HEMOSURE, INC.

• High Quality One-Step Test • Easy to Use • Results in 5 Minutes • CLIA Waived

TECHNICAL BULLETIN

Hemosure One-Step Immunological Fecal Occult Blood Test (iFOBT)

USA Lot P0112163054 and forward
China Lot L5041352 and forward

OVERVIEW

Historically the stool sampling stability in collection tube of the Hemosure iFOBT has been fourteen (14) days at room temperature and up to six (6) months in refrigerator at 39.2°F (4°C) or for twelve (12) months in freezer at -4°F (-20°C).

Due to our ongoing stability studies designed to measure lot to lot variances, we are pulling back our stool sampling stability in collection tube claim to a more conservative position for the Hemosure iFOBT. The stool sampling stability in collection tube changed from 14 days to 6 days stored at room temperature and can be stored up to 30 days in a refrigerator at 36°F-46°F (2°C-8°C). For these types of changes, we notify our customers by updating the published product insert.

PRECAUTIONS

Per the current CBER policy CPG Sec. 280.100-Stability Requirements-Licensed *In Vitro* Diagnostic Products explains, as a condition of licensure, that stability studies must be conducted before the application for a new IVD product is approved to ensure it will meet the expiration dating and storage conditions stated on the label. Post approval stability studies generally are not required for licensed IVDs. Exceptions to this include:

1. Stability studies that are required as a condition of approval of the license;
2. Stability studies for products that have undergone changes or deviations in the manufacturing process or formulation changes; and
3. Stability studies that are indicated as part of a corrective and preventative action plan developed in response to a failure investigation that would then support a previously cited expiration date.

The change in stool sampling stability in collection tube was not the result of any of the conditions listed above in points 1-3 and therefore is not reportable to the FDA because this product has been licensed since 2004 and is not the result of a design change or deviation in the manufacturing process or a formulation change. Nor is the stability changing a result of a corrective or preventative action.

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