
Ortho's Next Gen TSH3 Assay to Assess Thyroid and/or Pituitary Disorders Achieves CE Mark



[Ortho Clinical Diagnostics](#), a global leader of in vitro diagnostics, today announced its VITROS® Immunodiagnostic Products TSH3 (Thyroid Stimulating Hormone) Reagent Pack and Calibrator has achieved CE Mark and will be commercially available in the beginning of December* to aid clinicians in assessing and diagnosing thyroid and/or pituitary gland function.

This is especially beneficial in Europe, as studies have shown that nearly half of the 11% of Europeans with thyroid dysfunction are unaware of their condition.¹ If left untreated, thyroid disorders can be either life-threatening or cause health complications.

The VITROS® TSH3 assay has high value in offering reference intervals for both pediatric and pregnant patient populations, ensuring health care teams are able to more accurately diagnose and monitor patients' thyroid and/or pituitary function during these important phases of development causes thyroid hormones levels to fluctuate.

"Labs can rely on Ortho's TSH3 test when speed, accuracy and reliability count, like in an acute case of 'thyroid storm' that is life-threatening, or monitoring treatment over time," said Ajoy C. Mahtab, head of clinical labs business unit, Ortho Clinical Diagnostics. "Driven by Ortho's belief that Because Every Test is a Life™, Ortho is committed to providing labs with solutions to yield faster, more accurate, more reliable results so health care teams can make the most appropriate clinical decisions for their patients."

VITROS® TSH3 is a third-generation TSH assay² with improved accuracy that offers a 24-minute turnaround time (35% faster), 37% smaller sample volume to 50µL, and longer 40-day calibration stability, compared to the current VITROS® TSH assay. Further, the VITROS® TSH3 assay uses an Ortho VITROS® MicroWell Assay Design that is not susceptible to biotin interference, same as Ortho's VITROS® Anti-SARS-CoV-2 Total and IgG tests, VITROS® B•R•A•H•M•S PCT (Procalcitonin) assay, and VITROS® High Sensitivity Troponin I Assay among others.

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