

LGC Maine Standards announces the release of VALIDATE® FERT 3 for Roche cobas®

Provides easy, fast, and reliable documentation of linearity, calibration verification, and Analytical Measurement Range (AMR) verification

CUMBERLAND FORESIDE, MAINE, USA, August 24, 2021 /EINPresswire.com/ -- LGC Maine Standards¹ announces the release of VALIDATE® FERT 3 (Order No. 505ro) to meet the linearity and calibration verification needs of clinical laboratories running the Roche cobas® platform. The product, which includes analytes Anti-Müllerian Hormone (AMH) and Sex Hormone-binding Globulin (SHBG), is formulated in a human serum matrix, expanding the VALIDATE® Fertility portfolio for Roche cobas®, which currently consists of VALIDATE® FERT 1 (Order No. 502re) and VALIDATE® FERT 2 (Order No. 504re). VALIDATE® FERT 3 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



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press release

VALIDATE® products allow clinical laboratories to complete their required linearity and calibration verification, maximizing the reportable range while minimizing manual dilutions. 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® FERT 3 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 Standards is located in Cumberland Foreside, Maine, and manufactures VALIDATE® linearity and calibration verification kits for over 150

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 upon request.

For VALIDATE® FERT 1, VALIDATE® FERT 2, and VALIDATE® FERT 3 product details, [click here](#), or call +1 800-377-9684, or +1 207.892.1300.

¹LGC Maine Standards is the brand name for Maine Standards Company, LLC, and an entity of LGC Clinical Diagnostics Division.

About LGC Clinical Diagnostics

LGC's Clinical Diagnostics Division 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 SeraCare Life Sciences and Maine Standards Company, 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 300+ 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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