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

Improved leukemia patient care with molecular detection and quantification

Munyoro Guvamatanga, Advanced Biomedical Scientist
Anna Tarasewicz, Specialist Biomedical Scientist in Haematology & Blood Transfusion at BSUH

This flyer describes the experiences of a laboratory in Europe using the CE-IVD marked version of the *ipsogen* JAK2 RGQ PCR Kit and *ipsogen* CALR RGQ PCR Kit.

About the Laboratory

Brighton & Sussex University Hospitals NHS Trust (BSUH) operates laboratories at the Royal Sussex County Hospital, Brighton and the Princess Royal Hospital, Haywards Heath in the United Kingdom. The laboratory has ISO 15189 accreditation, and provides an extensive test repertoire in hematology, coagulation, blood transfusion and immunohematology. Since 2015, BSUH has provided molecular hemato-oncology testing for several molecular markers, including JAK2 V617F and CALR.

Munyoro Guvamatanga was employed as a Senior Specialist Biomedical Scientist in the Haematology Department at the Royal Sussex County Hospital between 2010 and 2020. He successfully set up and validated the molecular hemato-oncology service for the JAK2 V617F and CALR assays for the Haematology Department and trained colleagues in PCR procedures. He has experience in supervising the successful completion of two MSc research projects. Currently, he works as an Advanced Biomedical Scientist at the Hospital Services, State of Guernsey, while pursuing his PhD in Biomedical Science at the University of Portsmouth.

Anna Tarasewicz is a Specialist Biomedical Scientist in the Haematology and Blood Transfusion Department at the Royal Sussex County Hospital. While completing her BSc program in Applied Biomedical Science at the University of Brighton, she worked as a biomedical scientist student trainee at BSUH. With Munyoro as her supervisor, Anna recently completed her MSc in Biomedical Science, with the project focusing on the evaluation and validation of the *ipsogen* CALR RGQ PCR assay for the detection of *CALR* exon 9 mutations in suspected *BCR-ABL1*-negative myelo-proliferative neoplasms.

Munyoro Guvamatanga
Advanced Biomedical Scientist

"We needed a cost-effective onco-hematology solution with shorter turnaround times and improved sensitivity versus out-sourcing to the external laboratory. The solution had to be robust, easy to implement and scale-up, adapt-able to our existing platforms and covered by NEQAS for external quality assessment."

Anna Tarasewicz
Specialist Biomedical Scientist

"For patients, we established the testing algorithm with the Clinical Hematology team and were able to use one blood sample for both the JAK2 V617F and CALR assays, rather than returning to get more blood samples separately for each molecular marker."

The Challenge

Myeloproliferative neoplasms (MPN) are a group of diseases representing 30% of hematological malignancies. They are characterized by chronic accumulation of different cell types in the blood that are *BCR-ABL1*-positive or *BCR-ABL1*-negative. Polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF) are the three types of *BCR-ABL1*-negative MPN. The discovery of disease-specific molecular markers showed increased accuracy and promise in patients diagnosis as compared to some of the traditional approaches. Molecular techniques contribute to establishing the correct diagnosis and provide useful medical information to help clinicians in patients' personalized treatment strategy. The presence of *JAK2, CALR* or *MPL* mutation is a major criterion in the reference WHO 2016 criteria for the diagnosis of a *BCR-ABL1*-negative MPN in suspected patients (1). The focus of the laboratory was the sequential testing for suspected *BCR-ABL1*-negative MPN patients. "Before the implementation of QIAGEN's *ipsogen* solution in-house, we were sending samples to an external laboratory in London, which was a costly undertaking. Sample loss, improper sample storage and handling were additional issues that compromised the quality of the send away service. Often we were forced to follow up with the external laboratory for the results that breached the stated turnaround times. There was a need for the onco-hematology testing to be in our control, and the expertise was there, so we decided to bring the testing in-house," explains Munyoro.

Why a QIAGEN Workflow with *ipsogen* IVD Solution?

The aim of the laboratory was to have an in-house solution that would allow use of a sample from a single phlebotomy event, with one extraction for multiple assays in sequential testing for *BCR-ABL1*-negative MPN suspected patients. Specifically, the laboratory was interested in a solution that would also follow the molecular diagnostic algorithm for *BCR-ABL1*-negative MPNs at BSUH that is based on guidelines (Figure 1). "We needed a cost-effective solution with shorter turnaround times and comparable or better sensitivity to that offered by the reference laboratory. The solution had to be robust, easy to implement and scale-up, adaptable to our existing platforms, and covered by NEQAS for external quality assessment," says Munyoro. To accomplish this, BSUH partnered with QIAGEN to implement QIAGEN's testing workflow with the *ipsogen* solution. "We were assessing various platforms and methods, and the *ipsogen* solution was selected as the one that suits our departmental needs the most," says Anna. The laboratory started with the implementation of the *ipsogen* JAK2 RGQ PCR Kit, and then broadened the service to include the CALR assay. "As we were very pleased with the outcomes after using the CE-IVD *ipsogen* JAK2 RGQ PCR Kit, we were keen on evaluating the CE-IVD *ipsogen* CALR RGQ PCR Kit," added Anna.

