









ARK™ T4 Calibrator

This ARK Diagnostics, Inc. package insert for the ARK T4 Calibrator must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. The ARK T4 Assay test system includes separately provided test kits for the ARK T4 Assay, ARK T4 Calibrator and ARK T4 Control.

Customer Service

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Key to Symbols Used

	Batch code	 YYYY- MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Consult Instructions for Use		Calibrator
	Temperature limitation		

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Calibrator Kit  5027-0002-00

Negative Kit  5027-0002-01

1 Name

ARK™ T4 Calibrator

2 Intended Use

ARK T4 Calibrator is intended for use in calibration of the ARK T4 Assay.

3 Content

ARK T4 Calibrator is comprised of a synthetic protein matrix with the following concentrations of T4:

REF	Product Description	Quantity/Volume	
5027-0002-00	ARK T4 Calibrators T4, buffer, bovine serum albumin, and sodium azide	Dropper vials	
	A	0.0 µg/dL	1 X 4 mL
	B	1.0 µg/dL	1 X 4 mL
	C	2.0 µg/dL	1 X 4 mL
	D	4.0 µg/dL	1 X 4 mL
	E	12.0 µg/dL	1 X 4 mL
	F	20.0 µg/dL	1 X 4 mL

The measurement range of the ARK T4 Assay is 0.5 – 20.0 µg/dL.

REF	Product Description	Quantity/Volume
5027-0002-01	ARK T4 Calibrator A (Negative) Buffer, bovine serum albumin, and sodium azide	Dropper Vials
	Negative	0 µg/dL

4 Standardization

There is no internationally recognized standard for T4. ARK T4 Calibrators are prepared by gravimetric dilution of high purity T4 into a synthetic proteinaceous matrix free of T4.

5 Warnings and Precautions

- For veterinary use only.
- Do not mix calibrators from different lot numbers.
- Use each lot as a set.
- Calibrators contain ≤0.09% sodium azide.

6 Instructions For Use

- For a complete summary and explanation of the T4 assay, refer to the package insert for the ARK T4 Assay.
- Calibrators are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume (~40 µL/drop) into individual sample cups for each level. Consult instrument-specific sample volume requirements. Return caps to their original containers and keep tight.
- Store at 2-8°C. Use prior to the expiration date.

7 Procedure

Calibration

Perform a calibration using the ARK T4 Calibrators A, B, C, D, E, and F. Verify the calibration curve with quality controls according to the established laboratory quality assurance plan.

When to Re-Calibrate

- Whenever a new lot number of reagents is used
- Whenever indicated by quality control results
- Whenever required by standard laboratory protocols

8 Limitations of Procedure

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, controls, storage of product as directed, and good laboratory technique.

All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

9 Trademarks

ARK[™] is a trademark of ARK Diagnostics, Inc.

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