



# NEPHROCHECK<sup>®</sup> Calibration Verification Kit Package Insert



Manufactured for  
Astute Medical, Inc.  
3550 General Atomics Ct.  
Building 2  
San Diego, CA 92121  
USA

## Intended Use

The NEPHROCHECK<sup>®</sup> Calibration Verification (Cal Vers) Materials are to verify calibration of the NEPHROCHECK<sup>®</sup> Test System.

## Reagents

The NEPHROCHECK<sup>®</sup> Calibration Verification Kit includes five levels of lyophilized material prepared from human urine (collected from apparently healthy donors), as well as human TIMP-2 (Tissue Inhibitor of Metalloproteinase 2) and human IGFBP-7 (Insulin-like Growth Factor Binding Protein 7) proteins with protein stabilizers. TIMP-2 and IGFBP-7 proteins have been added to the urine to achieve specified target concentration levels that evenly span the reportable ranges. The expected concentrations and standard deviations are printed on the NEPHROCHECK<sup>®</sup> Expected Values Card enclosed with the NEPHROCHECK<sup>®</sup> Calibration Verification Kit.

## Warnings and Precautions

- The operator should use Standard Precautions when performing the NEPHROCHECK<sup>®</sup> Test or operating the ASTUTE140<sup>®</sup> Meter.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-s) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using FDA-approved testing methods.
- For *in vitro* diagnostic use.
- Do not use the kit beyond the expiration date printed on the outside of the box.
- The NEPHROCHECK<sup>®</sup> Calibration Verification Kit contains materials of human origin (urine). Handle these materials as if they are potentially infectious. Proper handling and disposal methods in compliance with federal and local regulations should be established.
- The NEPHROCHECK<sup>®</sup> Calibration Verification Kit is to be used only with the NEPHROCHECK<sup>®</sup> Test and ASTUTE140<sup>®</sup> Meter.
- Use only NEPHROCHECK<sup>®</sup> Calibration Verification Kits with the NEPHROCHECK<sup>®</sup> Test System.

- The NEPHROCHECK® Calibration Verification Kit requires the use of calibrated precision pipette(s). It is recommended that the users review the proper procedures for the use of these devices in order to ensure accurate dispensing of volumes.

### Storage and Stability

- The NEPHROCHECK® Calibration Verification material is lyophilized.
- Prior to opening the NEPHROCHECK® Calibration Verification Kit, inspect the vials for cracks, chips or broken seals. Do not use any vials if you encounter any damage.
- Prior to opening the NEPHROCHECK® Calibration Verification Kit, verify that the contents within each vial appear dry. Do not use any Calibration and Verification kit vial if the contents appear to be wet.
- Ensure the reconstituted NEPHROCHECK® Calibration Verification Material is completely dissolved prior to use. Do not use if contents do not appear to be fully dissolved.
- Once opened and reconstituted, each NEPHROCHECK® Calibration Verification Kit Vial is stable for 8 hours when stored capped at room temperature 20–25°C (68–77°F).
- Each NEPHROCHECK® Calibration Verification Kit Vial is intended for single use only. Each NephroCheck® Calibration and Verification Kit Vial should not be stored after opening or use.
- Each unopened NEPHROCHECK® Calibration Verification Kit Vial is stable until the expiration date printed on the box when stored refrigerated or frozen between -20°C – 4°C (-4°F – 39.2°F).

### Materials Provided

NEPHROCHECK® Calibration and Verification Kit (part number 500009) containing:

- NEPHROCHECK® Calibration Verification Vial Level 1 

CAL VERS	1
----------	---

 ..... 1 x 500 µL (lyophilized)
- NEPHROCHECK® Calibration Verification Vial Level 2 

CAL VERS	2
----------	---

 ..... 1 x 500 µL (lyophilized)
- NEPHROCHECK® Calibration Verification Vial Level 3 

CAL VERS	3
----------	---

 ..... 1 x 500 µL (lyophilized)
- NEPHROCHECK® Calibration Verification Vial Level 4 

CAL VERS	4
----------	---

 ..... 1 x 500 µL (lyophilized)
- NEPHROCHECK® Calibration Verification Vial Level 5 

CAL VERS	5
----------	---

 ..... 1 x 500 µL (lyophilized)
- NEPHROCHECK® Calibration Verification Kit Package Insert ..... 1
- NEPHROCHECK® Calibration Verification Expected Values Card ..... 1

