FDA clears Roche Cobas Pure for low- to mid-vol labs

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Sept. 19, 2022—Roche received FDA 510(k) clearance for the Cobas Pure, a modular solution that combines clinical chemistry, immunoassay, and ion-selective electrode diagnostic testing on a single platform with a footprint of about 21 square feet. The solution focuses on automating manual tasks, reducing hands-on maintenance time to five minutes per day.

The system performs up to 870 tests per hour and has access to Roche's full clinical chemistry and immunochemistry assay menu. The company says the menu will include more than 186 diagnostic tests across a range of disease areas, such as infectious diseases, oncology, and cardiology, within the first year after launch.

The Cobas Pure integrated solutions launched in March 2021 in countries that accept the CE mark.