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HEP-2 CIC PROJECT: HETEROGENEITY IN OPERATIONAL PROCESSING AND REPORTING RESULTS OF IFA HEP-2 PATTERNS WORLDWIDE

Topic: AS43 STANDARDIZATION OF DIAGNOSTICS

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Background and Aims

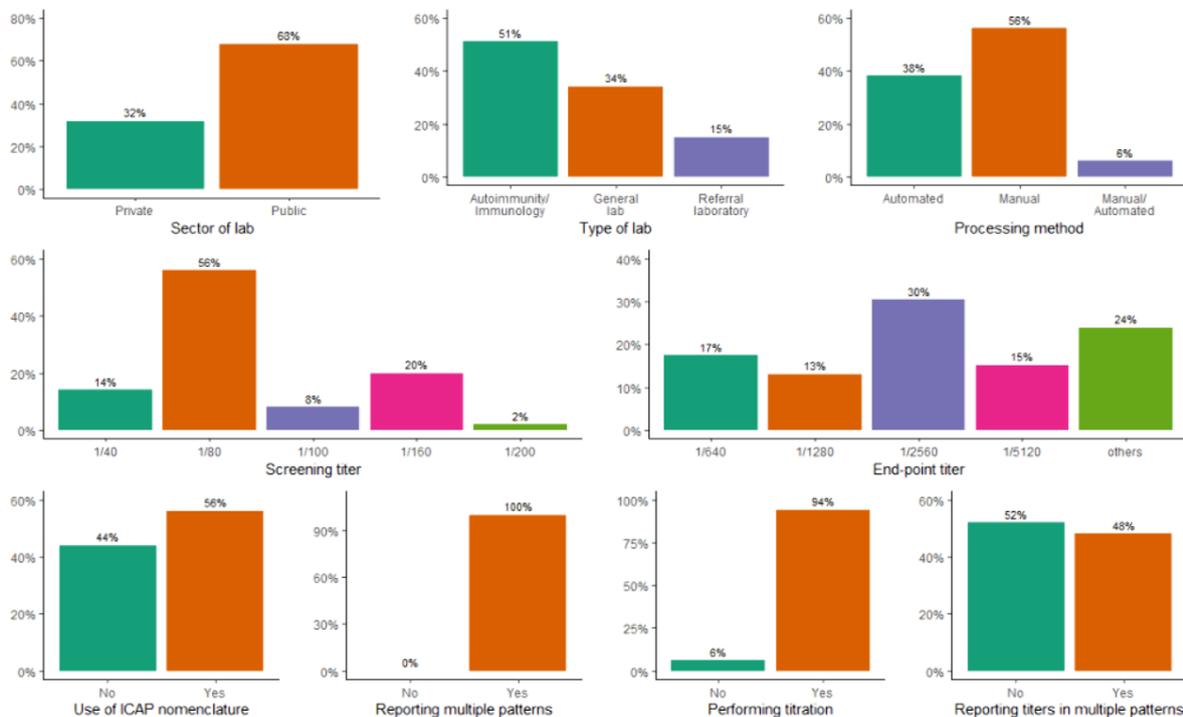
Historically, there is considerable heterogeneity in the recognition and classification of HEP-2 IFA patterns worldwide. Aiming to expand the efforts for international standardization in the HEP-2 IFA test, ICAP launched the HEP-2 CIC project: Clinical and Immunological Characterization of HEP-2 Patterns, which aims to collect information on methodology and result reporting in laboratories across the world.

Methods

Participating laboratories were selected obeying a criterion of global geographical representation and were required to provide information on the characteristics of the laboratory and the HEP-2 IFA methodological operation. Invited participating laboratories should have expertise in autoantibody testing, consistent scientific productivity in the field, and/or recommendation by members of the ICAP executive board.

Results

The study comprised data from 53 laboratories in 34 different countries and five continents. The image below summarizes the results obtained in the present study.



Conclusions

The HEp-2 IFA test is a very useful and worldwide used method for screening for autoantibodies against a host of cellular antigens. However, there is considerable variability in results obtained in different laboratories. Part of the heterogeneity derives from the diversity of HEp-2 slide brands with inherent differences in the methods of cell culture, fixation, permeabilization, as well as particularities in fluorescent conjugate and buffers. The present results add operational aspects that contribute to the heterogeneity in results, including heterogeneity in the screening and end-titer dilutions, manual versus automated processing, and nomenclature of patterns. These results emphasize the need for improvement in standardization and harmonization in the operational processing and reporting strategy of the HEp-2 IFA test.