### Materials Required But Not Provided

- ASTUTE140® Meter Kit (PN 500017)
- NEPHROCHECK® Test Kit (PN 500011)
- NEPHROCHECK® Test Buffer Solution (included in the NEPHROCHECK® Test Kit)
- Calibrated precision pipette, capable of dispensing 100 µL and 500 µL

### Quality Control Considerations

Good Laboratory Practice suggests that the NEPHROCHECK® Calibration Verification Kit should be tested:

- At least once every 6 months
- After ASTUTE140® Meter maintenance or servicing
- In accordance with local, state, and/or federal regulations or accreditation requirements

### Calibration and Verification Procedure

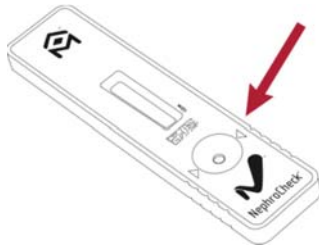
NOTE: THE NEPHROCHECK® Calibration Verification vials should be prepared following the procedures for preparing and testing patient samples with the NEPHROCHECK® Test. (For more details, see the NEPHROCHECK® Test Package Insert)


Prepare each NEPHROCHECK® Calibration Verification Kit Vial as follows:

1. Configure the ASTUTE140® Meter to test the Calibration Verification vial (See “Testing a Patient Sample” in the ASTUTE140® Meter User Manual for detailed instructions).

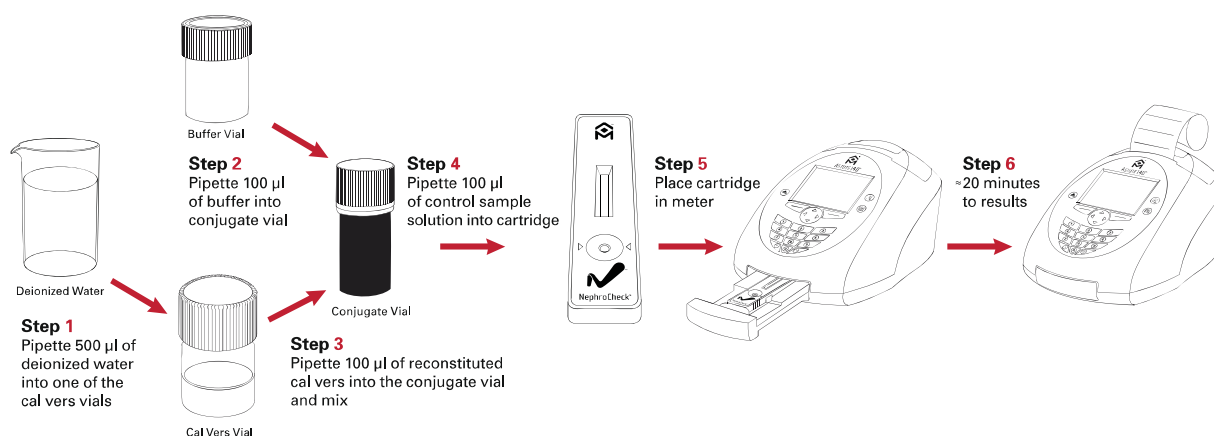
NOTE: When prompted for Patient ID, enter 001, 002, 003, 004, or 005 corresponding to each NEPHROCHECK® Calibration Verification Vial level to be run.

2. Remove the cap from a single NEPHROCHECK® Calibration Verification Vial (Level 1, 2, 3, 4 or 5).
3. Add 500 µL deionized water using a calibrated, precision pipette.
4. Recap the vial and invert the vial three times to mix.
5. Visually confirm the lyophilized material is completely dissolved before use.
6. Remove a new NEPHROCHECK® Test Cartridge and NEPHROCHECK® Test Conjugate Vial from the foil pouch and place on a flat surface.
7. Each NEPHROCHECK® Test Conjugate Vial contains a single conjugate bead. Remove the cap from the NEPHROCHECK® Test Conjugate Vial. Visually inspect the cap and vial to ensure that the conjugate bead has not adhered to the cap and is present in the vial. If the bead has adhered to the cap, place the cap on the vial and tap three times. Repeat if necessary until the bead drops into the vial. Do not touch the bead or attempt to remove the bead from the cap by any other means.
8. Pipette 100 µL of NEPHROCHECK® Test Buffer Solution (included in the NEPHROCHECK® Test Kit) into the conjugate vial containing the conjugate bead. This will result in reconstitution of the conjugate bead into solution.
9. Pipette 100 µL of reconstituted NEPHROCHECK® Calibration Verification solution into the NEPHROCHECK® Test Conjugate Vial that now contains the reconstituted conjugate bead solution. Mix thoroughly (mix at least three times using the pipette tip).
10. Pipette 100 µL of mixed Conjugate Vial solution into the designated sample port on the NEPHROCHECK® Test cartridge. Wait approximately one minute for the sample to be absorbed into the round well.



