

Blood Cancer Sample to Insight® Series: Real-Life Experience

Faster *BCR::ABL1* Mbcr detection and quantification for improved CML patient care

Volkan Baltacı, medical geneticist and founder of Mikrogen Genetic Diseases Diagnostic Center

About the laboratory

Mikrogen Genetic Diseases Diagnosis Center was founded in 2004 in Ankara, Turkey. Since then, with the expansion of its test repertoire, Mikrogen has been providing services to the Middle East, Africa and Europe as a genetic diagnostics laboratory developing novel methods and technologies for diagnosis. Mikrogen performs about 60,000 tests/month.

The laboratory has ISO 15189 accreditation and provides an extensive genetic testing portfolio including hematology, oncology, rare diseases and PGT-A/M diagnosis tests. Since 2016, Mikrogen has provided molecular oncohematology testing for several fusion biomarkers including *BCR::ABL1*.



The *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit (24) CE

The challenge

Chronic myeloid leukemia is a myelo-proliferative neoplasm that accounts for 15–20% of all adult leukemia cases (1). It is characterized by the chronic accumulation of certain blood cells that are *BCR::ABL1*-positive. Testing for *BCR::ABL1* fusion gene is key to monitoring CML in patients.

Since its establishment, Mikrogen has been carrying out pre-implantation genetic testing—including single-cell studies – with a strong logistic network and 2-day reporting periods.

In 2014, Mikrogen started focusing on rare disease screening and began to offer many single-gene sequencing services, including oncohematology testing. When it comes to oncohematology testing, labs generally struggle with targeting short reporting periods and meeting the need for testing portfolio variety.

Mikrogen was proactive and wanted to choose test solutions that would let them continue to deliver on speed and consistency.

The laboratory decided on QIAGEN's *ipsogen*® RT-PCR-test solutions. For CML cases specifically, they chose the *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit (24) CE.



Prof. Volkan Baltacı



Being able to get good technical assistance in case of any problems was another of our considerations," Baltacı explains. "QIAGEN Application Specialists were fully involved in implementing the *ipsogen BCR::ABL1* gene fusion assays. With their technical support, the implementation process was quite easy."

Volkan Baltacı, Professor,
Medical geneticist and Founder of Mikrogen Genetic Diseases Diagnosis Center.

Why the *ipsogen* BCR-ABL1 kit?

Mikrogen needed high-quality assay kits to meet its speed, specificity, sensitivity and reproducibility requirements, as well as a ready-to-use analysis tool for reporting test results. The chosen solutions needed to be compatible with its routine extraction protocols and qRT-PCR devices. It also needed to allow for fast and easy data analysis and reporting, in line with International Scale (IS) standardization.

The *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit met all the criteria.

The benefits

The *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit (24) CE provides high specificity, sensitivity and reproducibility, standardized to the IS which are all vital for monitoring. With them, the lab can report test results in a short time with high accuracy—eliminating test repetition, expediting turnaround times and keeping costs down.

Using the *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit (24) CE facilitated the ISO 15189 accreditation of Mikrogen. The IS-MMR calibrator included in the kits allowed us to demonstrate quantitative verification results needed for the accreditation processes.

Mikrogen has always had its eye on expanding its range of tests. "Thanks to the perfect experience with the *ipsogen* BCR-ABL1 assay kits, we plan to expand our test portfolio even more," Baltacı adds.

"We can now provide certainty to patients in very short periods of time, which in turn also accelerates the therapeutic actions to be taken. Moreover, we can import the sequential results of patients to software to track their diagnostic status".

Prof. Volkan Baltacı

The impact of COVID-19

As a laboratory solely focused on testing services, Mikrogen had to adapt quickly to the new and unexpected situation. They had to open a COVID-19 testing unit in the lab and assign personnel and equipment.

"However, even in the harshest days of the pandemic, all Mikrogen lab units, including the oncohematology department, continued to provide testing services with undeniable dedication so that our patients would not suffer," Baltacı explains.

Learnings

- QIAGEN's *ipsogen* BCR-ABL1 test solution allowed the laboratory to offer speedy, specific and sensitive tests to its business partners and patients. With the test kits, the laboratory prevented reporting delays and significantly shortened its turnaround times.
- The *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit (24) CE allowed for fast and easy data analysis and reporting, in line with International Scale (IS) standardization.
- The easy implementation process and technical support provided ensured little to no downtime, and did not impact the laboratory's operations.

References:

1. Findakly D, Arslan W. Clinical Features and Outcomes of Patients With Chronic Myeloid Leukemia Presenting With Isolated Thrombocytosis: A Systematic Review and a Case From Our Institution. Cureus. 2020 Jun 23;**12**(6):e8788. doi: 10.7759/cureus.8788. PMID: 32596094; PMCID: PMC7314366

In line with established HUGO Gene Nomenclature Committee (HGNC) recommendations for the fusion gene nomenclature (Bruford EA, et al. Leukemia. 2021, https://doi.org/10.1038/s41375-021-01436-6), we are implementing use of italics and double colon (::) for fusion genes designation (e.g. *BCR::ABL1*). However historical nomenclature (e.g. BCR-ABL1) may persist in our materials.

Learn more about CML and how QIAGEN is helping combat it **www.qiagen.com/cml**

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