Sebia IF program is now 1.5 times faster, yielding same performances than classical IF

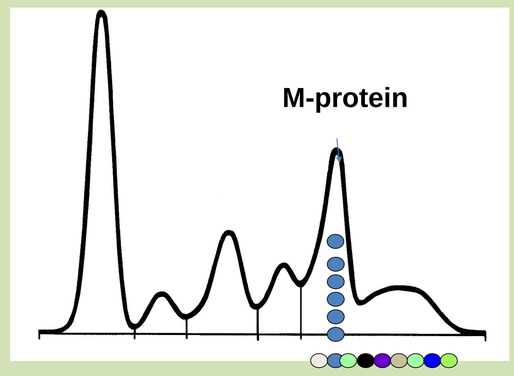
A. Chesnay [1], H. Bautista [2], G. Nouadje [2], F. Schellenberg [1] & E. Piver [1]

[1] Service de Biochimie & Biologie Moléculaire Hôpital Trousseau CHU Tours, [2] Sebia, Lisses, France.

Background

Monoclonal gammopathies are characterized by the presence of a monoclonal protein (MP) in the serum or in the urine of patients. At screening, immunofixation (IFE) is used to confirm monoclonality and to indentify the heavy-chain (gamma, alpha, mu, delta, or epsilon) and/or light-chain type (kappa or lambda) of an M-protein initially detected by protein electrophoresis (PE). In the follow-up, IFE is required when the M-protein is no longer visible on PE, moreover it allows assessing response to therapy. In order to improve labs workflow, Sebia has made its IF program 1.5 times faster.

The aim of the study was to assess the analytical performances of the IF program in its high speed evolution, compared to the results of previous versions.

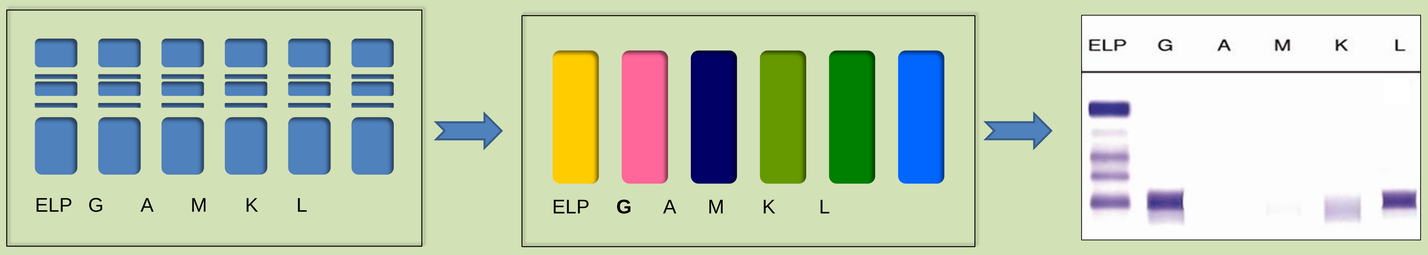


Materials and methods

PE **IFE**

•IFE were carried out on the Hydrasys Focusing system with both versions of IF programs and the Kit Hydragel 4 IF dynamic mask (Sebia, Lisses, France) according to manufacturer's instructions. Studies of limit of sensitivity and specifity have been made.
•Visual interpretation of results has been done independently by several experts

