New Access TSH (3rd IS) Assay Released with CE Mark for Use on the Beckman Coulter

Beckman Coulter Diagnostics is pleased to announce obtaining CE Mark and the release of its new Access TSH (3rd IS) assay for use with the company’s Access Family of Immunoassay Systems. This new assay is the next generation of the Access HYPERsensitive hTSH and Access Fast hTSH assays for the quantitative determination of human thyroid stimulating hormone (TSH, thyrotropin). The Access TSH (3rd IS) assay is an important enhancement to the company’s thyroid assay menu, which includes a full panel of thyroid tests that aid in the diagnosis of thyroid function.

The new Access TSH (3rd IS) assay offers laboratories:

- Confidence in patient results through standardization to the World Health Organization (WHO) 3rd International Standard (IS) for human TSH (IRP 81/565)
- Maximized laboratory workflow with a larger reagent pack size (100 tests/pack, 200 tests/kit) that improves laboratory efficiency
- Reliable and accurate results with an assay range that supports measuring patient samples as low as 0.005 μIU/mL

“CE Mark and release of our improved Access TSH (3rd IS) assay, a core assay in the thyroid panel, offers laboratories a necessary thyrotropin-monitoring tool for quicker, more reliable diagnosis and treatment of an underactive or overactive thyroid,” said John Blackwood, senior vice president, Chemistry and Immunoassay Business Unit, Beckman Coulter Diagnostics. “The newly designed assay improves time to first result while maintaining assay throughput.”

The Access TSH (3rd IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of human thyroid stimulating hormone (thyrotropin, TSH, hTSH) levels in human serum and plasma using the Access Immunoassay Systems. This assay is capable of providing 3rd-generation TSH results.

Additionally, the Access TSH (3rd IS) assay was developed to reduce interferences and to deliver robust lot-to-lot performance for reproducible results. The current standards of care necessitate that laboratories use third-generation TSH assays, like the Access TSH (3rd IS) assay, as this level of sensitivity is necessary for detecting differing degrees of TSH suppression.

Reference:
1. Instructions for Use B77706 B, Access TSH (3rd IS), Beckman Coulter, Inc.
2. Instructions for Use B77707 B, Access TSH (3rd IS) Calibrators, Beckman Coulter, Inc.

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