WHITEPAPER

Biocare Basics: Validation

BIOCARE MEDICAL

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Validation is an essential step for setting up a new laboratory procedure, whether it incorporates immunohistochemical (IHC) or routine hematoxylin and eosin (H&E) staining. The validation process involves repeatedly testing the procedure over a large quantity and range of specimens in order to ensure the procedure will yield consistent and reproducible results. This, in turn, ensures that the results will be diagnostically significant.

When Validation Would Be Required:[1]

- When changes in the fixation processing protocols are made.
- When an alternative fixative is being introduced.
- When a new decalcifying protocol is being introduced.
- When a new staining platform is being introduced (automated or manual).
- When a new release of software for a staining platform is being introduced.
- When a new IHC or ISH labeling detection protocol is being introduced.
- When a new antibody or molecular marker is being introduced, including an alternative clone or nucleic acid probe.
- When new control tissues or cells are being introduced.

The work associated with validating a new procedure can be difficult, laborious, and expensive. For this reason, laboratory personnel may prefer to take advantage of a pre-existing standardized and validated protocol. One such option is to utilize published information provided by peer-reviewed studies, external organizations such as CAP, or product inserts from manufacturers.[1] These sources may help narrow down the number of unknown variables in a procedure, but they cannot be used as substitutes for in-house validation. Laboratories are still responsible for carrying out their own validations. It is important to identify with your laboratory management, and/or accredited institutions, the specific requirements for validation in your lab.

Different countries and regulatory bodies have different standards regarding validation, and these local rules should be consulted before the start of a validation procedure.[1] For example, according to ASCO/CAP recommendations, when validating a primary antibody for an IHC or ISH protocol for Class II targets (prognostic or predictive markers), a minimum of 25 to 100 cases must be tested.[1] Both positive and negative cases are to be included and a portion of the positive cases should contain low expression of the target.[1] As part of the ongoing assessment and monitoring for any “drift” in test results, participation in external quality assessment programs is critical and the correlation between the internal and external testing should be very high (90% for positives and 95% for negatives).[1]

Instrumentation used in labs, such as tissue processors and automated staining platforms, must also be validated. Methods of validating instruments vary, but the intended purpose is the same: to prove that the instrument is working as expected, repeatedly and reliably.[1] Biocare provides full service installation and validation of its automated staining instruments and validation documentation is provided to the customer after installation is complete. Customers then need only to focus on validating their lab’s specific staining protocols. For this purpose, Biocare offers package inserts containing guidelines for optimization and validation for all its antibodies. Biocare also offers ready-to-use (RTU) systems which, when utilized as described in the package insert, may provide diagnostically useful results with minimal technician prep work.

Once initial validations are complete, it is not necessary to re-validate unless there has been a significant change in the test system, such as a new water supply.[1] However, verification of performance will be a continuous process.[1]

Biocare Medical prides itself on outstanding field services. Our team of experienced Technical Support members can help answer questions you may have, and our certified Field Applications Specialists can provide optimization and troubleshooting for your Biocare reagents and instrumentation. Have questions on available services, please contact your local Sales Representative or call 1-800-799-9499.

www.biocare.net

1. Colley, E. C., & Stead, R.H. (2013). Fixation and Other Pre-Analytical Factors. In C. R. Taylor & L. Rudbeck (Eds.), Immunohistochemical Staining Methods (6th ed., pp. 20-29). Dako Denmark A/S.