**CHEM.DIMENSION.ASSAY.5.0 AMMONIA BY DIMENSION**

**INTENDED USE**

The AMM method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of ammonia in plasma.

**PRINCIPLE**

Glutamate dehydrogenase (GLDH) catalyzes the condensation of ammonia and α-ketoglutarate with simultaneous oxidation of reduced nicotinamide adenine dinucleotide phosphate (NADPH). The decrease in absorbance at 340 nm, due to the disappearance of NADPH, is directly proportional to the ammonia concentration in the sample and is measured using a two cuvette (reagent blank), bichromatic (340, 383 nm) rate technique.

**DOCUMENT OWNER**

Manager, St. Vincent Jennings Hospital Laboratory

**RELATED DOCUMENTS**

CHEM.DIMENSION.1.0 *Operation of the Siemens Dimension RxL MAX, Xpand and EXL Clinical Chemistry*

*Systems*

CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**SPECIMEN**

A. Patient Preparation: None.

B. Sample Size:

 1. Primary tube: Compare the tube to the filling gauge supplied with the Dimension.

 2. SSC or Dimension sample cup: 53 µL plus 50 µL dead space volume.

C. Specimen Type: Plasma

1. Lithium heparin is the preferred anticoagulant.

2. EDTA and sodium fluoride anticoagulants do not interfere with the AMM method at concentrations normally found in blood collection tubes.

3. Sodium citrate (30 mmol/L) increases the AMM result by 35 µmol/L at an AMM concentration of 285 µmol/L.

D. Specimen Preparation:

1. The tube should be completely filled, stored tightly capped on ice and centrifuged immediately.

2. The specimen should be analyzed within 20 minutes of collection.

E. Storage and Stability:

Specimens should not be stored. Concentrations may more than double in plasma when stored at room temperature for 6 hours.

**REAGENTS**

A. AMM Flex® reagent cartridge, Cat. No. DF119

1. Preparation: Hydrating, diluting and mixing are automatically performed by the instrument.

 2. Storage and Stability:

a. Unopened reagent cartridges are stable until the date given on the packaging

when stored at 2 – 8 ⁰C.

 b. On board stability:

1) Sealed cartridge wells are stable for 30 days.

2) Open well stability is 3 days.

**EQUIPMENT**

Siemens Dimension® RxL MAX®, Xpand® or EXL™Clinical Chemistry System

**CALIBRATION**

A. Calibration Material: CHEM III Cal No. DC130

 1. Three levels: typical calibrator levels are 25, 500 and 1000 µmol/L; see the

package insert for exact values for the lot in use.

 2. See the package insert for preparation, storage and stability.

B. Calibration Frequency:

 1. For each new lot of Flex® reagent cartridges.

 2, Every 3 months for any one lot of reagent cartridges,

 3. After major maintenance or service if indicated by quality control results.

 4. When indicated by unacceptable QC data.

C. Procedure: See CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**QUALITY CONTROL**

A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure, HBL.GEN.7.0 for specific details.

**PROCEDURE**

Sampling, reagent delivery, mixing and processing are automatically performed by the Dimension® System. For details of this processing, refer to the Dimension® Operator’s Guide.

**RESULTS**

A. The instrument automatically calculates and prints the concentration of ammonia in µmol/L using the calculation scheme outlined in your Dimension® Operator’s Guide.

B. Results of the test should always be interpreted in conjunction with the patient’s medical history, clinical presentation and other findings.

**REPORTING RESULTS**

A. Expected values: 11 - 32 umol/L for ages 17 years and greater

 11 - 50 umol/L for ages 0 to 16 years

B. Critical values: Not applicable.

C. Sunquest Computer Entry

1. Manual Entry

Function: MEM

Worksheet: Site specific

Test Code: AMM

1. Online Entry

Function: OEM

Device: Site specific

Test Code: AMM

D. QLS Computer Entry

1. Enter: 3, 3, 1
2. Worksheet: Enter worksheet from QLS label.
3. Accession number: Enter JI number.

E. If the HIS or LIS system is down, see the appropriate Laboratory Computer Downtime Policy.

**PROCEDURE NOTES**

A. Expected Turnaround Time (TAT):

Nursing units are to be notified if the turnaround time is unable to be met per current MACL network turnaround time standards.

B. Backup method: When testing cannot be performed, the testing site’s backup policy should be followed.

**LIMITATIONS**

A. AMR: 10 – 750 µmol/L

1. Patient samples with AMM levels that exceed 750 µmol/L will autodilute. If a valid result cannot be obtained, a manual dilution should be made.

2. If a manual dilution is required, the specimen should be handled as follows:

a. Make an appropriate dilution with reagent grade water to obtain a result within the assay range.

b. Enter the dilution factor into the instrument when programming the sample.

c. Reassay. The resulting readout will be corrected for the dilution.

3. Specimens with concentrations greater than 1500 µmol/L are reported as >1500 µmol/L.

B. Interfering Substances:

The AMM method was evaluated for interference according to CLSI/NACCLS EP7-P. Bias

exceeding 10% is considered “interference”.

1. Do **not** use hemolyzed samples.

2. Bilirubin (unconjugated):

a. Bilirubin of 20 mg/dL did **not** interfere with a AMM result of 135 µmol/L.

b. Bilirubin of 40 mg/dL tripped a test report message, therefore the magnitude of the interference could not be determined.

3. Lipids:

a. Lipemia (Intralipid) of 50 mg/dL did **not** interfere with a AMM result of 133 µmol/L.

b. Lipemia (Intralipid) of 200 mg/dL tripped a test report message, therefore the magnitude of the interference could not be determined. Do not clear lipemia in samples that tripped a test report message as the results may be invalid.

 c. Cholesterol of 500 mg/dL increases AMM results at100 µmol/L by 80%.

 4. Digoxin at 5 ng/mL increases AMM results at100 µmol/L by 36%.

 5. Proteins:

a. IgG of 5 g/dL increases AMM results at100 µmol/L by 15%.

b. Total protein of 12 g/dL increases AMM results at100 µmol/L by 34%;

 6. Uric acid at 20 mg/dl increases AMM results at100 µmol/L by 492%.

7. Other substances: The AMM package insert contains a list of common drugs and other substances that do not interfere.

**CLINICAL SIGNIFICANCE**

Plasma ammonia concentration is an important reflection of the liver’s ability to convert toxic ammonia by-products into urea and then excrete the urea. Ammonia is a normal product of bacterial action on the contents of the gastrointestinal tract. The portal vein delivers ammonia to the liver, which is the only organ with the necessary enzymes to synthesize urea. Urea can then be easily excreted by the kidney. Elevated plasma levels of ammonia are associated with advanced liver disease, coma and other neurologic symptoms. Although ammonia determinations are of limited value in patients with known hepatic disease, they are useful in evaluating comatose patients or those with altered mental status of unknown origin. If ammonia levels are increased in these patients, hepatic involvement is indicated as a contributing factor.

**REFERENCES**

A. Siemens Dimension® Clinical Chemistry System AMM Flex® reagent cartridge package insert – US , Siemens Healthcare Diagnostics, Inc., Newark, DE, 6/26/2013.

B. Anderson, S. C. & Cockayne, S. (1993). *Clinical Chemistry Concepts and Applications*. Philadelphia, PA: W. Saunders Company.