



K-CHECK

Catalog No. 1555

For Urine, Serum, Plasma or whole Blood Ketones determination.

For *in vitro* diagnostic use only.

Caution: Not for internal use. Do not ingest.

Read complete instructions before performing the test.

Intended use: The K-Check tablets are intended to be used by trained laboratory professionals to determine the qualitative /semi-quantitative presence of two Ketone bodies i.e. acetone and acetoacetic acid in Urine, Serum, Plasma or Whole blood.

Quick Reference Instructions:

1. Place a tablet on a paper towel.
2. Add a drop of the test specimen or controls on to the tablet. Wait 60 seconds for urine; 2.5 minutes for serum/plasma and 10 minutes for blood.
3. Wipe off the excess serum or plasma and compare to the color chart below for results.

Principal and background: Pathologically, Ketosis may be caused by conditions such as diabetes mellitus, cortisol deficiency, growth hormone deficiency and toxic ingestion of ethanol or salicylates. Certain inborn errors of metabolism may also cause ketoacidosis. Mild to moderate elevation in serum levels of ketones is a physiological response to fasting (especially during infancy and pregnancy), prolonged exercise, or a ketogenic (high-fat, low-carbohydrate) diet.

Reagents: Active ingredients of K-Check tablets are sodium nitroprusside, aminoethanoic acid, dibasic sodium phosphate, sodium borate and lactose. The nitroprusside ion forms a purple colored complex with methyl ketones in the presence of aminoethanoic acid in an alkaline medium.

Specimen Requirement: Preferably, obtain a fresh specimen and perform the test promptly. If the test could not be performed immediately, the specimen may be refrigerated in a closed container for up to 48 hours.

Procedure :

1. Remove a tablet for each test and additional two tablets to perform the quality control. Securely recap the bottle.
2. Place the tablets on a white paper towel. With a marker/pen label below the tablets accordingly such as "Test", "Positive" and "Negative" controls.
3. Using a disposable transfer pipette, place a drop of the test specimen (urine, serum, plasma or whole blood) directly onto the tablet. For quality control, place a drop of positive and negative controls onto the respectively labeled control tablets. Always use a separate pipette for each specimen and each of the controls.
4. To read results compare the developed color to the color chart. Wait 60 seconds for a urine test. For **serum or plasma** wait 2.5 minutes before reading the results. Wipe off the excess serum or plasma. **For blood:** wait 10 minutes, clean off the clot with a gauze or paper towel, and compare to the color chart below. Any development of lavender to purple color is a positive test.



NEGATIVE
Approximate conc.
(acetoacetic acid)



SMALL
20 mg/dl



MODERATE
40 mg/dl



LARGE
80 mg/dl

5. Read the controls as follows after wiping off the excess control material:
 - a. A pale white color development of the tablet after the appropriate wait time is a negative test for acetone and acetoacetic acid.
 - b. Any development of a lavender/purple color after an appropriate wait time is a positive test for acetone and acetoacetic acid.
 - c. Compare the color intensity to the color chart for semi quantification of the results.

If the positive and negative controls do not yield the expected results as above, do not report the test results and call for technical assistance at 1-866-342-9976 or report to your supervisor.

CLIA Categorization: The K-CHECK reagent tablets are waived for Urine testing only; however, they are categorized as moderately complex, for serum, plasma or whole blood testing. The procedure above conforms to QC guidelines for the waived tests.

Sensitivity and Limitations: K-Check tablets will detect as little as 5mg/dl of acetoacetic acid and 20-25 mg/dl of acetone in urine. For serum, plasma or whole blood the K-CHECK Tablets are approximately 50% less sensitive. Therefore the lower limit of sensitivity is approximately 10 mg of acetoacetic acid/dl of serum plasma or whole blood. The reagent tablets do not react with betahydroxybutyric acid. Ketones are not detected in urine serum, plasma or blood under normal carbohydrate metabolism. Levodopa may cause a false positive test. Bromosulphalein and phenylketones may cause a reaction with the reagent similar to acetone and acetoacetic acid. Urines preserved with 8-hydroxyquinoline may give reaction ranging from orange red to mauve which is a false positive reaction. Use the same color chart for reading urine, serum, plasma or whole blood. The lesser sensitivity of the test for serum, plasma or whole blood is compensated by the increased "time to read" for these specimens.

Quality Control (QC) for serum, plasma or whole blood: Laboratories should follow the applicable government regulations and local guidelines for quality control. The control intervals should be adapted to each laboratory's requirements. The recommended **serum controls** can be purchased from BIOREX LABS (Cat. No. B1777). For further information on positive and negative controls, contact Biorex Labs at 866-342-9976 or info@biorexlabs.com. At least a positive and negative control must be run each time a new bottle of K-Check is opened. A positive control for urine can also be prepared by diluting 50 microlitres (one drop) of acetone to 40 ml of distilled water. The preparation should be comparable to "small" on the color chart.

Quality Control for Urine (CLIA waived): Perform QC with each test run. Follow the instructions under the "Procedure" section of the product insert.

Precautions: Protect the reagent tablets from humidity and light. Do not use if the tablets develop a tan or any other color than white. Do not use if the expected results are not obtained by known positive and negative controls.

Storage: 15-30°C; K-Check tablets are adversely affected by humidity / moisture. The bottle should be closed promptly and securely after removing the test tablets.

Availability: K-Check is available in a bottle of 100 tablets.

Bibliography:

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5. *Urinalysis and Body Fluids*, Susan King Strasinger DA MLS(ASCP); Marjorie Schaub Di Lorenzo MLS(ASCP)SH; F.A. Davis Company 6th Ed, 2014

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