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FDA Licenses 14 New Blood-Typing Tests

New tests help assure safe transfusions

On Jan. 10, the U.S. Food and Drug Administration licensed 14 new tests for determining a person's blood type, a process essential to a safe U.S. blood supply and safe transfusions.

"These 14 new tests will provide blood establishments and transfusion services with additional choices to help assure safe, well-matched transfusions," said Jesse L. Goodman, M.D., M.P.H., director of FDA's Center for Biologics Evaluation and Research. "The tests offer a broader diversity of reliable blood-typing tests and will help protect against product shortages."

Knowing the blood types for blood donors and patients is critical; patients may experience serious, possibly life-threatening reactions from mismatched transfused blood. The most familiar blood types are A, B, O, and Rh.

The OLYMPUS PK System Blood Group and Phenotyping Reagents use monoclonal antibodies to test for the A, B, O, and Rh factors as well as for other factors that signify a rarer blood type.

Monoclonal antibodies, which are proteins produced in a laboratory from genetically identical cells, have the ability to bind to and detect a specific substance, such as the proteins used in blood typing.

The tests are manufactured by DIAGAST of Loos Cedex, France.

For more information, visit www.fda.gov.

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