POINTE SCIENTIFIC, INC.
5449 Research Drive • Canton MI 48188 • USA

Alcohol Standard

Intended Use

The Alcohol standard is intended as a means of calibrating various ethanol assay methods.

It is recommended that control materials having known component concentrations be assayed to validate the calibration. Controls are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

Product Description

The standard is supplied as a one level standard, 1 x 5 ml, as a ready-to-use liquid requiring no reconstitution or dilution. It is prepared in a bovine albumin matrix fortified with ethanol and reagent grade chemicals. Preservatives, including thimerosal, have been added to inhibit microbial growth.

FOR *IN VITRO* DIAGNOSTIC USE ONLY

Storage and Stability

1. Store the standard at 2-8°C.
2. When stored at 2-8°C, the standard is stable until the expiration date stated on the label.
3. The standard has an open vial stability of four months after opening and use.
4. Discard the standard if it is turbid or there is any evidence of microbial contamination.

Procedure

1. Remove the standard from the refrigerator and allow to come to room temperature (20-25°C) for 15-20 minutes.
2. Gently invert the standard to assure homogeneity of the contents. Avoid foaming.
3. Treat the standard as you would a patient sample in accordance with the manufacturer's requirements of the test method.
4. Immediately recap the standard and return it to 2-8°C when not in use.

Calibration

Refer to reagent and/or instrument manufacturer's instructions. Calibration setpoints are established from interlaboratory data. Refer to vial label for standard setpoint concentration.

Limitations

Any future changes made by the manufacturer of a test method may give different values from the indicated range. Limitations of the test method are included in the package insert for the reagent kit or instrument being used.

Manufactured for Pointe Scientific, Inc.
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