IFA), historically known as the antinuclear antibody (ANA) test.

- Activities of ICAP in the period 2020/2021 include:
  - Over 3,200 registered users from over 100 countries in the five continents.
  - First ICAP training module released free of charge at the website; second, third, and fourth modules are in preparation.
  - Website translated into 13 languages with 2 more ready-to-go in late 2021.
  - FAQ – committee members address questions raised from users on a regular basis
  - The ICAP patterns classification algorithm was edited and updated in 2021.
• Over 3,200 registered users from over 100 countries in the five continents.
• First ICAP training module released free of charge at the website; second, third, and fourth modules are in preparation.
• Website translated into 13 languages with 2 more ready-to-go in late 2021.
• FAQ – committee members address questions raised from users on a regular basis
HEp-2 CIC project: Clinical and Immunological Characterization of HEp-2 IFA Patterns

March 12, 2021 • Quality Assessment and Standardization Committee (QAS)

By Professor Luis E. C. Andrade, Rheumatology Division, São Paulo Federal University, São Paulo, Brazil

This is a project of the Autoantibody Standardization Committee and the International Consensus on ANA Patterns (ICAP), under the Quality Assessment and Standardization Committee of the International Union of Immunological Societies (UIIS).

Autoantibodies are a hallmark of systemic autoimmune diseases and the indirect immunofluorescence assay on HEp-2 cells (HEp-2 IFA), historically known as the antinuclear antibodies (ANA) test, is usually performed as part of the initial diagnostic workup in these patients. HEp-2 IFA offers preliminary information on the possible autoantibodies in a given sample, according to the morphological immunofluorescence patterns. Since 2014, the International Consensus on ANA Patterns (ICAP), an UIIS initiative, has developed a consensus classification of the most consistent HEp-2 IFA patterns, with representative images and detailed information available at www.anapatterns.org.
World distribution of the participants

MIDDLE EAST AND AFRICA
- India
- Algeria
- Saudi Arabia
- Kuwait
- Israel
- Egypt
- South Africa

CENTRAL AND SOUTH AMERICA
- Argentina
- Brazil
- Ecuador
- Colombia
- Chile
- Uruguay
- Mexico

ASIA AND OCEANIA
- Russia
- Australia
- New Zealand
- South Korea
- Hong Kong
- Japan
- China

NORTH AMERICA
- USA
- Canada

36 countries
52 participating centers
Publications

Report progress 2020/2021

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- Leukocyte Subcommittee
Jamie Scott, USA

• Overall goal: To standardize (and/or make interoperable) metadata, following well-defined clinical and experimental ontologies to support sharing of all types of big data for immunology.

• From the wide variety of BDI, we chose to first focus on three types of data:
  • Flow cytometry/CYTOF data
  • RNA-seq data
  • Adaptive immune receptor repertoire sequencing (AIRR-seq) data.

• Six meetings were held over the past year.

• Selection of appropriate members, approved the proposal for this subcommittee, and completed its Terms of Reference.
• Research Topic in Frontiers in Immunology

• Allergen Subcommittee

• Autoantibody Standardization Subcommittee

• Big-Data for Immunology Subcommittee

• Complement Subcommittee

• Cytokine Subcommittee

• Leukocyte Subcommittee
In 2020 ➔ 207 laboratories from >30 countries participated in the full program (determination of 20 complement parameter including multiple autoantibodies and activation products)

In the past 12 months ➔ the 13th and 14th complement external quality assessment programs (EQA)

13th EQA (March 2021) ➔ 186 Labs enrolled ➔ 11 parameters are included (restricted to the widely used complement determinations and anti-C1q)

14th EQA (October 2021) ➔ 222 labs have now participated.
Complement Subcommittee - 2021

Michael Kirschfink, Germany

Publications


Complement Subcommittee - 2021

Michael Kirschfink, Germany

Publications


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The International Cytokine and Interferon Society (ICIS) Standards Committee was established to make recommendations regarding interferon and cytokine standards and standardization. The Committee works closely with WHO, NIBSC, NIH, the Biodefense and Emerging Infections Resources Repository (BEI Resources), pharmaceutical manufacturers, and regulatory agencies. Contributed the manuscript “The First WHO International Standard for Adalimumab: Dual Role in Bioactivity and Therapeutic Drug Monitoring” to the Research Topic edited by the QAS Committee. Currently, the ICIS Standards Committee has expanded its activities to embrace the standardization of therapeutic monoclonal antibodies against cytokines/receptors.
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The goal of this project was to define the expression patterns of all established CD molecules using 8 color-flow cytometry.

This project determined the quantitative expression of these cell markers in 44 different subsets of leukocyte and lymphocyte of the blood, tonsil, and thymus.

Website, database, publications, and lectures

• The HCDM/HLDA web www.hcdm.org has been improved
• A database with the expression results corresponding to CD1 to CD100 has been already finished and will be open to the public and can be found on our website www.hcdm.org (http://bioinformin.cesnet.cz/CDmaps/).
• Engel P Antibody validation for flow cytometry. Reproducible Science Week (ABCAM) Cambridge (UK).1st June. 2020 (virtual meeting)
• Engel P Reproducibility Crisis and Antibody Validation for Flow Cytometry ISAC Webinar. 3rd March 2021 (virtual meeting)
Independent fund raising linked to specific projects

• **Autoantibody Standardization Subcommittee**
  
  • Self funding using unrestricted educational grants from private industries in the area of diagnosis ➔ US$ 35,000

• **Leukocyte Committee**

  • Funding for specific projects: **56,000 Euros**
    
    • Biolegend, Thermo Fisher, BD, Biolegend, ExBio, Bio-techne (R&D)
Autoantibody Standardization Subcommittee