

# LEICA BIOSYSTEMS WHITE PAPER

## COMPARISON OF MANUAL AND AUTOMATED FISH PROCESSING

Leica Biosystems partnered with ProPath to evaluate workflow and quality when manual FISH processing is transferred onto a BOND-III processing module with XL for BOND FISH probes.

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Fluorescence in situ Hybridization (FISH) testing continues to be an important platform/method for identification of genetic abnormalities in cancers. FISH assays can aid in rendering a definitive diagnosis and/or can determine which therapy(s) is most appropriate for the patient. Accuracy and turn-around time of these tests are critical for providing optimal patient care.

Here we evaluated the BOND-III Processing Module from Leica Biosystems, which fully automates processing of tissue sections for FISH studies along with IHC and ISH. We compared the results generated, the quality of the FISH stains, and the time and efficiency of fully automated processing using the BOND-III platform compared to the Leica Biosystems' manual methods with use of the ThermoBrite Processing System.

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For In Vitro Diagnostic Use.

\*Projections and Realized Results are specific to the institution where they were obtained and may not reflect the results achievable at other institutions.

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### Who are we?

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ProPath is a physician-owned medical practice and laboratory specializing in anatomic and clinical pathology. We offer a complete menu of core clinical testing as well as specialty testing, including FISH. Our FISH department performs over 100 validated probes using both formalin-fixed, paraffin-embedded (FFPE) tissue and hematologic specimens.

### Methods

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Six FISH products from the Leica menu were used in the evaluation, 3 manual probe pairs and their 3 XL FISH probe comparative products. Probes were selected based on availability of suitable samples in-house for testing. Tissue sections from a total of 30 cases (10 per probe) were processed using the current manual method and using the BOND-III platform. Cases consisted of FFPE tissue samples that were representative of how that probe is used in our laboratory. Slide processing was performed according to the manufacturer's instructions, either manually or on the BOND-III platform. All 60 resulting slides were assessed as positive or negative for the probe-specific alteration (copy number change or rearrangement) and rated for quality using an internal scoring method. The results of comparative samples across the two methods were then reviewed for concordance.

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### Results: Concordance

All FISH probes		Result using Automated Processing		
		Negative	Positive	No result
Result using Manual Processing	Negative	20	0	0
	Positive	0	9	0
	No result	0	1	0

### Summary/Conclusion

Overall the concordance was very high between slides prepared manually and by the BOND-III platform. All cases generated concordant results except for 1 case in which the manually prepared slide could not be interpreted due to poor quality.

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### Results: Quality Comparison

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For Probe 1, 4/10 (40%) cases, the manual and automated slide preparations were determined to have similar quality. For 6/10 (60%) cases, the slides prepared by the BOND-III platform was of superior quality compared to the slides prepared manually.

For Probe 2, 7/10 cases (70%), the manual and automated slide preparations were determined to have similar quality. For 3/10 (30%) cases, the slides prepared by the BOND-III platform was of superior quality compared to the slides prepared manually. For one sample, the quality of the BOND-III platform prepared slide was given the highest quality score, while the manually prepared slide was given the lowest quality score.

For Probe 3, 6/10 cases (60%), the manual and automated slide preparations were determined to have similar quality. For 2/10 (20%) cases, the slides prepared by the BOND-III platform was of superior quality compared to the slides prepared manually. For one sample, the quality of the BOND-III platform prepared slide was given the highest score, while the manually prepared slide was given the lowest score. For 1/10 (10%) cases, the quality of the slide prepared manually was superior to the quality of the slide prepared by the BOND-III platform.

### Summary

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In general, slides prepared by the BOND-III platform were assessed as having similar or superior quality compared to slides prepared manually. On average, XL FISH probes processed on the BOND-III platform were perceived to have staining quality 22% better than the manual method with comparator probes.