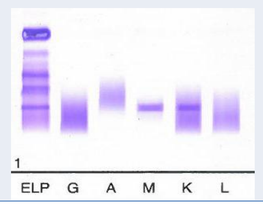
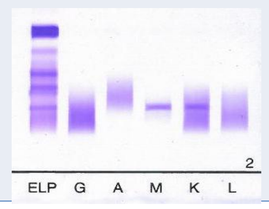
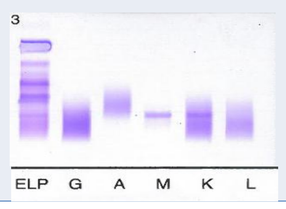
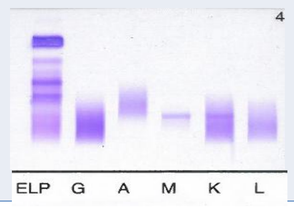
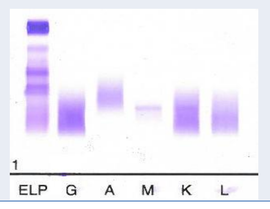
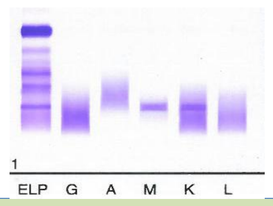
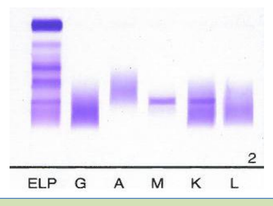
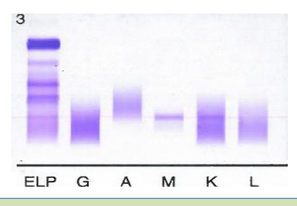
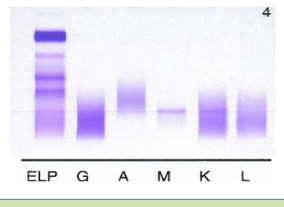
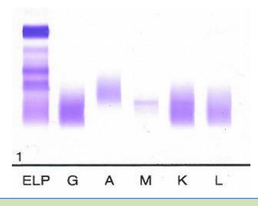
Immunofixation technique



The current IF program is 1.5 times faster than the ancient version

Results

Limit of sensitivity

Concentration (g/L)	2	1	0,5	0,25	0,125
Previous version					
New version					

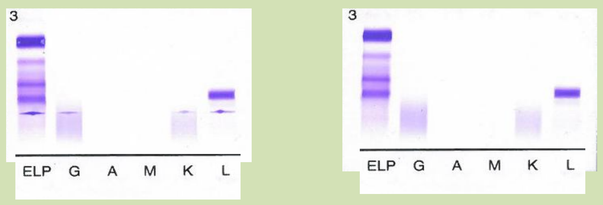
•In this table is reported the example of dilution of a MP IgM kappa diluted into a normal serum.
•The same test have been made with the same MP diluted into a serum with a hypogammaglobulinemia.
•Tests have been also made in this two conditions of serum dilution with a MP IgG lambda and IgA kappa.

•The three MP were detectable in both conditions up to 0.125 mg/L. For a given dilution, the band intensity and migration position were identical with both version of the programs.

Specificity

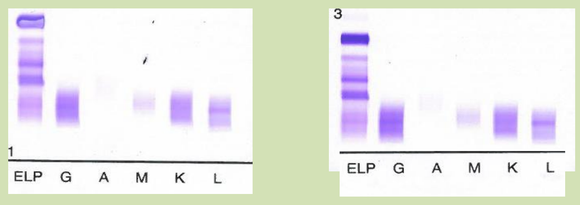
Specificity was tested with serum samples (n=25) collected from: 1) patients with a known gammopathy, 2) patients with MP at PE and unknown symptoms, 3) patients with abnormal kappa/lambda ratio and non-conclusive with the PE.

1) **Previous** **New**



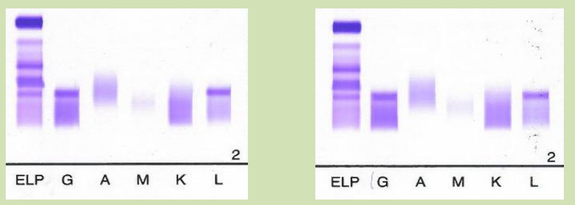
Free light chains or lambda IgD or lambda IgE

2) **Previous** **New**



Oligoclonal profile

3) **Previous** **New**



MP IgG lambda

The 25 samples yielded identical IFE patterns with both previous and adapted programs, confirming the presence or absence of MP as well as the presence of oligoclonality and hypergammaglobulinemia.

Conclusion

Overall results obtained with the adapted IF program demonstrate an equivalent sensitivity and specificity to the previous Sebia IF assay.