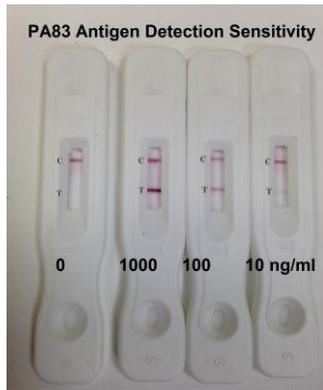


## Sensitivity of the test



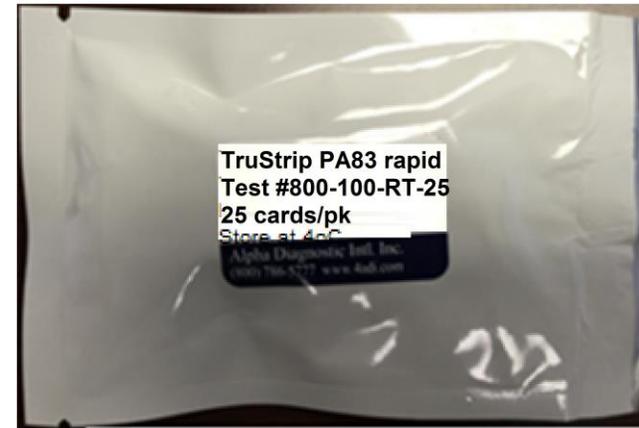
The sensitivity of the rapid test was tested using purified recombinant PA83 protein **in the sample buffer**. The test has a sensitivity of ~10 ng/ml (test line is visible as a faint line, see pic on the right). Intensity of the test line is proportional to the antibody concentration. Therefore, it is possible to get a semi-quantitative concentration of the antibody in the sample by comparing it with a known concentration of the reference standard. We recommend testing of each individual humanized antibody before and after mixing with other antibodies.

The test has also detected the PA83 in human serum. We recommend testing 50 ul serum with 50 ul of sample buffer (or 50% serum). The rapid is not intended nor validated to diagnose anthrax patients. Influence of buffer formulation or non-drug additives has not been assessed.

## Related Items

800-100-P83	Anthrax Protective Antigen 83 (PA83) Protein ELISA kit, 96 tests,
900-100-83T	Mouse Anti-Anthrax Protective Antigen 83 (PA83) Ig's ELISA kit,
900-105-83G	Mouse Anti-Anthrax Protective Antigen 83 (PA83) IgG-specific ELISA
900-110-83G	Bovine/Cow Anti-Anthrax Protective Antigen 83 (PA83) IgG ELISA kit
900-115-83G	Swine Anti-Anthrax Protective Antigen 83 (PA83) IgG ELISA kit, 96 tests
900-120-83T	Rabbit Anti-Anthrax Protective Antigen 83 (PA83) Ig's ELISA kit, 96 tests
900-125-83G	Bison Anti-Anthrax Protective Antigen 83 (PA83) IgG ELISA kit, 96 tests
900-126-LFG	Bison Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-127-EFG	Bison Anti-Anthrax Edema Factor (EF) IgG ELISA kit, 96 tests
900-130-83T	Goat Anti-Anthrax Protective Antigen 83 (PA83) Ig's ELISA kit, 96 tests
900-135-83G	Deer/Elk Anti-Anthrax Protective Antigen 83 (PA83) IgG ELISA kit,
900-140-83T	G. pig Anti-Anthrax Protective Antigen 83 (PA83) Ig's ELISA kit, 96 tests
900-150-83T	Monkey Anti-Anthrax Protective Antigen 83 (PA83) Ig's ELISA kit,
900-160-83T	Human Anti-Anthrax Protective Antigen 83 (PA83) Ig's ELISA kit
900-165-83G	Human Anti-Anthrax Protective Antigen 83 (PA83) IgG ELISA kit,
900-170-83G	Sheep Anti-Anthrax Protective Antigen 83 (PA83) IgG ELISA kit,
900-200-LFM	Mouse Anti-Anthrax Lethal Factor (LF) Ig's ELISA kit, 96 tests
900-210-LFH	Human Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-220-LFR	Rabbit Anti-Anthrax Lethal Factor (LF) Ig's ELISA kit, 96 tests
900-230-LFG	Swine/Feral Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-235-LFM	Swine/Feral Anti-Anthrax lethal Factor (LF) IgM ELISA kit, 96 tests
900-240-LFB	Bovine Anti-Anthrax lethal Factor (LF) IgG ELISA kit, 96 tests
900-250-LFG	Goat Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-260-LFG	Sheep Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-270-LFD	Deer/Elk Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-280-LFM	Monkey Anti-Anthrax Lethal Factor (LF) IgG ELISA kit, 96 tests
900-300-EFM	Mouse Anti-Anthrax Edema Factor (EF) Ig's ELISA kit, 96 tests
900-310-EFH	Human Anti-Anthrax Edema Factor (EF) IgG ELISA kit, 96 tests
900-320-EFR	Rabbit Anti-Anthrax Edema Factor (EF) Ig's ELISA kit, 96 tests
900-330-EFG	Swine/Feral Anti-Anthrax Edema Factor (EF) IgG ELISA kit, 96 tests
900-335-EFM	Swine/Feral Anti-Anthrax Edema Factor (EF) IgM ELISA kit, 96 tests
900-340-EFB	Bovine Anti-Anthrax Edema Factor (EF) IgG ELISA kit, 96 tests

