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ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS

INTENDED USE:

The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS may be used to comply with CLIA regulations or to test the viability of either the ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 strip devices. The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS are formulated as a POSITIVE CONTROL and a NEGATIVE CONTROL. The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS will give false results if used on any other test or instrumentation since they are formulated specifically for use with the ALCO-SCREEN[®] and/or the ALCO-SCREEN[®] 02.

RECOMMENDED FREQUENCY:

The ALCO-SCREEN[®] and the ALCO-SCREEN[®] 02 are pre-calibrated at the time of manufacture, and guaranteed to perform to specification if the product is properly stored between 50-80°F (10-27°C). Therefore, Chematics, Inc. recommends testing at the following intervals:

1. Upon receipt of an ALCO-SCREEN[®] and/or ALCO-SCREEN[®] 02 shipment.
2. If the shipment contains more than one lot of product, then each lot should be evaluated.
3. If the product has not been stored properly, or is suspected to be stored at temperatures outside the specified range.

Performance of the ALCO-SCREEN[®] and/or the ALCO-SCREEN[®] 02 can be evaluated at frequencies specified by state and federal regulations, which may vary from Chematics, Inc. recommended intervals.

STORAGE AND STABILITY:

The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS should be stored refrigerated 35-46°F (2-8°C) to maintain optimum stability. **DO NOT FREEZE**. The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS should not be used beyond the expiration date printed on the bottle label. If the ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS become cloudy or form a precipitate, do not use and discard properly.

PRECAUTIONS:

1. For use with the ALCO-SCREEN[®] and/or ALCO-SCREEN[®] 02 only.
2. The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS are manufactured from synthetic materials and do not pose an infectious hazard when used as intended. However, in keeping with good laboratory practice, they should be considered potentially capable of transmitting infectious disease, and handled accordingly.
3. Any product unused by the expiration date should be discarded with according to local government regulations.
4. If the ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS become cloudy or form a precipitate, do not use and discard properly.
5. Dilution or addition of any substances to the ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS invalidates the test results.
6. The ALCO-SCREEN[®] / ALCO-SCREEN[®] 02 CONTROLS are not for human consumption or injection.
7. This Control contains Sodium Azide: To prevent formation of explosive metal azides dispose of waste by flushing with copious amount of water or according to local government regulations.

PROCEDURE:

ALCO-SCREEN®/ ALCO-SCREEN® 02 CONTROLS are substituted for saliva samples for both products, and therefore utilize the test procedure of the ALCO-SCREEN® and ALCO-SCREEN® 02



1. Allow the ALCO-SCREEN®/ ALCO-SCREEN® 02 CONTROLS to come to room temperature. Mix contents thoroughly.
2. Place one to two drops of the solution on the ALCO-SCREEN® test pad. Start the timer immediately.
3. After ten seconds, shake the excess solution from the test pad.
4. At 2 minutes, observe the color of the test pad.

Expected Results

Positive Control: The test pad shows any color change ranging from light green to dark blue. The Positive control must test positive.

Negative Control: The test pad shows no color change and matches the Negative color block on the foil package. The Negative control must test negative.



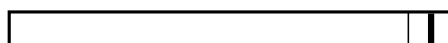
1. Allow the ALCO-SCREEN®/ ALCO-SCREEN® 02 CONTROLS to come to room temperature. Mix contents thoroughly.
2. Place one to two drops of the solution on the ALCO-SCREEN® 02 test pad. Start the timer immediately.
3. After ten seconds, shake the excess solution from the test pad.
4. At 4 minutes, observe the color of the test pad.

Expected Results

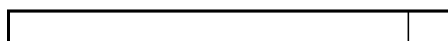
Positive Control: A distinct colored line appears on the test pad. The Positive control must test positive.

Negative Control: The test pad shows no color change and matches the Negative color block on the foil package. The Negative control must test negative.

INTERPRETATION



Positive Result



Negative Result

Contact Chematics, Inc. at 1-800-348-5174 for technical assistance.

Made in U.S.A. by Biochemical Diagnostics, Inc., Edgewood, New York 11717