

**FOR PROFESSIONAL USE ONLY**

Rx Only

**PRINCIPLE****INTENDED USE**

The Access Ferritin Calibrators are intended to calibrate the Access Ferritin assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

**SUMMARY AND EXPLANATION**

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

**TRACEABILITY**

The measurand (analyte) in the Access Ferritin Calibrators is traceable to WHO 3<sup>rd</sup> International Standard for ferritin (IS 94/572) (human, recombinant). Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

**REAGENTS****PRODUCT INFORMATION****Access Ferritin Calibrators****Cat. No. 33025: S0–S5, 4.0 mL/vial**

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Signs of possible deterioration are control values out of range.
- Refer to calibration card for exact concentrations.

<b>S0:</b>	Buffered bovine serum albumin (BSA) matrix with surfactant, < 0.1% sodium azide, and 0.5% ProClin* 300. Contains 0.0 ng/mL (mg/L) ferritin.
<b>S1, S2, S3, S4, S5:</b>	Human liver ferritin at levels of approximately 10, 50, 200, 500, and 1,500 ng/mL (µg/L), respectively, in buffered BSA matrix with surfactant, < 0.1% sodium azide, and 0.5% ProClin 300.
<b>Calibration Card:</b>	2

\*ProClin is a trademark of LANXESS Corp.

## WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.<sup>1</sup>
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

## REACTIVE INGREDIENTS

 **CAUTION**

**Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.**

## GHS HAZARD CLASSIFICATION

FERRITIN CALIBRATOR S0      WARNING



H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use. Ethoxylated alkyl alcohol 0.1 - 0.5% reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

FERRITIN CALIBRATORS S1, S2, S3, S4, S5      WARNING



H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use. Ethoxylated alkyl alcohol 0.1 - 0.5% reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

	Safety Data Sheet is available at <a href="http://beckmancoulter.com/techdocs">beckmancoulter.com/techdocs</a>
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## CALIBRATION

### CALIBRATOR REQUIRED

The Access Ferritin Calibrators are provided at six levels – zero and approximately 10, 50, 200, 500, and 1,500 ng/mL – prepared gravimetrically from human liver ferritin. Assay calibration data are valid up to 28 days.

Calibrators run in duplicate.

## **TESTING PROCEDURE(S)**

### **PROCEDURE**

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

## **PROCEDURAL NOTES**

### **LIMITATIONS**

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

## **ADDITIONAL INFORMATION**

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

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May be covered by one or more pat. -see [www.beckmancoulter.com/patents](http://www.beckmancoulter.com/patents).

### **REVISION HISTORY**

#### **Revision J**

IFU updated to add Dutch, Finnish, Macedonian, Traditional Chinese, and Estonian

#### **Revision K**

New release of IVDR compliant IFU.

#### **Revision L**

Added Translations.

#### **Revision M**

Added Translations.

#### **Revision N**

Updated ProClin trademark statement.

#### **Revision P**

Updated Translations.

#### **Revision R**

Updated "Product Information" section.

### **SYMBOLS KEY**


Glossary of Symbols is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs) (document number C02724).

## REFERENCES

1. HHS Publication, 5<sup>th</sup> ed., December 2009. Biosafety in Microbiological and Biomedical Laboratories.

EC	REP
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