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Dear Valued Client,

The College of American Pathologists (CAP) and the American Society for Clinical Oncology (ASCO) have recently developed evidence-based recommendations to improve the accuracy of ER and PR testing.[1][2] These new guidelines extend the current CLIA regulations requiring laboratories to ensure quality laboratory testing and that appropriate validations take place. Therefore, the purpose of this letter serves to document that Clarient has adopted and validated the recent changes in the ASCO/CAP guidelines.

The Clarient Validation: Clarient uses the in vitro diagnostic ER (6F11 clone) and PR (1294 clone) antibodies recommended in the ASCO/CAP guidelines.[1] Both antibodies have been validated in our laboratory by reviewing breast carcinomas in tumor microarray format and showing over 99% concordance with the assay developed by D. Craig Allred, M.D., Ph.D.[3][4] Statistical analysis showed that Clarient ER PR expression rate is within the range of positivity reported in the literature.

Further, to assure the accuracy of our reporting, Clarient subscribes to ER and PR Proficiency Testing from CAP, NEQUAS (U.K. Proficiency Test) and NORDIC QC (European Proficiency Testing).[5]

Use of Image Analysis: The ASCO/CAP panel agreed that acceptable performance standards may include image analysis. The image analysis tool should be viewed as an aid to pathologists in verifying manual scoring. If image analysis is used, a pathologist should confirm the accuracy of image analysis result in the context of the entire tissue section.

For additional information regarding the certification and validation of Clarient, please refer to the Regulatory and Licensing information on the About Us tab at www.clarientinc.com.[5] For additional information regarding the guidelines and validation, please refer to the full and complete guidelines through the CAP Reference Resources and Publications on www.CAP.org.[6]

Sincerely,

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6. *American Society of Clinical Oncology/College of American Pathologists Guildeline Recommendations for Immunohistochemical Testing of Estroggen and Progesterone Receptors in Breast Cancer.* **Hammond, MEH et al.** 2010, Arch Pathol Lab Med, Vol. 134, pp. 907-922.