CHEM.VITROS.ASSAY.6.0 AMMONIA BY VITROS (AMON)

STATEMENT OF PURPOSE

The AMON method used on the Vitros Clinical System is an in vitro diagnostic test intended for the quantitative determination of ammonia in plasma. Ammonia is a waste product of protein catabolism; it is potentially toxic to the central nervous system. Increased plasma ammonia may be indicative of hepatic encephalopathy, hepatic coma in terminal stages of liver cirrhosis, hepatic failure, acute and sub-acute liver necrosis, and Reye's syndrome. Hyperammonemia may also be found with increasing dietary protein intake.

PRINCIPLE

The VITROS AMON Slide is a multilayered, analytical element coated on a polyester support.
A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Water and nonproteinaceous components travel to the underlying buffered reagent layer, and the ammonium ions are converted to gaseous ammonia. The semipermeable membrane allows only ammonia to pass through and prevents buffer or hydroxyl ions from reaching the indicator layer. After a fixed incubation period, the reflection density of the dye is measured using the white background of the spreading layer as a diffuse reflector.

OWNERS

Hospital Based Laboratories

RELATED DOCUMENTS

CHEM.VITROS.1.0 *Operation of the 250 and 350 Vitros Analyzer Systems*
CHEM.VITROS.2.0 *Vitros 250 and 350 Calibration Procedure*
CHEM.VITROS.3.1 *Vitros Test Codes, AMR's, CRR's, Critical and Normal Ranges*
CHEM.VITROS.15.0 *Operation of the Vitros 4600 Analyzer System*
CHEM.VITROS.16.0 *Vitros 4600 Calibration Procedure*
CHEM.VITROS.17.0 *Vitros 4600 System Assay Quality Control*

SPECIMEN

A. Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
B. No patient preparation required.
C. Keep on ice until analysis.
D. Heparinized plasma.
E. Do NOT use hemolyzed specimens.
F. Centrifuge specimens and remove the plasma from the cellular material within 15 minutes of collection.
G. Handle and store specimens in stoppered containers to avoid contamination and evaporation.
H. Specimen stability
    1. Room temperature: Not Recommended
    2. Refrigerated: ≤3 hours
    3. Frozen: ≤24 hours

I. Mix samples by gentle inversion and bring to room temperature (18–28°C) prior to analysis.
J. Analyze immediately

REAGENTS

A. AMON Vitros Slides:
   1. Remove the slide cartridges from storage.
      a. Inspect the packaging for signs of damage.
      b. Do not use slide cartridges with damaged or incompletely sealed packaging.
   2. Warm the wrapped cartridge at room temperature for 60 minutes when removed from Freezer.
   3. Unwrap and load the cartridge into the slide supply.
      a. Be careful when opening the outer packaging with a sharp instrument so as to avoid damage to the individual product packaging.

B. Storage & Stability:
   1. Unopened: Frozen: ≤-18°C: Until expiration date on package
   2. Opened On-analyzer: ≤ 1 week.

EQUIPMENT

Vitros Chemistry Analyzer

CALIBRATION

A. VITROS Chemistry Products Calibrator Kit 5
   1. Refer to the Instructions for Use for VITROS Calibrator Kit 5.
   2. Refer to Vitros Calibration Procedure

B. Calibration Required when:
   1. When the slide lot number changes.
   2. When critical system parts are replaced due to service or maintenance
   3. Calibration or calibration verification at least once every six months
   4. As needed

QUALITY CONTROL

A. Analyze two levels of quality control material each day of patient testing, after a calibration and after specified service procedures are performed.
B. Refer to your site model Vitros Analyzer Operation Procedure.
C. Refer to General Laboratory Quality Control Performance, LAB.GEN.QC.2.0 for specific details

PROCEDURE

A. AMON Vitros slides are required to perform the ammonia test. This test is performed after the slides are calibrated and QC ran.

B. Load specimen on Vitros per Vitros Operation procedure.

CALCULATIONS

Reflectance from the slide is measured at 600 nm after the fixed incubation time. Once a calibration has been performed for each slide lot, ammonia concentration in unknown samples can be determined using the software-resident endpoint colorimetric math model and the response obtained from each unknown test slide.

REPORTING RESULTS

A. The instrument automatically calculates and prints the concentration of ammonia in µmol/L.

B. Measurement Range, Reference Range, Critical Values: Refer to CHEM.VITROS.3.1 *Vitros Test Codes, AMR's, CRR's, Critical and Normal Ranges*

1. If ammonia activities exceed the system's measuring (reportable or dynamic) range:
2. Dilute the sample with an equal volume of reagent-grade water.
3. Reanalyze.
4. Multiply the results by 2 to obtain an estimate of the original sample's ammonia concentration.
5. On-Analyzer Dilutions are performed using FS Diluent Pack 3.

LIMITATIONS

Glucose ≤ 600 mg/dL

REFERENCES

Vitros Chemistry Products Online Guide