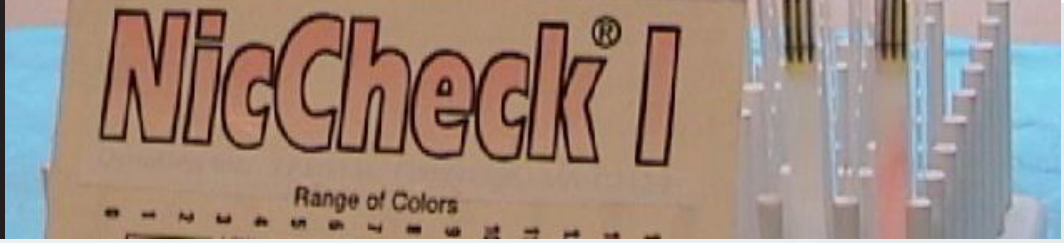
NicCheck I
Assay Instructions & Notes



Specimen Collection & Preparation

IMPORTANT:
- collect urine in clean container
- storage properly
- do not add preservatives to specimen
- bring all stored specimens to room temperature before testing

NicCheck I test strips may be used with any freshly voided, stored (refrigerated or frozen) urine specimens or with urine collected under special conditions, such as first-morning specimens and post-prandial urine specimens. The urine specimen must be collected in any clean container. Preservatives must not be added to the urine specimen. If testing cannot be performed within 4 hours after collection of the urine, the specimen must be stored at 2-8 ºC. If stored at 2-8 ºC, testing should be performed within 48 hours. The specimens must be brought to room temperature prior to testing, and mixed thoroughly before use. The test may also be performed on specimens stored frozen at -20 ºC. The frozen specimens may not be frozen and thawed more than three times. Studies beyond three freeze-thaw cycles have not been conducted. If stored frozen, the specimens must be thawed and brought to room temperature prior to testing.

NOTE: **NicCheck I** test strips function appropriately in the pH range of 4.5-8.5. The test may react as false negative if the pH of the urine is outside of this range. Normal urine has a pH of 4.5-8.0 with an average pH of 6.0.

Strip Handling Procedures

IMPORTANT:
- handle strip at arrow end with gloves
- remove strip with clean forceps
- strip facing down in test tube
- must use a 13 x100 clear tube
- close canister or foil pouch tighly to protect used strips
- protect strips from extra lighting and humidity

Each test strip should be carefully removed from the canister or foil pouch by only handling the strip at the arrow end. Handling other parts of the test strip must be avoided. Use of proper lab procedures calls for the use of gloves to handle the strips, alternatively a pair of clean forceps may be used to remove the strips from the canister. The test strip must be placed in the 0.5 mL urine sample with the indicator arrow pointing downward in order for the urine sample to diffuse past the reagents in the proper sequence. **The test reaction must be performed in a 13 x 100 mm clear tube in order to enclose the length of the entire test strip.**

NOTE: The canister or foil pouch must be closed tightly after removal of the required number of strips necessary to perform the proper number of tests being performed at that time. The strips are very sensitive to humidity and must be kept stored in the canister or foil pouch they are provided in. DO NOT TRANSFER OR STORE STRIPS IN ANY OTHER CONTAINER.

STRIP STORAGE INSTRUCTIONS

NicCheck I test strips do not require refrigerated shipping. **Upon receipt, the canister should be kept at 2-8 ºC when not being used. The test strips should be protected from unnecessary light and humidity and the canister or foil pouch must be kept tightly closed after removal of the required number of strips.**

If the strips are left at ambient lab temperatures mistakenly for short periods of time (10-40 hours) and then returned to the refrigerator the tests should still perform properly as the tests are more sensitive to high humidity exposure than high temperatures.

Indications of Strip Instability

A bright yellow, pink, violet or VERY dark brown color if seen on the test strip may indicate instability. However, a pale brown color may be observed at the lower end (bottom) of an unused test strip.

NicCheck Test Procedure

1. Obtain a urine specimen, then transfer 0.5-1.0 mL of urine to the very bottom of a 13 x 100 mm test tube or equivalent clear 13 mm diameter tube. **Try to avoid the touching of the side walls of the test tube.**
2. Remove a **NicCheck I** test strip from the canister or foil pouch, handling the strips only at the arrow end. **Do not touch any other part of the test strip.** Alternatively, a clean pair of forceps may be used to remove the test strip from the canister.
3. Place the **test strip directly into the urine specimen with the arrow pointing downward** into the specimen.
4. After introduction of the test strip into the specimen, **observe results after 15 minutes**. For differentiation into "low" versus "high" consumption of nicotine, comparison of the test results to the color chart provided must also be determined after 15 minutes. For consistency or in the case of high humidity, you should cover the tubes with parafilm, a paper or card-board card, or anything flat that will sit on the top of the tubes.

