

FDA clears Thermo Fisher assays for preeclampsia

September 2023—Thermo Fisher Scientific announced FDA clearance of its Brahms PIGF plus Kryptor and Brahms sFlt-1 Kryptor novel biomarkers for the risk assessment and clinical management of preeclampsia. The assays received FDA breakthrough designation in May.

The blood-based biomarkers are designed to be used with other laboratory tests and clinical assessments to aid in the risk assessment of pregnant women who have been hospitalized for hypertensive disorders of pregnancy to determine if they are at risk of progressing to preeclampsia with severe features within two weeks after testing.

The assays run on the company's Brahms Kryptor Compact Plus chemistry analyzer, which can deliver results in less than 30 minutes.

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