

LGC Maine Standards announces the release of VALIDATE® Body Fluids 3

Allows for easy, fast, and reliable documentation of linearity, calibration verification, and Laboratory Developed Test (LDT) validation

CUMBERLAND FORESIDE, MAINE, UNITED STATES, December 21, 2021 /EINPresswire.com/ -- LGC Maine Standards¹ announces the release of VALIDATE® BF3 (Order No. 207ro) to meet the linearity, calibration verification, and validation needs of clinical laboratories running body fluid Laboratory Developed Tests (LDT) for Cancer Antigen 19-9 (CA 19-9) and Carcinoembryonic Antigen (CEA). The product is formulated in human ascites fluid, expanding the VALIDATE® Body Fluids portfolio, which currently



VALIDATE® Body Fluids 3 for easy, fast, and reliable documentation

consists of VALIDATE® BF (Order No. 205bf) and VALIDATE® BF2 (Order No. 206ro). VALIDATE® BF3 test kits are liquid and ready-to-use; simply dispense the solution from each dropper bottle, directly into five sample cups, and run in replicates to verify the assay's reportable range.



VALIDATE® products allow clinical laboratories to complete their required linearity and calibration verification, maximizing the reportable range while minimizing manual dilutions."

spokesperson

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Use of this product, while augmenting daily QC, assists with fulfilling various quality regulatory requirements – such as Analytical Measurement Range (AMR) and Reportable Range – for linearity and calibration verification under CLIA '88, CAP, COLA, JCAHO, JCI, and ISO 15189.

The addition of VALIDATE® BF3 to LGC Maine Standards'

expanding portfolio of products demonstrates a continued commitment to manufacture high-quality linearity and calibration verification products that meet industry needs.



LGC Maine Standar

ds is located in Cumberland Foreside, Maine and manufactures VALIDATE® linearity and calibration verification kits for over 165 analytes, including General Chemistry, ACTH, Anemia, Body Fluids, Bone, Cardiac, Diabetes, Fertility, Hemostasis, Osmolality, POC, Sepsis, Serum Proteins, Therapeutic Drug Monitoring, Thyroid, Tumor Markers, and Urine Chemistry.

LGC Maine Standards' MSDRx® data reduction software is available at no charge for real-time data analysis, or a laboratory can send their data to LGC Maine Standards where a technical specialist will complete the data analysis and return a report within five business days. Peer group comparison is also available upo n request.

For VALIDATE® BF, VALIDATE® BF2, and VALIDATE® BF3 product details, click here, or call +1 800-377-9684, or +1 207.892.1300.

¹LGC Maine Standards is a product brand of LGC <u>Clinical Diagnostics</u>, Inc.

About LGC Clinical Diagnostics

LGC Clinical Diagnostics business unit develops and manufactures a comprehensive portfolio of catalog and custom-developed diagnostic quality solutions and component materials for the extended life sciences industry. We partner with IVD assay developers, and pharmaceutical, CRO and academic institutions in commercialization activities across the entire diagnostic pipeline - from concept and early-stage research, through expedited product development and onwards into routine clinical use. Laboratorians and diagnostic professionals across disciplines of clinical chemistry, immunochemistry, serology, molecular diagnostics and clinical genomics rely on LGC's products to support accurate and reliable diagnostic results.

Our operating entities include LGC Clinical Diagnostics, Inc. (formerly known as SeraCare Life Sciences and Maine Standards, LLC), and Technopath Clinical Diagnostics which are in vitro diagnostics (IVD) manufacturers of quality measurement tools (calibrators, controls, linearity, EQA/PT, biological materials) and The Native Antigen Company, which is a manufacturer and supplier of viral antigens. Our 400+ employees operate FDA-registered and ISO 13485-accredited facilities in Maine, Massachusetts and Maryland, USA, and an ISO 9001-accredited facility in Oxford, UK.

Each day, our world-class staff, scientific expertise, operational efficiency, and superior quality systems are ready to support the range of advanced technologies that collectively improve

patient outcomes - from the widely adopted and established through to cutting-edge NGS and precision diagnostics.

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