Interpretation of Results

NEGATIVE: absence of color

POSITIVE: pale to dark pink

Yellow spot or purple line near top of arrow should be disregarded.

The appearance of a pale pink to dark pink color on the strips is a positive reaction and indicates the presence of nicotine and/or its metabolites in the specimen. Occasionally, colors in the spectrum of orange to reddish pink may be observed. These are also to be considered as true positive reactions. Color development usually occurs along the length of the test strip. The intensity of color on the strip at the end of 15 minutes may be compared to those on the color chart (see #7), to differentiate between "low" versus "high" nicotine consumption. If the color on the test strip matches in intensity or is darker in intensity than the pink color on the color chart, the result is interpreted as a "high" positive. Absence of a color in the pink to red spectrum is considered a negative result.

The pink color may be leached into the urine sample if the strip has been stuck to the side wall of the 13 X 100 mm test tube. In this case the urine will take on a pink color which also indicates a positive result. In this case if you are interested in being able to differentiate between "low" versus "high" nicotine consumption, you will need to repeat the test.

NOTE: When the **NicCheck I** test reaction is complete, both for positive and negative samples, it is normal for a yellow spot to develop at the top end of the strip (near the arrows), this may also be accompanied by a purple/violet line and is not meant to be used for interpreting results.

Limitations of the Procedure

EFFECT RESULTS:

- daily consumption of 500+ mm of niacin
- more than 1 ml of urine in test tube
- performing urine test in collection container
- arrow strips facing the wrong way during test
- urine on side of test tube
- no covering tube in area of high humidity

Consumption of therapeutic levels (daily dose of 500 mg or greater) of niacin may result in a false-positive reaction by the **NicCheck I** test.

Delivering more than 1 mL of urine into the test tube for the **NicCheck I** test may result in improper color development due to inability of the sequential reaction to occur. Delivering less than 0.3 mL of urine will be insufficient to wet the full length of the test strip. These volumes are base on the 13 mm diameter test tube.

Performing the **NicCheck I** test in the beaker or urine collection container used for collecting the urine specimen is unacceptable. Since the color development depends upon the sequential reaction of reagents along the entire length of the test strip, it is important to use a 13 X 100 mm test tube which has a proper diameter and is long enough to enclose the entire length of the strip.

For color development, the test strip must be placed with the arrow pointing downward into the tube.

Urine must be delivered directly to the bottom of the test tube in order to avoid sticking of the test strip to the inner wall of the tube. If the test strip sticks to the inner wall of the test tube, it does not allow for proper color development along the length of the test strip. The urine may wick the color off the strip and turn the color of the urine pink which is also an indication of a positive result however you may be unable to differentiate between "low" versus "high" nicotine consumption.

Under conditions of high humidity the test tube containing the **NicCheck I** test strip must be kept covered. For consistency you may want to cover the NicCheck test while it is being performed. Parafilm, a paper or cardboard card, or anything flat may be used.

The **NicCheck I** result should be read 15 minutes after introduction of the test strip into the urine. Reading the reaction after 25 minutes may result in a decrease in the color intensity on the NicCheck test strip.

WARNINGS AND PRECAUTIONS

There have been no reports of hazards associated with the appropriate use of the NicCheck I test strips. Body fluid specimens must be considered to be infectious and must be handled with appropriate precautions.

While performing the test, cyanogen chloride is produced in situ in a very small quantity as an intermediate. The concentration of this intermediate generated during the NicCheck I reaction is 2.3% of the reported inhalation limit in man if exposed for 10 minutes. However, it should be mentioned that cyanogen chloride is toxic and an irritant. It may be harmful if swallowed or inhaled or absorbed through skin. Clothing, eye, and skin contact with the NicCheck I test strip must be avoided. If skin contact is made, the affected area must be flushed thoroughly with water. Vapors or mists or dusts must not be inhaled. The NicCheck I test should be run in a ventilated area. The test strip must not be ingested.

Chloramine-T and potassium thiocyanate are present on the strip in micromolar quantities. They may irritate the eyes or skin upon contact. They can cause allergic reaction if mishandled.

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