



December 09, 2016

URGENT FIELD SAFETY NOTICE

FSCA#0916: Kleihauer Kit, 0098100

Dear Laboratory or Blood Bank Manager,

This field safety notice is to inform you that Immucor has received higher than typical rate of complaints concerning Kleihauer kit Cat #: 0098100 from the European market.

Issue Details:

The reports are of inconsistent staining of cells and false positives reactivity with negative control samples. The reports indicate the stain is not sufficiently removed from the adult cells during the elution step; therefore it is difficult to distinguish fetal cells from the adult cells. A false positive reaction with the negative control invalidates the test results and a repeat of the test is needed. Such repeat of testing may lead to delay in analysis of patient results and ultimately delay in patient treatment.

Actions Taken by the manufacturer:

Immucor has investigated all received complaints. Our investigation has not been able to reproduce the issue in testing in response to the complaints or identify any device performance deficiency.

We want to take this opportunity to highlight guidelines currently in the package insert that are important for optimal test performance:

- 1) Samples may be drawn into EDTA, heparin, ACD, CPD, CPDA-1, CP2D. Samples older than 4 days are likely to show improper elution.
- 2) Careful attention should also be paid to the prescribed duration of fixation (3 minutes), counterstaining (2 minutes) and elution (30 seconds).
- 3) It is recommended to carefully select samples used as positive control, if possible use samples of known genetic background. Samples from pregnant women should not be used.

Based on review of the complaints, we have identified improvements that can be made in the package insert precautions to help users avoid potential errors. We are adding the following precautions on the packaging insert:

Immucor, Inc.
IMMUCOR Medizinische Diagnostik GmbH
Robert-Bosch-Straße 32
63303 Dreieich, Germany
www.immucor.com

1. The Kleihauer kit fixing reagent and elution reagent contain methanol. Methanol can evaporate if the reagent is maintained open. Evaporation of the methanol may cause inconsistent staining.
2. As the Kleihauer kit test is reliant on the visual discrimination of fetal and adult red blood cells (RBCs) by staining intensity (dark pink fetal vs. minimally stained adult RBCs), the presence of F-cells containing intermediate concentrations of fetal hemoglobin (HbF) can complicate the interpretation. F-cells are RBCs containing 20%–25% HbF and are elevated in inherited hemoglobinopathies including sickle cell disease and β -thalassemia, hereditary persistence of fetal hemoglobin (HPFH), acute stress erythropoiesis, and pregnancy. The presence of F-cells may give either a false-positive test result or may overestimate the magnitude of a true feto-maternal hemorrhage (FMH).

Actions to Be Taken by the user:

- 1) Ensure that you are following the most recent version of the manufacturer's Instructions for Use / kit insert.
- 2) Pass a copy of this Field Safety Notice to all those who need to be aware of it within your organization and maintain awareness of this issue.
- 3) Please verify your receipt of this notification by completing the attached form and returning it to us by facsimile +49610380566390, e-mail vigilance.eu@immucor.com or by mail to: IMMUCOR Medizinische Diagnostik GmbH; Robert-Bosch-Strasse 32, Germany.

The relevant National Competent Authorities have been advised of this FSCA.

We apologize for inconveniences this issue has caused. If you have any questions, please contact Technical Service.

Sincerely,

Yves Ohandja
Manager Quality and Regulatory Affairs Europe



FSCA#0916

Response Form

I verify that our facility was made aware of the voluntary field action of Kleihauer Kit, 0098100	
Printed Name:	
Signature:	Date:
Position:	
Facility / Institution:	