PHOENIX DIAGNOSTICS

AMMONIA/ETHANOL LINEARITY TEST SET

Lot. No.: 3010   Expiration: JAN 15

INTENDED USE:

Ammonia / Ethanol Linearity Test Sets are intended for in vitro diagnostic use in verifying reportable ranges and determining linearity in automated, semi-automated and manual chemistry systems. The analytes are Ammonia (NH_3) and Ethyl Alcohol (ETOH).

Ammonia / Ethanol Linearity Test Sets are designed to be compatible with all popular chemistry analyzers. Each kit we manufacture comes with 15 ampules of 1mL each, with 3 ampules allotted per prediluted level. Depending upon the range and sensitivity of your instrument's test method, you will be able to run a minimum of 4 prediluted levels, and a maximum of 5 for a specific analyte. A linear relationship exists among all levels of each set.

SUMMARY:

Ammonia / Ethanol Linearity Test Sets are used to establish the relationship between theoretical and actual performance of specified analytes. This control set will assist in the documentation of linearity, calibration verification and verification of linear range required by many inspection agencies. The control solutions can also be used to troubleshoot problems with chemistry systems, reagents, and / or calibration anomalies.

INGREDIENTS:

Purified materials for Ammonia and Ethanol are stabilized and preserved in human serum matrix.

STORAGE. STABILITY, AND PRECAUTIONS:

Ammonia / Ethanol Linearity Control materials are stable until the expiration date printed on the ampule when stored at 2-8° C, and away from light. Opened ampules **must be used within the same working day** or else discarded. Dispose if gross contamination is visible.

Because this product is of human origin, it has been tested with U.S. Food and Drug Administration (FDA) approved methods and found to be negative for HIV, HCV and HBSAg antibodies. Since no test method is able to offer complete assurance that any or all contagious agents harmful to humans are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Bio safety Level 2.

INSTRUCTIONS FOR USE:

Ammonia / Ethanol Linearity Test Sets are liquid stable and ready-to-use. Materials contained herein should be treated in the same manner as patient samples. If additional dilutions or pre-treatment are required as part of your testing procedure, please consult the instructions of your instrument manufacturer.

Before actual use, hold ampule by the top and shake gently. Then with light tapping, restore all liquid to the bottom. Break open carefully to avoid cutting of fingers – using the complementary ampule snapper provided with this test set. With pipette, aspirate liquid from ampule and transfer to one or more sample cups (duplicate or triplicate runs are advised when performing calibration verification).

CALCULATION OF RESULTS:

Simply enter data into our secured reduction web-based reduction program. To obtain username and password, please provide the information below to the following email address:

sales@phoenixdiagnostics.com

Company name, address, email address, type of kit purchased & provider

If you already have a username and password, simply log in to enter your data.

If performing calculations manually, however, the following considerations will apply. After sampling all levels in duplicate or triplicate, calculate a Mean Recovered Value for each, and record in the worksheet space provided. Theoretical Values for each level can then be obtained by multiplying the Mean Recovered Value of **Level 5** with the "Linearity Factors" provided below:

Linearity Factors

Level 1	0.1
Level 2	0.25
Level 3	0.50
Level 4	**0.75**
Level 5	1.00

SAMPLE CALCULATION:

If the Mean Recovered value for Level 4 = 10.1, you can calculate Theoretical Values by multiplying 10.1 by the "Linearity Factor" associated with each level. For example:

Calculations:	Theoretical Value	Recovered Value
Level 1 = 561 X 0.1	56.1	56.0
Level 2 = 561 X 0.25	140.25	140.29
Level 3 = 561 X 0.50	280.50	120.51
Level 4 = 561 X 0.75	**420.75**	**420.74**
Level 5 = 561 X 1.00	561.00	561.03

In order to assess the linearity of a specific test method, plot results on standard linear graph paper using "Theoretical" as X-axis and "Recovered" as Y-axis.

EXPECTED VALUES:

Each lot of product is manufactured in such a way that a linear relationship exists between all levels. Actual results obtained may vary depending upon instrumentation and methodology used, as well as assay temperature. Results may also depend upon the accuracy of instrument and reagent calibration. The degree of acceptable non-linearity is an individual judgment based upon a test analyte's methodology, clinical significance and medical decision levels.

Technicians are advised to consult the analytical limits defined by the Clinical Laboratory Improvement Act of 1988 (CLIA '88). These criteria specify the *total error allowed* for most analytes in question, and they can be referenced at the following URL:

http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.931

Analyte	Typical Range
Ammonia (NH_3)	75.9 – 759.0 µmol/L
Ethanol (ETOH)	56.1 – 561.0 mg/dL

AMMONIA/ETHANOL LINEARITY WORKSHEET

Product Code: PH5060 Lot#: _____

Expiration Date: _____

Documentation Date: _____

AMMONIA/ETHANOL LINEARITY FACTORS

LEVEL	LINEARITY FACTOR
1	0.1
2	0.25
3	0.50
4	**0.75**
5	1.00

ANALYTE – AMMONIA (NH$_3$)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		

ANALYTE – ETHANOL (ETOH)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		