

Intended Use

For *in vitro* diagnostic use only.

The Pointe Scientific, Inc. Ammonia / Alcohol Control set is to be used for monitoring the accuracy and precision of various ammonia and / or ethanol assay methods and to validate quantitation of patient samples. The controls contain components of known concentrations and 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 Pointe Scientific, Inc. control material is supplied as a two level control set, 2 x 5 ml, as a ready-to-use liquid requiring no reconstitution or dilution. It is prepared in a aqueous base fortified with ethanol and reagent grade chemicals. Preservatives have been added to inhibit growth.

Precautions

Normal precautions exercised in handling laboratory reagents and/or infectious biological materials should be followed. Dispose of waste observing all local, state and federal laws.

Storage and Stability

Ensure that you tightly seal the vials after reconstitution and use to prevent evaporation during storage. Ensure that you store the vials upright to prevent spills or leakage.

	Storage	Stability
Unopened	2-8°C	Refer to the label on each vial and on the package for the expiration date.
Open Vial Stability	2-8°C	20 days

General Instructions for Use

Use the quality control material according to the directions accompanying the instrument or the assay procedure used. Treat the quality control material in the same manner as patient samples.

1. Gently invert the vial and swirl to assure contents are homogenous.
2. Remove the screw cap and gently remove the rubber stopper from the vial.
3. Perform assay.
4. Record the results according to your quality assurance program.

Expected Results

Refer to the expected results supplied for mean and range value assignments. See table below. Verify vial lot number with those on this assay sheet.

Assay	Unit	Level 1		Level 2	
		mean	range	mean	range
Ammonia *	umol/L	40	29-51	226	181-271
Alcohol **	mg/dl	50	42-58	258	217-299
	mmol/L (SI)	10.9	9.2-12.6	56.0	47.0-65.0

* Data generated using Beckman AU400 and Cobas Mira.

** Data generated using Hitachi 717 and Cobas Mira.

The assay values and expected ranges are target values derived from inter laboratory data. The expected range values include variations of instrument

and laboratory handling. The assay values were obtained using in-date Pointe Scientific reagents available at the time of testing. Updates to the listed values may be made based upon additional data that becomes available or, if necessitated by a modification to a test method. The mean values established for your laboratory should fall within the ranges shown in Expected Results; however laboratory means may vary during the life of the control. Each laboratory should establish its own mean and precision parameters.

Limitations

The results obtained using the quality control material depends on several factors: erroneous results can occur from improper storage, inadequate mixing, or sample handling errors associated with instrument or assay procedures. Do not use the quality control material if there is visible evidence of microbial growth in the vial. For more information about procedural limitations, refer to your instrument manual or assay product insert.

Disposing of Materials

Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

Technical Assistance

For technical assistance and customer service contact Pointe Scientific, Inc. at 800-445-9853 or 800-757-5313, or by fax at 734-483-1592.

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 2°C - 8°C

IVD



Manufactured for
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