11. Using the grips on the side of the NEPHROCHECK® Test cartridge, position the cartridge inside the ASTUTE140® Meter drawer with the Astute Medical logo towards the inside of the meter drawer. Keep the NEPHROCHECK® Test cartridge horizontal and avoid tipping the test cartridge during placement into the ASTUTE140® Meter drawer.
12. Close the ASTUTE140® Meter drawer. In approximately 20 minutes the Calibration and Verification result will be displayed (The NEPHROCHECK® Test incubation time must be  $\leq$  25 minutes from the sample incubation time set in the ASTUTE140® Meter). The ASTUTE140® Meter will display a single numerical value per level run.
13. Press the  key to open the ASTUTE140® Meter drawer. Each calibration verification vial and conjugate vial is intended for single use only. Remove the NEPHROCHECK® Test cartridge and discard the cartridge, the Calibration Verification Vial, and the conjugate vial in accordance with local regulations. The NEPHROCHECK® Calibration Verification Kit Vial is intended for single use only.
14. Repeat steps 1–13 for the remaining four levels of NEPHROCHECK® Calibration Verification Kit Vials.

## NEPHROCHECK® Calibration Verification Preparation Process



## Results

The ASTUTE140® Meter automatically calculates a single numerical risk result for each NEPHROCHECK® Calibration Verification level that is tested. This result is displayed on the ASTUTE140® Meter screen after the NEPHROCHECK® Test procedure is completed; results for the individual markers are not displayed. Compare the displayed result with the information provided on the back of the NEPHROCHECK® Expected Values Card to ensure the results fall within the published ranges. If any of the levels fall outside the acceptable range, test that specific level again using a new NEPHROCHECK® Test Kit. If it does not fall into the assigned range after re-testing, contact Astute Medical Technical Support. The NEPHROCHECK® Test results are also stored in the ASTUTE140® Meter memory and may be accessed at any time (See “Review and Management of Test Results” in the ASTUTE140® Meter User Manual).

## Expected Results

Expected values are determined by testing the NEPHROCHECK® Calibration Verification materials with the NEPHROCHECK® Test during product manufacturing. The expected value ranges are determined from the average and standard deviation of these testing results.

## Standardization

The NEPHROCHECK® Calibration Verification Kit is traceable to reference standard solutions that contain defined mass (concentration) of TIMP-2 and IGFBP-7 proteins, in accordance with EN ISO 17511. The NEPHROCHECK® Calibration Verification materials and NEPHROCHECK® Test cartridges are traceable to the same reference standard solutions.

## Limitations of the Procedure

The ranges given for the expected values are intended only as guidelines. Laboratories should determine their ranges and standard deviations based on their own testing policies and tolerance limits.

## Ordering and Contact Information



















NEPHROCHECK® Calibration Verification Kit (PN 500009)

For questions regarding the use or performance of the NEPHROCHECK® Calibration Verification Kit or any Astute Medical, Inc. product, please contact Astute Technical Support.

