| **Magnesium in Plasma/Serum or Urine** | | | | |
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| **Purpose** | This procedure provides instructions for performing Magnesium in Plasma/Serum or Urine. | | | |
| **Policy Statements** | This procedure applies to all personnel running the Siemens Dimension Vista | | | |
| **Principle** | The MG method used on the Dimension Vista clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of magnesium in **serum**, **heparinized plasma** and **urine**.  The magnesium method is a modification of the methylthymol blue (MTB) complexometric procedure described by Connerty, Lau, and Briggs. The barium salt of ethylenebis (oxyethylenenitrilo) tetraacetic acid (Ba-EGTA) is used to reduce interference due to calcium that also reacts with MTB.  MTB forms a blue complex with magnesium. Calcium interference is minimized by forming a complex between calcium and Ba-EGTA (chelating agent). The amount of MG-MTB complex formed is proportional to the magnesium concentration and is measured using a bichromatic (600 and 510 nm) endpoint technique. A sample blank is used to minimize bilirubin interference. | | | |
| **Clinical Significance** | Magnesium is, next to potassium, the most prevalent intracellular ion. Although the need for such high intracellular MG concentrations has not been definitely explained, many enzymes involved in lipid, carbohydrate, and protein metabolism require MG as an activating ion. In general, low serum MG levels produce muscle irritability, which if not corrected will cause tetany (prolonged involuntary muscle spasms). In this respect, magnesium resembles calcium. High MG levels reduce muscle and nerve irritability, and very high levels result in anesthesia (loss of sensations of touch, temperature, pain, etc.) and cardiac arrest. Up to 40% of hypokalemic patients are also hypomagnesemic  **Increased MG Levels:** may occur in kidney failure.  **Decreased MG Levels:** may be found in prolonged intravenous feeding, acute alcohol intoxication, primary hyperaldosteronism (increased production of the hormone aldosterone by the adrenals. This hormone regulates electrolyte metabolism.), malabsorption syndromes (diseases of the small intestine which produce inadequate absorption of various nutrients, vitamins, minerals, etc.), diabetic coma, hyperparathyroidism, alcoholic cirrhosis, - especially when associated with delirium tremens (the "DTs"). | | | |
| **Analyzer** | **PRIMARY METHOD:** Siemens Dimension Vista 500  **SECONDARY (BACKUP) METHOD:** Siemens RXL Max | | | |
| **Sunquest Test Codes** | **MG**: Magnesium in plasma or serum in mg/dL  **UMGR**: Magnesium in urine in mg/dL  **UMGQ**: Quantitative urine magnesium, timed collection | | | |
| **Specimen** | Plasma (lithium heparin) preferred  Serum  Urine: Timed (24 hour) or Random collection no preservatives.  **Minimum volume:** 0.2 mL  **Stability:** RT / 7 days, 2-8 °C / 7 days, < -20°C / 1 year, Urines stable 2-8°C / 7 days  **Rejection criteria:** Unlabelled specimens.  **Preparation:**   1. Timed urine collections are measured for total volume, and the collection date and time recorded for the start and end of the collection. Enter this information into Sunquest by ordering the test PV on the same accession number. 2. Whole blood serum specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis. 3. Serum/plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection. 4. Lipemic serum/plasma samples should be ultrafuged. 5. Specimens should be free of particulate matter. 6. Transfer serum/plasma or prepared urine to a properly labeled RXL SSC or tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time. | | | |
| **Reagents** | **PRIMARY METHOD:**   |  |  |  | | --- | --- | --- | | ***Product Description*** | ***Product Code*** | ***Stability*** | | MG Flex® reagent cartridge,  All reagents are liquid and ready to use. | K3057 | **Store at:** 2 – 8 °C  **Unopened:** Refer to carton for expiration date.  **On-board:** Sealed wells on the instrument are stable for 30 days.  **Open well stability:** 7 days for wells 1-12 | | CHEM 1 CAL | KC110 | **Store at:** 2 - 8 °C.  **Unopened:** Refer to carton for expiration date.  **On-board:** Once the vial stopper is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista® System.  **Opened**: Once the cap is removed, assigned values are stable for 7 days when recapped and stored at 2-8 C. Do not use on board the Vista. Exposure to light will degrade bilirubin. | | | | |
