

CASE STUDY

BOND-PRIME: Revolutionising today's diagnostic climate

Many clinical pathology laboratories today experience a number of challenges in their day-to-day drive to provide an efficient service and timely results. One key factor is the ever-increasing number of immunohistochemistry (IHC) slides per year that require processing. The workload has been driven in part by the backlog in cancer cases, but also by the increasing complexity of the cases, and the cancer incidence in the UK.^{1, 2}

Leading institutions like North West London Pathology (NWLP), with strong leadership embrace a compelling vision and their values provide the foundation of their organisational culture serving as guiding principles for all of their endeavours. The values - being expert, collaborative, patient focused and caring - reflect their commitment to excellence and support their drive to leverage their scientific knowledge.



The executive team at NWLP fully support and facilitate opportunities for innovation. This has fostered the NWLP Cellular Pathology team to identify this opportunity to improve the service through innovation, in order to address the challenge of an ever-increasing workload in a post-pandemic era.

The team at this laboratory evaluated a new cutting edge technological advanced IHC / ISH stainer given the increasing workload and with a desire to be a recognised centre of excellence to support sustainable clinical services.

Currently the department process 160,000 slides per year. NWLP have worked in close collaboration with Leica Biosystems to trial the new BOND-PRIME system and prepare a case to undertake an ambitious asset replacement programme. As part of the evaluation, 32 routine BMT Lymphoma antibodies and 4 MMR markers were validated and run on one BOND-PRIME processing module over the six-week trial time.

Laboratory staff feedback covered a number of workflow areas

- Label slides, load slide on the BOND-PRIME straight away without sorting any slides prior to the run. This saved 90 min preparation time per day.
- The IHC Protocol times were shorter (or fast) enabling more runs to be carried out during the day.
- Unloading of processed sides was easy and did not require any additional prep such as washing before taking up to xylene and cover slipping.
- Maintenance procedures on the BOND-PRIME were easy to carry out and included lower maintenance requirements compared to the current IHC/ISH system.



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- Educational goal IHC and ISH are constantly evolving to accommodate clinical and diagnostic advances. Staff that thought they understood the rationale and background of IHC and ISH, have now been introduced to the benefits of evolving research and technology innovations to realise that the constraints of the past no longer apply. The BOND-PRIME characteristics can be directly translated into practical changes for established protocols that can improve the service and their understanding of the patient treatment pathway.
- The ability to adopt a continuous throughput workflow eliminated a number of bottlenecks spent waiting for protocols to finish before more IHC can be loaded on to the platform.
- Staff have been actively engaged in the trial, gaining exposure and experience in areas of lab management that previously they had limited experience in. This included design of a testing plan and devising proposed workflow patterns for the proposed future service.
- Staff have fed back that they felt engaged and that their feedback and opinions were being highly valued and part of the process.

Quality of staining observed during our evaluation

The NEQAS scoring system was used as outlined below to assess the quality of BOND-PRIME staining during this laboratory evaluation.

| UKNEQAS ISO 15189 approved scoring | | Score achieved | No. Antibodies tested | |
|------------------------------------|-------------------|----------------|-----------------------|--|
| 5 | Excellent | 5 | 18 | |
| 4 | Pass | 4 | 10 | |
| 3 | Pass (borderline) | 3 | 2 | |
| 2 | Fail (borderline) | 2 | 0 | |
| 1 | Fail | 1 | 0 | |

Comments from Pathologists in NWLP

- 1. The slides are very clean which helps the true staining pop.
- 2. The turnaround times (TAT) better align with the new government KPI targets announced.
- 3. The majority of the antibodies delivered a more crisp stain especially for the RTU's tested.



For In Vitro Diagnostic Use

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A key target area to improve our service level to meet our 'Patient focused' value is the MMR service

We evaluated four ready-to-use Mismatched Repair (MMR) antibodies for the detection of MMR protein deficiency from Leica Biosystems on the BOND-PRIME. Slides were processed on the current platform and the BOND-PRIME at the same time. The start time and end time were recorded and used to calculate the TAT.



| BOND-PRIME vs. Current MMR panel TAT Results | Start Time | Finish Time | Time to complete in |
|---|---------------|----------------|------------------------|
| | | | minutes |
| BOND-PRIME | 10:15:00 | 11:55:00 | 100 |
| Current MMR Platform | 10:15:00 | 13:40:00 | 205 |

The laboratory can now run more MMR cases per day given the faster MMR TAT on BOND-PRIME vs the current platform processing MMR slides. Another benefit to our laboratory is that no additional staff were required in processing the MMR slides to reduce the TAT and improve our service level.

Conclusion:

To meet the ever-increasing service requirements, innovation is essential. In collaboration with Leica Biosystems, NWLP has been able to evaluate a new laboratory IHC/ISH workflow solution and discover opportunities for improvement that meets both the current and future service needs.

With the increasing service size, the functionality and capacity of the BOND-PRIME offers the ability to deliver faster diagnostic results. The BOND-PRIME processing module combines a faster TAT with good quality staining output to allow for cases to be turned around in just over an hour which is beneficial for rapid diagnosis and meeting the growing MDT deadlines. The BOND-PRIME fits nicely with the known BOND-III system to allow for an efficient and robust diagnostic service. Finally, the BOND-PRIME IHC/ISH stainer is breaking down barriers to revolutionise staff's knowledge and adaptability with integrating innovative workflows.

References

- 1. Newley Diagnosed Cancers and the COVID-19 pandemic: tumour stage migration and higher early mortality https://spcare.bmj.com/content/early/2021/10/27/bmjspcare-2021-003301
- 2. Cancer News Over 2 million people in backlog for cancer care <u>https://news.cancerresearchuk.org/2020/06/01/over-2-million-people-in-backlog-for-cancer-care/</u>



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