

Institution

**Fakultní nemocnice Hradec
Králové**

Vlastník

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also an indirect method. Our method is suitable even for more complex samples with multiple clones and allows individual clones to be matched or distinguished from each other. Our method is based on the principle of HPLC with UV detection, which distinguishes it from other protocols. The new method is particularly beneficial for the patient, as the MRD check will be less invasive and only a blood draw will be sufficient instead of a bone marrow collection. This less invasive monitoring is also associated with a possible increase in the interval of follow-ups, which could catch a relapse earlier than is currently the case, when patient follow-up is limited to a maximum number of bone marrow collections (approximately 1 per year). According to the tests performed, the new method is about 6 times more sensitive than immunofixation electrophoresis, which will allow better estimation of the depth of treatment response and earlier detection of relapse. It can distinguish pathological antibodies from therapeutic antibodies administered to the patient, which in some tested samples after treatment meant an incorrectly determined therapeutic response. It can also better handle oligoclonal profiles in samples and typify the M-proteins contained in them. It can identify original clones present before treatment or distinguish them from clones that appeared after treatment. All this from about 60 µl of serum. The method uses a common analytical instrument, which makes it easy to use and thus has the potential to replace standard immunofixation electrophoresis, avoiding invasive and problematic bone marrow aspiration and thus facilitating early detection of disease relapse due to the possibility of close patient monitoring at short intervals.

Commercial opportunity

MM represents about 10 % of all blood cancers. Its incidence in the Czech Republic is increasing from 6.3 to 18.8 living MM patients per 100,000 population in the period 1990-2014. The incidence of MM is higher in the Afro-Caribbean population. The global prevalence of MM is currently set at 0.7 %, which represents approximately 1 case in 132 individuals. The majority of MM patients are not cured (almost 50 %) and 100 % of patients relapse after treatment. Monitoring of patients is therefore very important. The method is now being prepared to complete full analytical and clinical validation according to Act No. 375/2022 Coll. on medical devices and in vitro diagnostic medical devices, which introduces the IVDR Regulation into Czech legislation. The validation will take place in the laboratory of the Department of Clinical Biochemistry and Diagnostics of the University Hospital Hradec Králové, as a laboratory of a healthcare facility compliant with EN ISO 15189. A minimum of 760 samples will be involved. This will increase

the commercialization potential of the methodology and reduce the risks for a potential investor who would finance the commercialization of the technology as an IVDR certified kit or as a SW for a chromatograph.