Erba Lachema s.r.o.

ADVISORY NOTICE

39_2026_Total bilirubin DCA_Intended Use Change

Product: Bilirubin total DCA, **BIL T DCA 330**
Ref Code: XSYS0087

Dear customers,

With a mission to continuously enhance user experience and satisfaction, we would like to inform you about change of Intended Use for Bilirubin Total DCA (XSYS0087).
The assay is now also intended for monitoring bilirubin levels in neonates as an aid in the clinical management of neonatal hyperbilirubinemia.

The change cover also release of new test settings for BIL T DCA reagent for bilirubin total measurements in neonatal samples (available since end of July 2026). Recent studies demonstrated significant improvement in reagent performance and received patient results across neonatal samples while using these test settings.

To be able to use this kit for neonatal samples on Erba XL analyzers please upload test setting file named BTNEO, available in default parameters settings and Carry over pairs since version 57 (and later versions), which can be downloaded from Erba Knowledge base.

Also, the sample type acceptable for Bilirubin Total DCA assay is changed as follows:
Acceptable specimens are:

- Serum
- K_2-EDTA plasma

With the previously reported Li-heparinized plasma, it was not possible to ensure a non-interfering Li-heparin concentration of up to 5 IU/ml in all types of commercially available collection tubes. For this reason, this sample type has been removed from the instructions for use.

Please update your instruction for use.
In case of any questions, please do not hesitate to contact your local ERBA team.

Best regards,

Erba Lachema s.r.o.
Technical Product Management

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