# KIS™ Test Instructions


**United States Department of Agriculture**
Food Safety Inspection and Service

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# Overview

The Charm KIS™ test for kidney is an antibiotic detection test for kidney tissue. Its principle of detection is microbial inhibition. Bacteria, cultured in agar with purple pH indicator media and kidney extract, generate acid that produces a yellow color. In the presence of antibiotic, the bacterial growth is inhibited and the test remains blue/purple. The test can be used for fresh or thawed kidneys.

After reading and reviewing these KIS test instructions you should be familiar with the following:

- The apparatus and supplies
- How to prepare and store the Negative Control
- Swabbing the sample and performing the KIS test
- Interpreting the results

# Apparatus and Supplies

You will need the following apparatus and supplies to perform the KIS test:

- Heating block such as the Digital Dry Block Heater
- Swab/Testing Device
- Negative Control (Reconstituted Negative Control from Charm)
- Timer
- Ink pen
- Permanent marker
- Deionized or distilled water
- Device for delivering 1ml of water
- A rack, or similar device, to hold the KIS tests

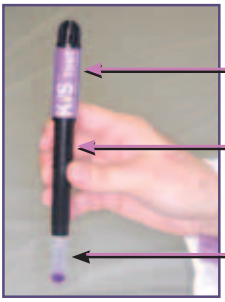
Required materials for KIS™ test. (USDA photo)

# 1. KIS TEST

## A. Bag


Note the lot number on each bag. Each lot of tubes may have a different required incubation time. So, it is important to check the label on the bag for the incubation time.

## B. Tube Description




This is the individual KIS Test Device. It is composed of three main parts. The top part contains the cap and swab. Next is the Tube Housing or middle section. The third part of the KIS device is the vial. Each part will be discussed further.

### Cap and Swab

The cap of the KIS device pops off to expose the swab.

### Tube Housing

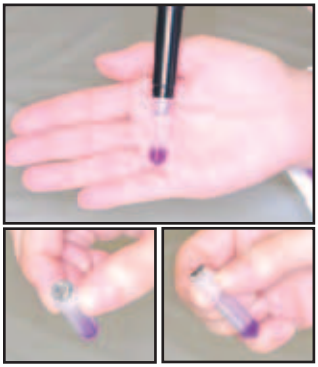
There are molded threads on the Tube Housing. These are the threads that you will "engage" when performing the KIS test. At the top of the tube, above the threads, is the cookie cutter like edge.

### Cookie Cutter Edge

Use this top edge of the tube to cut the kidney before swabbing. Use the start of the threads as a depth guide to cut approximately 2 cm into the cortex of the kidney.

## Vial

The vial has an upper and lower foil that the swab will pierce. Between these two foils there is a clear solution. At the bottom of the vial you see the solid purple growth medium or agar. This medium or agar will turn yellow in the absence of an antibiotic. Be sure the lower vial is tightened and secured in tube housing when testing is performed.



## 2. Using the Digital Dry Block Heater

***Depending on when results will be read, there are two methods for using the Digital Dry Block Heater.***

### A. Timed Mode-Reading results for up to 16 hours after heating

When setting the timer, it is important to subtract 15 minutes from the prescribed time printed on the test kit label. This is because the test tubes are allowed to continue to incubate and then cool within the unit prior to reading. Plug in the Digital Dry Block Heater and press the Standby Button. To set the temperature, press the up/down arrows to the right of the temperature display until you reach the desired temperature of 64.0 degrees C. A single pressing of either key will change the set temperature by 0.1 degree C. To quickly change the temperature, press and hold the up/down arrows. When

you release the button, the display will blink off then on, indicating the new set temperature has been accepted. To start the unit heating to the set temperature (64.0 degrees C), press the on/off button to the right of the temperature display to activate the heating function. A green indicator light will illuminate next to the on/off button. The temperature display will alternate between the set and actual temperatures. There are three audible beeps to indicate the set-point temperature has been reached. It is important to allow several minutes for the temperature to stabilize throughout the whole block before use. To set the timer, press the up/down arrows to the right of the time display until you reach the desired time. To start the timer, press the on/off button to the right of the time display. The timer will begin to count down. When 00 minutes and 00 seconds (00:00) is reached, the unit will beep five times. Both the time and heating functions will shut off automatically and the time display will default back to the set time. To repeat for the same temperature and time, press temperature on/off button and allow the temperature to reach the 64.0 degree C. Then simply press the timer on/off button to start the timer. See manufacture's instructions for further details about this function.

