BECKMAN COULTER

CE 2797

ACCESS
Immunoassay Systems

# Instructions For Use

# Access Thyroglobulin Calibrators



REF 33865

**FOR PROFESSIONAL USE ONLY**

**Rx Only**

## PRINCIPLE

### WARNING

The presence of serum autoantibodies to thyroglobulin (TgAb) can interfere with assays for thyroglobulin (Tg). Therefore, sera which contain TgAb, even at very low levels, should not be tested for Tg.

The concentration of thyroglobulin in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the Tg assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining Tg levels serially is changed, additional sequential testing should be carried out to confirm baseline values.

### INTENDED USE

The Access Thyroglobulin Calibrators are intended to calibrate the Access Thyroglobulin assay for the quantitative determination of thyroglobulin levels in human serum and plasma 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 Thyroglobulin Calibrators is traceable to the European Community Bureau of Reference (BCR) CRM 457 thyroglobulin standard. 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 Thyroglobulin Calibrators**

**Ref. No. 33865: S0–S5, 2.0 mL/vial**

- Provided lyophilized.
- Reconstitute each vial volumetrically with 2.0 mL distilled water. Allow 30 minutes for dissolution. Mix gently before use.
- Lyophilized calibrators are stable until the expiration date stated on the label when stored at 2 to 10°C.
- Reconstituted stability is 4 months at 2 to 10°C.
- Signs of possible deterioration are control values out of range or failure of calibrators to completely reconstitute.
- Calibration cards: one calibration card with description 'Access Tg' is provided for use with Ref. No. 33860 and a separate calibration card with description 'Access Thyg' is provided for use with Ref. No. C71762.
- Refer to calibration card for exact concentrations.

| | |
|---|---|
| **S0:** | HEPES buffer with bovine serum albumin (BSA), < 0.1% sodium azide, and 0.5% ProClin* 300. Contains 0.0 ng/mL thyroglobulin. |
| **S1, S2, S3, S4, S5:** | Human thyroglobulin at levels of approximately 1.0, 10, 100, 250, and 500 ng/mL, respectively, in HEPES buffer with BSA, < 0.1% sodium azide, and 0.5% ProClin 300. |
| **Calibration Card:** | 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.[1]
- 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

| | | |
|---|---|---|
| THYROGLOBULIN 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% |
| THYROGLOBULIN 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% |

| | |
|---|---|
| SDS | Safety Data Sheet is available at beckmancoulter.com/techdocs |

# CALIBRATION

### CALIBRATION INFORMATION

The Access Thyroglobulin Calibrators are provided at six levels - zero and approximately 1.0, 10, 100, 250, and 500 ng/mL. Calibrators are prepared gravimetrically from purified human thyroglobulin and buffered BSA based matrix. Assay calibration data are valid up to 56 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.

The Summary of Safety and Performance is available from the EUDAMED database: ec.europa.eu/tools/eudamed



### REVISION HISTORY

**Revision A**

Initial release.

**Revision B**

Updated ProClin trademark statement.

**Revision C**

Added Translations.

### SYMBOLS KEY

Glossary of Symbols is available at techdocs.beckmancoulter.com (document number C02724)

# REFERENCES

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

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