## TruStrip™ Rapid Gold Anthrax Protective Antigen 83 kDa (PA83)



**Cat# 800-100-RT-25 (25 tests)**  
**Cat# 800-100-RT-100 (100 tests)**

**A lateral flow immunochromatographic test for the qualitative or semi-quantitative detection of Anthrax PA83 antigens in biological buffers (Results in 2-10 mins)**



**ALPHA DIAGNOSTIC  
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## TruStrip Rapid Gold PA83 Protein Test-Contents

Components	#800100-RT-25	#800100-RT-25
TruStrip PA83 rapid test cards, individually packed in sealed pouch # 800101	25 cards	50 cards
PA83 antigen standard, 1 vials (0 ng/ml), 0.5 ml solution #800102NC	1 vial	1 vial
PA83 antigen standard, 1 vials (100 ng/ml), 0.5 ml solution #800103PC	1 vial	1 vial
PA83 dilution buffer # 800104	10 ml	10 ml
Complete Instruction Manual #800-100-RT-50	1	1

### Intended Use

TruStrip™ Rapid Gold anthrax PA83 antigen Test is a lateral immunochromatographic test card for the qualitative or semi-quantitative detection of PA83 antigen in biological buffers or in serum or plasma. This test is especially suited to test purified toxin or during manufacturing process. The test is not validated for detection in blood, serum or plasma. This kit is for research use only, not for diagnostic or therapeutic use.

### INTRODUCTION

Anthrax is a zoonotic disease caused by the spore-forming bacterium *Bacillus Anthracis*. The disease most commonly occurs in wild and domestic mammals (e.g., cattle, sheep, goats, camels, antelope, and other herbivores). Anthrax occurs in humans when they are exposed to infected animals or tissue from infected animals or when they are directly exposed to *B. Anthracis* or the spores. Depending on the route of infection, anthrax disease can occur in three forms: cutaneous, gastrointestinal, and inhalation. *B. Anthracis* spores can remain viable and infective in the soil for many years.

*B. Anthracis* has also been manufactured as a biological warfare agent because of the ability of its spores to be transmitted by the respiratory route, the high mortality of inhalation anthrax, and the greater stability of *B. Anthracis* spores compared with other potential biological warfare agents. *B. Anthracis* evades the immune system by producing an anti-phagocytic capsule. In addition, *B. Anthracis* produces three proteins - protective antigen (PA), lethal factor (LF), and edema factor (EF) - that act in binary combinations to form two exotoxins known as lethal toxin and edema toxin. PA and LF form lethal toxin; PA and EF form edema toxin. LF is a protease that inhibits mitogen-activated protein kinase-kinase. PA is required for binding and translocating LF and EF into host cells. PA is an 83 kD protein that binds to receptors on mammalian cells and is critical to the ability of *B. Anthracis* to cause disease. After binding to the cell membrane, PA is cleaved to a 63 kD fragment that subsequently binds with LF or EF. LF or EF bound to the 63 kD fragment undergoes receptor-mediated internalization, translocation into the cytosol.