## B. Continuous Heating Mode-Reading results in approximately 3 hours.

For continuous heating, which allows for back to back runs, press and hold the on/off button to the right of the time display. After (3) three seconds, the display will indicate the previous set time. Simultaneously press both the up and down arrows, the display will indicate zero (0:00). Make sure temperature is at the 64.0 degree C set point. To start the timer, press the on/off button to the right of the timer display. It is strongly advised that a secondary timer, such as a portable timer, is also used. The timer will show accumulated time. Remove the tests when the prescribed time indicated on the KIS label has been reached. To stop the timer, simply press the on/off button to the right of the timer display. To reset the timer, for the next batch, press the same on/off button for (3) three seconds. 0:00 should now be displayed. See manufacturer's instructions for more details.

## 3. Setting the portable timer

To set the portable timer press hours and minutes to adjust the time to match the incubation time required. Press start to begin the timer. When done, press Stop and then Clear to reset the timer to zero. Read the manufacturer's instructions for further details.

## Procedure

1. **Plug in the Digital Dry Block Heater and press the Standby Button.**
   To set the temperature, press the up/down arrows to the right of the temperature display until you reach the desired temperature of 64.0 degrees C. A single pressing of either key will change the set temperature by 0.1 degree C. To quickly change the temperature, press and hold the up/down arrows. When you release the button, the display will blink off then on, indicating the new set temperature has been accepted. To start the unit heating to the set temperature (64.0 degrees C), press the on/off button to the right of the temperature display to activate the heating function. A green indicator light will illuminate next to the on/off button. The temperature display will alternate between the set and actual temperatures. Please note the actual temperature prescribed for the test is 64 ± 2 degrees C. There are three audible beeps to indicate the set-point temperature has been reached. It is important to allow several minutes for the temperature to stabilize throughout the whole block before use.

2. **How to Prepare and Store the Negative Control Solution**
   A negative control must be analyzed with each batch of samples. Place a Negative Control tablet into the container provided and reconstitute the tablet with 1 milliliter of either deionized or distilled water. Shake the vial for 10 seconds to dissolve the tablet. Shake the vial again after five minutes. The negative control solution is now ready to use. The reconstituted negative control solution can be stored refrigerated and used for up to 5 days. Label accordingly to assure proper storage and use.

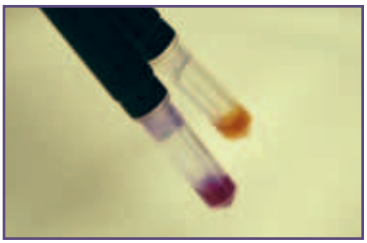
## Analysis

1. Begin by selecting the number of KIS tests that corresponds to the number of kidneys to be tested. Remember you will need one additional KIS test for the Negative Control. Place all your KIS tests in the test tube rack.
2. Using the permanent ink marker label each tube to be used with a unique identifier to the kidney tested. For example, the last three digits of the retain tag number can be recorded. Label the Negative Control tube as the Negative Control.
3. It is helpful to loosen the swabs on all the KIS tests prior to swabbing the kidneys and line up the kidneys in the order that you will test them.
4. Next, expose the swab from the tube housing by pulling the swab handle from the KIS™ body. Use the exposed open end of the KIS™ tube housing like a cookie cutter to make a circular cut in the kidney cortex that is about ½ inch (1 to 2 cm) deep. Note: Be sure to remove fat layer.
5. Hold the shaft to support the swab and place cotton tip inside the circular cut in the kidney tissue. Twirl and move the swab tip around the cut for about 30 seconds or until the swab is saturated with fluid. Assure the swab is thoroughly saturated. Any whitish appearance in cotton tip of swab indicates more absorption is needed. Remove any particulates from the swab.
6. Place the swab that is saturated with kidney fluid back into the labeled tube housing but **DO NOT** pierce the top foil on the vial yet. Repeat steps one through five for all of the kidney samples to be tested.
7. For the Negative Control, place the KIS swab in the test tube containing the reconstituted Negative Control for 10 seconds. Place the swab that is saturated with Negative Control into labeled Negative Control tube housing but **DO NOT** pierce the top foil on the vial yet.
8. Next pierce the top foil on the vial with the saturated kidney fluid swab and the Negative Control swab. Hold the KIS device upright, and while pressing downward, slowly activate by engaging the cap with tube housing threads into the tube body. Screw down half way so that the swab only pierces through the top vial foil seal and goes into top clear liquid but not through the bottom foil seal.