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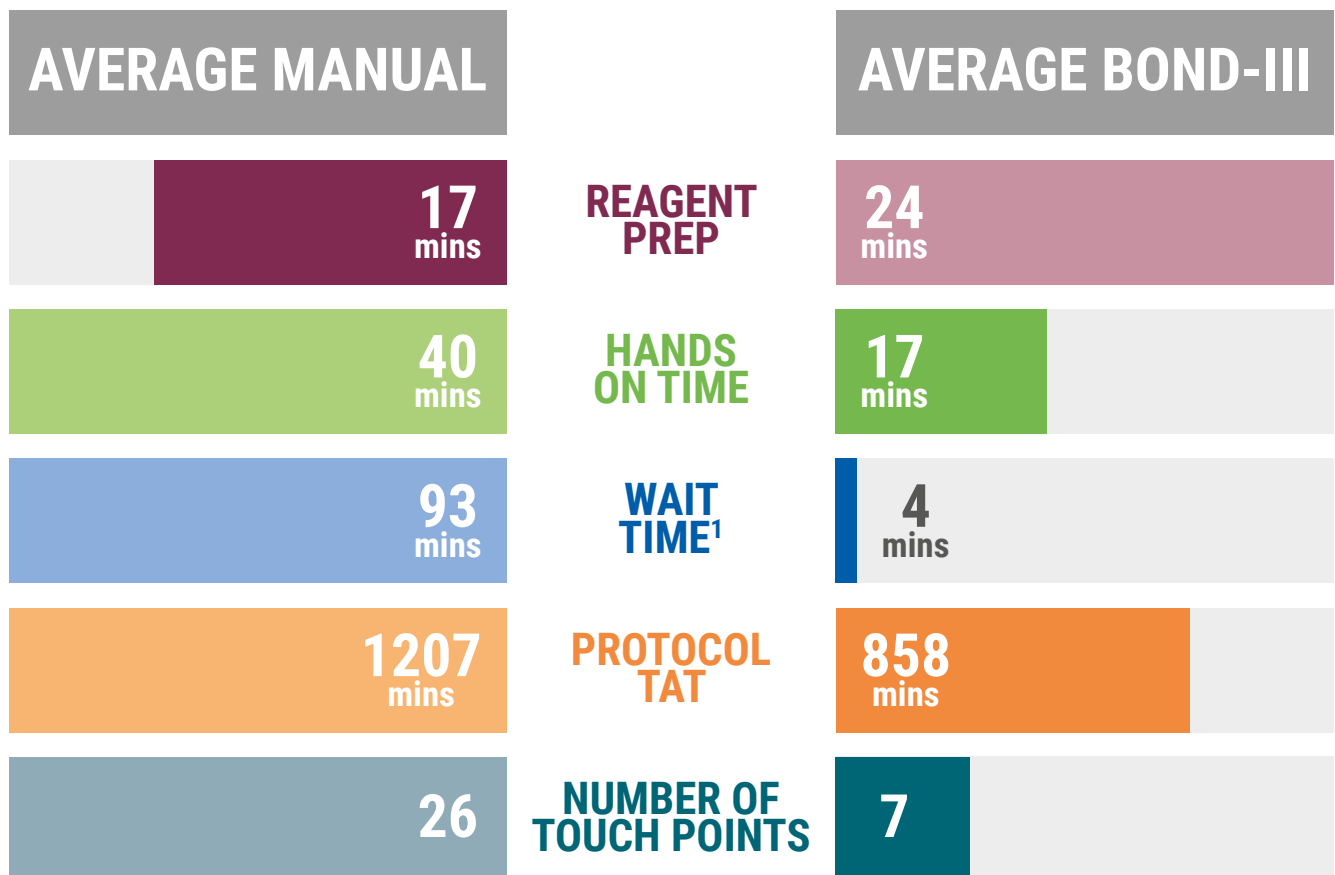
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## Results: Comparison of workflow, hands-on time, and total processing time



<sup>1</sup> Wait time does not include the hybridization incubation time

The BOND-III platform performed all steps from Dewax to post-Hybridization Wash with only the slide dehydration to prepare for DAPI counterstain application and coverslipping occurring at the bench and requiring manual processing as part of the XL BOND FISH staining. Slide dry time, preparation, and application of DAPI counterstain was not included in the analysis; this is a manual process that is equivalent between both methods.

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### Summary

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Although the BOND-III processing module took on average 5 minutes longer to prepare for slide processing compared to preparation needed for manual processing, this time was quickly recovered across the remainder of the protocol.

Automation on the BOND-III processing module resulted in a reduction of hands-on time from the start of the first protocol step through dehydration pre-DAPI counterstain of 23 minutes and a reduction in the number of touch points from 26 to 7. Accompanying this is the significant reduction of wait time from 93 minutes to 4 minutes. It is worth noting that many of the manual protocol steps are only 1-10 minute incubations and these time periods are insufficient to walk away and accomplish other tasks to support the laboratory workflow.

### Conclusion

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Overall, the automated XL BOND FISH staining on the BOND-III processing module reduced the protocol turn-around time by just under 6 hours and returned almost 2 hours of lab personnel resource time back to support other laboratory functions. The delayed start feature on the BOND-III allows more control and flexibility of workflow. Protocols can be scheduled to start at any time, including after shift hours were finished, so that processing is completed at a time that is convenient for the laboratory's workflow.

In this study, compared to manual staining, the XL BOND FISH staining generated concordant results, similar or superior stain quality, and resource savings.

The application specialists from Leica can help you to optimize your assay on the BOND. For support questions, email: [Kreatech.Support@leicabiosystems.com](mailto:Kreatech.Support@leicabiosystems.com) and Leica can help you to reduce your staff's hands-on time for FISH.

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