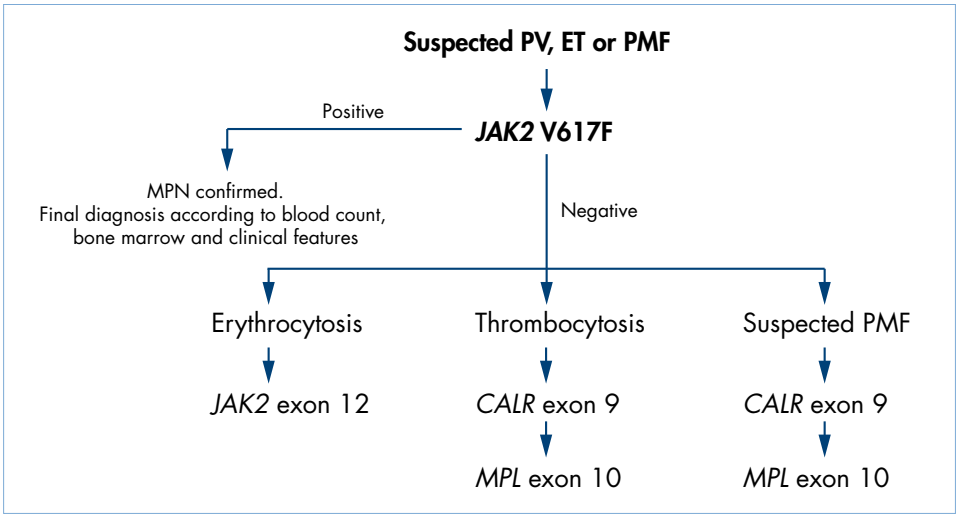

Figure 1. Molecular diagnostic algorithm for *BCR-ABL1*-negative MPNs at BSUH (adapted from reference 2).

The Benefits

"QIAGEN's *ipsogen* assays were able to provide precise, accurate and reproducible results with good sensitivity (0.042% limit of detection for JAK2 V617F), and the detection of two main mutation types for *CALR* (1 and 2) and other minor variants. The testing workflow is easy and intuitive to implement and reduced the onboarding time for staff who were able to operate the system quickly," Anna says. Munyoro adding, "QIAGEN Application Specialists were very knowledgeable and helpful during the implementation process of the *ipsogen* assays in our laboratory. We had a very positive experience with the assays and the service we received from QIAGEN's Technical Support team." QIAGEN's *ipsogen* solutions allowed the laboratory to use a sample from a single phlebotomy event, one extraction for multiple assays, in a locally set up reflex testing for suspected *BCR-ABL1*-negative MPN patients. "For patients, we established the testing algorithm with the Clinical Haematology team and were able to use one blood sample for both the JAK2 V617F and CALR assays, rather than returning to get more blood samples separately for each molecular marker," explains Anna. Each element of the testing workflow – from sample processing, running the sample on the Rotor-Gene® Q real-time PCR system, and the automated analysis and reporting on the QIAGEN Rotor-Gene AssayManager® software v.2.1 – delivered a complete end-to-end testing solution to the laboratory. "The inclusion of QIAGEN Rotor-Gene AssayManager software v2.1 for both JAK2 V617F and CALR improved our processes and quality control, by eliminating the need for manual data input, and overcoming the issues of transcription-related errors. We were able to record all the data seamlessly, as all the detailed information, including instrument data, lot numbers, expiration dates, and quality control was readily available as a – single report," comments Anna. With QIAGEN's *ipsogen* solution, BSUH scaled up productivity and improved their turnaround time. Also, the *ipsogen* CE-IVD solution facilitated ISO 15189 accreditation (to date for JAK2; CALR not yet inspected) of the laboratory. "The in-house setup allowed us to save on costs and avoid issues experienced with improper sample handling and processing when outsourcing the analysis to an external laboratory. The Sample to Insight workflow in liaison with our Clinical Haematology team improved the quality of service we were offering our patients," concludes Anna.

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The Impact of COVID-19

The COVID-19 pandemic affected BSUH's available resources. Anna says, "We were quickly thinking outside the box to implement many adaptations in our lives and workplaces. During the peak of the pandemic, all of our available resources, including equipment and staff, were dedicated to diagnosis of COVID-19." The laboratory also had to repurpose and refurbish space to accommodate new equipment for COVID-19 testing. Due to the overwhelming workload and pressure on staff members, temporary suspension of the hemato-oncology in-house testing seemed rational. "Although this was not ideal, the temporary suspension of some of our blood cancer testing was a necessary adjustment to mitigate the pressure created from the COVID-19 crisis," Munyoro added.

Learnings

- QIAGEN's *ipsogen* solutions allowed the laboratory to use one EDTA sample from a single phlebotomy event, one extraction for multiple assays, in a locally set up reflex testing for suspected *BCR-ABL1*-negative MPN patients.
- The testing workflow with *ipsogen* assays was easy to implement and intuitive, further improving efficiency by reducing the onboarding time for staff who were able to operate the system quickly.
- QIAGEN Rotor-Gene AssayManager software v2.1 improved the laboratory's processes and quality control, by eliminating the need for manual data input, and overcoming the issues of transcription-related errors. The laboratory was able to record all the data seamlessly, as all the detailed information including instrument data, lot numbers, expiration dates and quality control was readily available as a – single report.

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Cited references

1. Arber, D.A. et al. (2016) The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia.Blood 127, 2391.
2. Bench, A. et al. (2013) Molecular diagnosis of the myeloproliferative neoplasms: UK guidelines for the detection of JAK2 V617F and other relevant mutations. British Journal of Haematology 2013 Jan;160(1):25-34.