9. Start the two minute timer. Care should be taken to avoid piercing the bottom seal. If the bottom seal is accidentally pierced then, screw the swab completely down and wait two minutes. Repeat above for all the swabs and note that each swab should sit in the top clear liquid layer for two minutes.
10. After the two minutes are up, completely screw down the swab so it is directly above the purple agar. Hold the KIS test vertically and lightly tap 5 times on a hard surface to force any residual liquid down on top of the purple agar.
11. Fully retract the swab, and lightly tap the vial 5 times again. You should see fluid on top of the purple agar. Repeat for all KIS tests.
12. Determine and select your reading interval. Tests can be read in approximately 3 hours or held for up to 16 hours after the test has been automatically shut off and cooled. It is strongly advised that a secondary timer, such as portable timer is also used.
    a. *Timed Mode-Reading results for up to 16 hours after heating*
       See Section 2.A for instrument set up.
       Note: In order to read tests, refer to step 16 and be sure to allow tubes to remain and cool in the heating block.
    b. *Continuous Mode-Reading results after approximately 3 hours.*
       See Section 2.B for instrument set up.
       Note: In order to read tests, refer to step 15 and be sure to remove tubes after time has elapsed.
13. Check the digital dry block heating block to see if it is stabilized and reading 64 ± 2 degrees C.

14. Insert the Negative Control and all the KIS tests into the heating block. Be sure each of the lower vials are tightened and secured in the tube housing when being inserted into the heating block.

15. Remove the KIS tests and Negative Control, when the time indicated on the KIS label has been reached and allow them to cool. Wait a few minutes before making an interpretation.
16. If using the auto shut off feature, the incubator will cool and vial color will remain stable in the incubator for up to 16 hours.



Tests should be read after the recommended incubation time. If performed in the shut off mode or if removed from the incubator, the tests will be stable up to 16 hours.

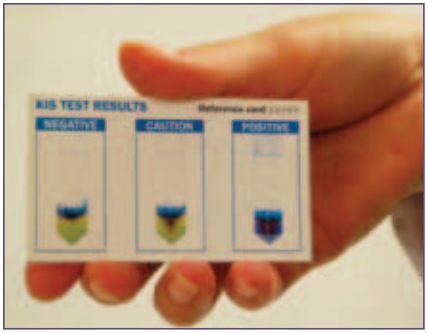
## Interpretation

Compare agar color to interpretation card provided with the test kit. Read results under cool white fluorescent light and compare to the color chart. Do not read color under direct sunlight. The Negative Control must be yellow for the sample results to be considered valid.

## Results

- Yellow or yellow/green colors are **negative**.

- Blue/purple colors are **positive**. Assure purple color throughout vial.




- Yellow or yellow/green in lower half of vial with blue/purple or brown in upper half of vial are **CAUTION**. These samples **shall** be interpreted as **negative since there is not a consistent blue/purple color throughout the tube**.

## Conclusion

To recap, you should now be familiar with the following:

- The equipment required for the KIS test
- How to prepare and store the Negative Control
- How to use the tube to cut the kidney
- How to swab the cut kidney
- How to perform the KIS test
- How to interpret the results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