|  | **SECONDARY (BACKUP) METHOD**   |  |  |  | | --- | --- | --- | | ***Product Description*** | ***Product Code*** | ***Stability*** | | MG Flex® reagent cartridge,  All reagents are liquid and ready to use. | DF57 | **Store at:** 2 – 8 °C  **Unopened:** Refer to carton for expiration date.  **On-board:** Sealed wells on the instrument are stable for 30 days.  **Open well stability:** 2 days for wells 1-8 | | CHEM 2 CAL | DC20 | **Store at:** 2 – 8 °C  **Unopened:** Refer to carton for expiration date.  **Opened:** Use Immediately. | | | | |
| **Risk and Safety** | Follow laboratory safety policies and procedures.  Dispose of used MG reagent cartridges in the caustic waste provided by Children’s Safety department  Safety data sheets (MSDS/SDS) available on [www.siemens.com/diagnostics](http://www.siemens.com/diagnostics) | | | |
| **Calibration** | **PRIMARY METHOD:**   |  |  | | --- | --- | | Analytical Measuring Range | 0.2–20.0 mg/dL | | Reference Material: | CHEM 1 CAL (KC110) | | Suggested Calibration Levels: | Level 1 (Calibrator A): 0.3 mg/dL  Level 2 (Calibrator B): 21.1 mg/dL | | Calibration Scheme: | 2 levels (n=5) | | Calibration Frequency: | Every 90 days for any one lot  For each new lot of Flex® reagent cartridges  After major maintenance or service, if indicated by quality control results  As indicated in laboratory quality control procedures | | Analytical Measuring Range and Calibration Verification | * Cal Verification and AMR verification are performed at least once every six (6) months. * Touch Advanced 🡪 Calibrations 🡪 Calibrations by Lot, select method MG and “Order a Linearity Study” * See iGuide “Calibration by Lot” for more information. |   **SECONDARY (BACKUP) METHOD**   |  |  | | --- | --- | | Analytical Measuring Range: | 0.0-20.0 mg/dL | | Reference Material: | CHEM 2 CAL (DC20) | | Suggested Calibration Levels: | Level 1: 0.0 mg/dL  Level 2: 9.0 mg/dL  Level 3: 18.0 mg/dL | | Calibration Scheme: | 3 levels (n=3) | | Calibration Frequency: | Every 90 days for any one lot  For each new lot of Flex® reagent cartridges  After major maintenance or service, if indicated by quality control results  As indicated in laboratory quality control procedures | | Analytical Measuring Range and Calibration Verification | * Once every 6 months confirm the reportable range by analyzing Maine Standards Validate GC1 according to the manufacturer’s instructions. * Enter data using Maine Standards MSDRx free software, and send reports to technical specialist for review. * Investigate unacceptable results. | | | | |
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| **Quality Control (Plasma/Serum)** | **PRIMARY METHOD:**  **Biorad Multiqual (Human) Levels 1 & 3**  **Frequency:** Two levels each day of use  **Stability:** Stable until the date on vial when stored at -20 to -50 °C protect from light. Thawed and unopened, 7 days at 2 -8 °C. 7 days on board the Vista, and 5 days opened and stored at 2 – 8 °C  **Preparation**: Allow the control to stand at 18 – 25 °C for 30 minutes until completely thawed. Gently mix the vials until homogeneous to dissolve any precipitate.  **Sunquest Control names:** Level 1 = C-MQ1, Level 2 = C-MQ3  **SECONDARY (BACKUP) METHOD**  **Biorad Liquichek™ Unassayed Chemistry Control (Human) Levels 1 & 2**  **Frequency:** Two levels each day of use  **Stability:** Refer to the current product insert.  **Preparation:** Allow the controls to thaw at 18 – 25 °C for 30 minutes or until completely thawed. Genrly swirl the vials until homogeneous to dissolve any precipitate.  **Sunquest Control names:**  Level 1= C-X1, Level 2= C-X2 | | | |
| **Quality Control (Urine)** | **PRIMARY METHOD:**  **Biorad Liquicheck Urine Chemistry Control Levels 1 & 2**  **Frequency:** Two levels each day of use  **Stability:** Stable until the date on vial when stored at 2 – 8 °C, or unopened on board the Dimension Vista, and 30 days opened and stored at 2 – 8 °C  **Sunquest Control names:** Level 1 = C-UR1, Level 2 = C-UR2 | | | |
| **Calculations** | **UMGQ** = Mg in mg /24 Hrs = Mg (mg/dL) x Total Volume in mL  1000  Timed Urine calculations are performed by the Laboratory computer system when all necessary information is present. Enter the measured urine magnesium value in mg/dL, collection time in hours, and the volume | | | |
| **Interferences** | **PRIMARY METHOD:**  Hemolysis, Icterus & Lipemia (HIL) Index Values:   |  |  |  | | --- | --- | --- | | **H** | **I** | **L** | | 3 | - | - |   Interfering Substances:   * EDTA of 200 mg/dL decreases the MG result by 0.4 mg/dL at a magnesium concentration of 1.8 mg/dL * Because magnesium is three times more concentrated in erythrocytes than in serum, hemolyzed samples will give spuriously elevated results * Refer to the product insert for a list of substances that have been shown to have no measurable effect on the MG result at typical concentrations.   **SECONDARY (BACKUP) METHOD**   * Because magnesium is three times more concentrated in erythrocytes than in serum, hemolyzed samples will give spuriously elevated results * Hemoglobin of 300 mg/dL increases magnesium concentration of 0.97 mg/dL by 14% * Bilirubin (unconjugated) of 60 mg/dL increases a magnesium concentration of 0.97 mg/dL by 14% * Lipemia of 3000 mg/dL increases a magnesium concentration of 0.92 mg/dL by 14%   Refer to the product insert for a list of substances that have been shown to have no measurable  effect on the MG result at typical concentrations | | | |
