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Change Notification

Affected products	A051 (Biotinylated polyclonal antibody to microbial transglutaminase (MTG)) E021 (Microbial Transglutaminase (MTG) ELISA)
Reason	Change of polyclonal antibody serum as former sera were used up.
Change description	New A051 lots are produced from the new antibody serum (1926aA175). The antibody used for coating of E021 plates is also produced from the new antibody serum (1926aA175).
Conformity assessment	The ELISA performance of an A051 lot produced using the new serum was evaluated in comparison to a previously manufactured A051 lot produced using the former serum. The results demonstrated comparable performance. E021 plates coated with a new antibody lot produced from the new serum were evaluated and demonstrated performance comparable to that of plates coated with previous antibody lots.
Measures	The change control process has been completed. The new serum 1926aA175 will be implemented for the production of A051 and for the manufacture of antibodies used in E021 plate coating, starting with lots produced in calendar week 26, 2026. This change notification is available on the website.
Document release date	17 July 2026
Revision Number	1
Note	This document is valid without a signature.