## Contact Information

Astute Medical, Inc.  
 3550 General Atomics Ct.  
 Building 2  
 San Diego, CA 92121  
 USA  
 Phone: +1 (855) 317-2788 (Monday thru Friday, 8am – 5pm PST)  
 Fax: +1 (858) 332-0690  
 Email: [technicalsupport@astutemedical.com](mailto:technicalsupport@astutemedical.com)  
 Website: [www.astutemedical.com](http://www.astutemedical.com)

## Symbol Glossary

	Manufacturer
	Consult instructions for use
	Catalog number
	Batch code
	Use by YYYY-MM-DD
	Do not reuse
	Temperature limitation
	Biological risks
	Average
	Standard deviation
	Contents of package
	Expected value
	Calibration Verification Kit
	Calibration Verification Vial 1
	Calibration Verification Vial 2
	Calibration Verification Vial 3
	Calibration Verification Vial 4
	Calibration Verification Vial 5

## End User License Agreement

PURCHASE AND/OR USE OF THIS PRODUCT SHALL CONSTITUTE ACKNOWLEDGMENT AND ACCEPTANCE OF THE TERMS AND CONDITIONS OF THIS END USER LICENSE AGREEMENT

Astute Medical, Inc. (together with its affiliates, "Astute") hereby grants to the purchaser/user ("you", "your") of this product the limited license to use this product solely for the purpose as specified on the approved label therefor. You hereby agree that you shall use this product solely for such purpose and for no other purpose.

If you do not agree with each of the terms and conditions set forth in this End User License Agreement, please contact Astute within ten (10) days after receipt of this product to return the unused and unopened product for a full refund.

LIMITED WARRANTY. FOR THE APPLICABLE WARRANTY PERIOD, ASTUTE WARRANTS THAT THIS PRODUCT SHALL BE (A) OF GOOD QUALITY AND FREE OF MATERIAL DEFECTS, (B) FUNCTION IN ACCORDANCE WITH THE MATERIAL SPECIFICATIONS REFERENCED IN THE PRODUCT MANUAL, AND (C) APPROVED BY THE PROPER GOVERNMENTAL AGENCIES REQUIRED FOR THE SALE OF PRODUCTS FOR THEIR INTENDED USE AS DESCRIBED IN THE APPLICABLE PRODUCT MANUAL OR INSERT THROUGHOUT THE PRINTED EXPIRATION DATE, OR IN THE CASE OF THE ASTUTE140® METER FOR A PERIOD OF TWELVE (12) MONTHS FROM THE DATE OF SHIPMENT (THE "LIMITED WARRANTY"). IF THIS PRODUCT FAILS TO MEET THE REQUIREMENTS OF THIS LIMITED WARRANTY, THEN AS YOUR SOLE REMEDY, ASTUTE SHALL EITHER REPAIR OR REPLACE, AT ASTUTE DISCRETION, THIS PRODUCT.

EXCEPT FOR THE LIMITED WARRANTY STATED IN THIS SECTION, TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, ASTUTE DISCLAIMS ANY AND ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT REGARDING THIS PRODUCT.

ASTUTE'S MAXIMUM LIABILITY FOR ANY CUSTOMER CLAIM SHALL NOT EXCEED THE NET PRODUCT PRICE PAID THEREFOR.

NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR LOSS OF BUSINESS, PROFITS, DATA OR REVENUE, EVEN IF A PARTY RECEIVES NOTICE IN ADVANCE THAT THESE KINDS OF DAMAGES MIGHT RESULT.

The Limited Warranty above shall not apply if this product has been subjected to physical abuse, misuse, abnormal use, use inconsistent with the product manual or insert, fraud, tampering, unusual physical stress, negligence or accidents.

Any warranty claim pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

You agree to use this product in strict accordance with all applicable local, state and federal laws, regulations and guidelines, and industry practices.

You further agree that you shall not resell or otherwise transfer this product to any other person or entity, without the prior express written approval of Astute Medical, Inc. Information about commercial resale or distribution of the products of Astute Medical, Inc. may be obtained by e-mailing us at [info@astutemedical.com](mailto:info@astutemedical.com) or by writing to us at Astute Medical Inc., General Atomics Court, MS 02/641, San Diego, CA, 92121, USA.

No amendment or addition to this End User License Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.

©2014 Astute Medical, Inc. Astute Medical®, the AM logo, ASTUTE140®, NEPHROCHECK® and the NEPHROCHECK® logo are registered trademarks of Astute Medical, Inc. in the United States. AKIRISK™ is a trademark of Astute Medical, Inc. in the United States. For information regarding trademarks and other intellectual property applicable to this product, please see [AstuteMedical.com/US/About/IntellectualProperty](http://AstuteMedical.com/US/About/IntellectualProperty). PN 0311 Rev A 2014/07/23