| **Reference Range** | Serum/Plasma: 1.5 – 2.5 mg/dL \*  \* Children’s Hospitals and Clinics of Minnesota verified the reference range by using historic patient results over multiple age groups in November 2013.  Urine:  Non established | | | |
| **Critical Values** | Plasma/Serum: < 1.2 or > 6.6 mg/dL.  Critical values must be called according to the Critical Limit Test Value Policy. | | | |
| **Limitations** | Linear range of detection: 0.2–20.0 mg/dL  The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Operator’s Guide for troubleshooting. | | | |
| **Dilutions** | **PRIMARY METHOD:**   |  |  | | --- | --- | | Maximum Dilution: | 1:2 | | Surplus Rack: | Samples with results >20.0 mg/dL reflex to a 1:2 dilution. | | Limited Rack: | Samples with results >20.0 mg/dL should be repeated as an Add-On Test with a 1:2 dilution. | | Manual Dilution: | Do not manually dilute |   **SECONDARY (BACKUP) METHOD**  **Above 20.0 mg/dL**   |  |  | | --- | --- | | Maximum Manual Dilution: | 1:3 | | Diluent: | Reagent Grade Water | | Manual Dilution: | Manually prepare a 1:3 dilution with reagent grade water  Enter dilution factor on RXL Max and Reassay | | | | |
| **Result Reporting** | **PRIMARY METHOD:**   * Results between **0.2–20.0 mg/dL** without error messages are released * Serum/Plasma/Urine results below 0.2 mg/dL: report as < 0.2 mg/dL. * Results >20.0 mg/dL without error messages are reported following a maximum dilution of 1:2 * Results with “assay range” appended following a maximum dilution of 1:2 are reported as >40 mg/dL * Append appropriate HIL comments. Refer to [CH5.101 HIL on Dimension Vista](http://khan.childrensmn.org/Manuals/Lab/SOP/Chem/Procedure/206820.pdf) * Timed Urine collection results: The Laboratory Information System calculates urine magnesium on timed and random collections when all necessary information is present. Report the numerical value.   **SECONDARY (BACKUP) METHOD:**   * Results between **0.1–20.0 mg/dL** without error messages are released * Serum/Plasma results below 0.1 mg/dL: report as < 0.1 mg/dL. * Results >20.0 mg/dL without error messages are reported following a maximum dilution of 1:3 * Results with “assay range” appended following a maximum dilution of 1:3 are reported as >60 mg/dL * Append Sunquest text code to results reported on hemolyzed samples:   + SLH for slight hemolysis   + MH for moderate hemolysis   + GRH for grossly hemolyzed samples. May interfere with testing. | | | |
| **Specimen Storage** | Promptly stopper tested specimen and store upright in specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. | | | |
| **References** | 1. Vista MG Flex® reagent cartridge insert sheet Siemens Healthcare Diagnostics, Inc. 2013-08-20 E, PN 781057.001 2. MG Flex® reagent cartridge insert sheet Siemens Healthcare Diagnostics, Inc. 2016-02-26 PN 717057.001 – US Rev 3. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001 4. Biorad Multiqual Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 5. Biorad Liquichek Urine Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 6. [Clin Chim Acta.](https://www.ncbi.nlm.nih.gov/pubmed/24012827) 2013 Nov 15;426:46-50. doi: 10.1016/j.cca.2013.08.025. Epub 2013 Sep 5 7. [Clin Chem Lab Med.](https://www.ncbi.nlm.nih.gov/pubmed/27155007) 2016 Dec 1;54(12):e379-e381. doi: 10.1515/cclm-2016-0064 | | | |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Unknown |  | Magnesium on Dimension AR, Initial Version |
|  | Deane L Riedel | August 2000 |  |
|  | L. Lichty | August 2005 | Magnesium in plasma, serum or urine |
|  | L. Lichty | July 31, 2006 | Magnesium on Dimension RxL MAX |
|  | D. Helfinstine/ L. Lichty | April 1, 2011 | New Format, Updated package insert information. Renumbered from CH 3.33 |
|  | L. Lichty | March 19, 2013 | Clarify maximum dilution reporting, amend AMR |
|  | L. Lichty | December 10, 2013 | Convert reporting units to mg/dL, update product insert |
|  | L. Lichty | 12/17/2013 | Siemens MG CLSI procedure for Vista, Issue Date 2013-08-20 Rev. E |
|  | D. Helfinstine | June 15, 2015 | Updated information for Dimension Vista. |
|  |  | Kelsi Brown | July 6, 2017 | Added procedure for RXL back-up method. Updated package insert. |
|  |  | E. Bartos | Sept. 19, 2017 | Removed Acidification of Urine per publications |