An improved vaccine for livestock, based on a live encapsulated avirulent variant of *B. Anthracis*, has served as the principal veterinary vaccine. AVA, the only licensed human anthrax vaccine in the United States, is produced by BioPort and is prepared from a cell-free filtrate of *B. Anthracis* culture that contains no dead or live bacteria. The strain used to prepare the vaccine is a toxigenic, non-encapsulated strain known as V770-NP1-R. The filtrate contains a mix of cellular products including PA83 and is adsorbed to aluminum hydroxide as adjuvant. More advanced vaccines are based upon recombinant purified PA83 proteins (Vaxgen).

### PRINCIPLE OF THE TEST

Anthrax PA83 protein is captured by specific antibodies on the test line and detected by Gold-labeled antibody conjugate. The test line is visible as a reddish-brown line on the card. Control lines contains antibodies that captures gold labeled antibodies. The control line must be obtained with or without humanized antibodies to assure the integrity and functionality of the rapid test.

### PRECAUTIONS

The ADI TruStrip rapid test is intended for *in vitro research* use only. For proper analysis of results, be sure to include positive and negative controls, blanks, and/or protein standards as appropriate. All test must be done as appropriate for the sample and disposed accordingly. Applicable MSDS, if not already on file, for the following reagents can be obtained from ADI or the web site for Proclin-300 (0.1% v/v in standards, and assay buffers). [http://4adi.com/commerce/info/showpage.jsp?page\\_id=1060&category\\_id=2430&visit=10](http://4adi.com/commerce/info/showpage.jsp?page_id=1060&category_id=2430&visit=10)

### STORAGE AND STABILITY

The test are stable at 2-8°C for 1-year or until the expiration date printed on the label.

### Items Required but not supplied with this kit

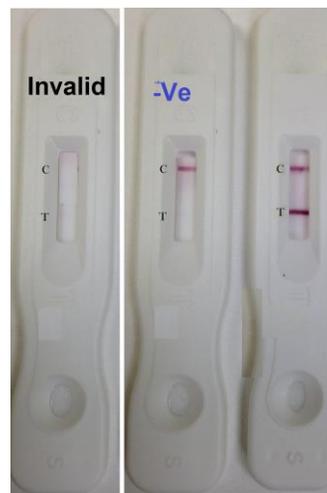
*Precision pipettes* (25-100 µl) for and dispensing of samples. .

### Samples

Test sample should be common biological buffers such as PBS or Tris at pH 6.5-8.0. Expected PA83 concentration should be 0.100-10 ug/ml for best performance. Supplied standards should be mixed 1:1 with the user buffer to make sure that the buffers are not adversely impacting its detection. Not tested for serum or plasma.

### TruStrip Rapid Gold Anthrax PA83 test Procedure

Approx. size of the cards



non-function of the kit. (See the images above).

1. Remove the rest device from foil pouch and place it on a flat and dry surface. Bring all reagents to room temp (25-28°C).

2. Dispense 100 ul each of supplied -ve, +ve controls, and samples into the **sample wells (S)** on the card. **Note:** Do not overload the sample (>100 ul). If sample is limiting then sample diluent can be added to make the 100 ul volume.

3. Leave the device for **1-5 mins at room temp and watch the development of red lines in the control (Control, top) and the result zone (R bottom)**. Top control line must always be visible in order for the test to be valid. The bottom result line appears within 1-5 mins and results recorded (see examples on page 3). Non-Specific faint test line may appear after 7 min even in the absence of negative samples. So you must record the results within 1-5 mins. No lines also makes the test invalid and may indicate expiration or

4. Record results by taking the picture or store the device in a plastic bag at room temp.