510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k033921

B. Analyte:
Ammonia

C. Type of Test:
Quantitative

D. Applicant:
Diagnostic Chemicals Limited

E. Proprietary and Established Names:
Ammonia-L3K® Assay

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1065 Ammonia Test System, Enzymatic method
2. Classification:
   Class I
3. Product Code:
   JIF,
4. Panel:
   Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for use:

The Ammonia-L3K® Assay is a testing device for the quantitative determination of Ammonia in plasma. Ammonia measurements are used in the diagnosis and treatment of sever liver disorders, such as cirrhosis, hepatitis, and Reye's Syndrome.

2. Special condition for use statement(s):

For In Vitro Diagnostic use only.
Prescription Use

3. Special instrument Requirements:

Hitachi® 911 analyzer

H. Device Description:

Ammonia-L3K Reagent is a solution containing a buffer (pH 8.0 at 25^0), 10 mmol/ α-ketoglutarate, at least 6 KU/L GLDH (microbial), 0.2 mmol/L NADPH analog, stabilizers, and a preservative.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Ammonia-Incorporating Dynamic Stabilization Technology (DST)
2. Predicate K number(s):
   K974620
3. Comparison with predicate:
   Both devices are for the quantitative determination of the same analyte in the same matrixes. Both devices employ enzymatic colorimetric reaction.

J. Standard/Guidance Document Referenced (if applicable):

NCCLS EP5-A - Evaluation of Precision Performance of Clinical Chemistry Devices
NCCLS EP6-P – Evaluation of the Linearity of Quantitative Analytical Methods
NCCLS EP9-A – Method Comparison and Bias Estimation Using Patient Samples

K. Test Principle:

Ammonia reacts with α-ketoglutarate and reduced cofactor to form L-glutamate and the cofactor. The reaction is catalyzed by glutamate dehydrogenase. The decrease in absorbance due to the oxidation of the reduced cofactor can be monitored at 340 nm and is proportional to the ammonia concentration.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
   Data was collected on three aqueous standards in 40 runs conducted over 20 days.

Level	Level	Total SD	Total SD	Total CV	Within Run SD	Within Run SD	Within Run CV
umol/L	ug/mL	umol/L	(ug/mL)		Umol/L	(ug/mL)	
48.01	0.819	3.76	0.064	7.9	2.64	0.045	5.6
125.23	2.133	4.40	0.075	3.5	2.64	0.045	2.1
337.29	5.745	5.81	0.099	1.7	2.58	0.044	0.8

b. Linearity/assay reportable range:
Performed according to NCCLS Guideline EP6-P, the linearity of the procedure described is 1175.0 u mol/L (20.0 ug/mL). The lower limit of detection of the procedure described is 5.8 umol/L (0.1 ug/mL). This data results in a reportable range of 5.8-1175.0 umol/L.

c. Traceability (controls, calibrators, or method):
NA

d. Sensitivity:
The lower limit of detection of the procedure is 5.8 umol/L (0.1 ug/mL)

e. Analytical specificity:

Interference from icterus, lipemia, hemolysis, and plasma pyruvate were evaluated on Hitachi 911 analyzer using a significance criterion of >10% variance from control. No significant icterus interference was found at bilirubin levels from 0-684 umol/L (0-40 mg/dL) in a 167 umol/L (2.8 ug/mL) ammonia sample. Intralipid levels from 0-1000 mg/dL [0-33.87 mmol/L (0-3000 mg/dL) triglycerides] were studies with acceptable results to level of 250 mg/dL Intralipid [8.46 mmol/L (750 mg/dL) triglycerides] in a 154 umol/L (2.6 ug/mL) ammonia sample. No significant ascorbic acid interference was found at ascorbic acid levels from 0-3000 ug/dL in a 147 umol/L (2.5 ug/mL) ammonia sample. Plasma pyruvate levels up to 0.75 mmol/L (6.6 mg/dL) do not cause interference.

f. Assay cut-off:
NA

2. Comparison studies:
   a. Method comparison with predicate device:
   The performance of this method (y) was compared with the performance of similar ammonia method (x) on a Hitachi 911. Forty patient sample ranging from 11.1 – 811.4 umol/L (0.19 – 13.82 ug/mL) gave a correlation coefficient of 0.9990. Linear regression analysis gave the following equation:
   Y = 0.95 X – 0.8 umol(-0.01 ug/mL)

   b. Matrix comparison:
   NA

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable.
   b. Clinical specificity:
   Not applicable.
   c. Other clinical supportive data (when a and b are not applicable):
   Not applicable.

4. Clinical cut-off:
   NA

5. Expected values/Reference range:
   12 – 47 umol/L (0.20 – 0.80 ug/mL). These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

M. Conclusion:

I recommend that the Ammonia-L3K® Assay is substantially equivalent to the legally marketed predicate device.