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| **Mumps IgG** | | | |
| **Purpose** | This procedure provides instructions for performing LIAISON® Mumps IgG on the DIASORIN LIAISON XL. | | |
| **Policy Statements** | This procedure applies to all laboratory technical staff responsible for performing LIAISON® Mumps IgG testing on the DiaSorin Liaison XL. | | |
| **Principle** | The LIAISON® Mumps IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON XL® Analyzer family for the qualitative determination of IgG antibodies to mumps virus in human serum. It is intended to be used as an aid in the determination of serological status to mumps virus.  The method for qualitative determination of specific IgG to mumps virus is an indirect chemiluminescence immunoassay (CLIA). The principal components of the test are magnetic particles (solid phase) coated with recombinant antigen and a conjugate of mouse monoclonal antibody to human IgG linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, mumps virus antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, the antibody conjugate reacts with mumps virus IgG that is already bound to the solid phase. After each incubation, unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and indicates the presence or absence of IgG to mumps virus in calibrators, samples or controls. | | |
| **Clinical Significance** | Mumps is a viral illness caused by a member of the paramyxovirus family and is transmitted by respiratory droplets. It has an incubation period of 14-25 days after which time prodromal symptoms occur and last anywhere from three to five days. After the prodromes, the symptoms of the viral infection depend on which organ is affected. The most common presentation is a parotitis, which occurs in 30-40% of patients. Other reported sites of infection are the testes, pancreas, eyes, ovaries, central nervous system, joints, and kidneys. A patient is considered infectious from about three days before the onset of symptoms and up to four days after the start of active parotitis. Infections can be asymptomatic in up to 20% of persons.  Prior to vaccine availability about 50% of children contracted mumps; however mumps vaccination programs (part of measles, mumps, rubella, varicella [MMRV] vaccination) have had a marked effect on the incidence of the disease and the complications associated with it.  When mumps was a common disease of childhood, the diagnosis was established largely on clinical grounds alone. With the decreased incidence of mumps, many physicians no longer readily recognize the symptoms. In addition, typical clinical signs and symptoms may be absent in under-immunized or immunocompromised individuals; approximately 20 to 30% of infections are sub-clinical. Parotitis, the hallmark of clinical diagnosis, is also now known to be present in other viral and non-viral diseases or conditions. Mumps-like symptoms in acutely ill children who previously received the MMRV vaccine have been associated with Epstein-Barr virus, human parainfluenza viruses (HPIV), adenovirus, and human herpesvirus type 6. Therefore laboratory confirmation of mumps virus infection is now more important in establishing the diagnosis. | | |
| **Instrument** | DiaSorin LIAISON® XL  Sunquest Method Code: **XL** | | |
| **Sunquest Test Code** | MUMPG | | | |
| **Sample** | Serum is the only acceptable specimen for this assay collected aseptically by venipuncture. Refer to specimen collection procedures.Grossly hemolyzed, lipemic or particulate samples are not recommended.Minimum volume: 200 μLStability: 2-8 °C / 9 days, 30 days at -20 ºC or colderDo not store in self-defrosting freezer.Rejection criteria: Unlabeled tube, plasma, or grossly hemolyzedPreparation:Whole blood specimens should be centrifuged as soon as clotted, according to Specimen Processing procedures prior to analysis. See Processing Procedure Manual.Clarify samples having particulate matter, turbidity, lipemia, or erythrocyte debris.Remove air bubbles before testing.Transfer serum to a properly labeled tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.If samples are stored frozen, mix thawed samples well before testing. Avoid repeated freeze-thaw cycles. Check for and remove air bubbles before assaying | | |
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| **Materials** | **Reagents** | **Supplies** | **Equipment** |
|  | LIAISON® Mumps IgG ([REF] 318840)LIAISON® Control Mumps IgG ([REF] 318841) | Polypropylene sample tubes | DiaSorin Liaison XL System |
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| **Reagent Integral Preparation** | **How to prepare and load new reagent integrals**   1. Remove from refrigerated storage, maintaining upright orientation 2. Inspect integral for leakage 3. Mix magnetic particle for 30 seconds 4. Seat test integral in Xcelerator for 30 seconds 5. Gently rotate the magnetic particle vial for 30 seconds 6. Remove new integral sealing flaps slowly 7. Remove all liquid from the surfaces of the membranes to prevent cross-contamination of the reagent vials by blotting using a kim wipe folded in half lengthwise 8. Open the reagent bay on the analyzer 9. Using a smooth motion, insert the integral into an unoccupied lane in the reagent area until it rests firmly against the docking pins at the rear.   **Note:** if more than one integral of the same reagent is loaded place the newest integral to the right of the old integral. The analyzer will sample from the left integral until empty then move right. | | |
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|  | Reagent Integral Storage and Stability:Upon receipt, the reagent integral must be stored in an upright position to facilitate resuspension of magnetic particles.Stored sealed, the reagents are stable at 2-8°C up to the expiration date.After removing the seals, the reagent integral is stable for eight weeks when stored at 2-8°C or on board the LIAISON® Analyzer. Record new expiration date on the integral.Do not freeze.The Reagent Integral must not be used past the expiration date indicated on the kit and reagent integral labels. | | |
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| **Special Safety Precautions** | For additional information, refer to Safety Data Sheets available on StarNet.Avoid direct contact with potentially infected material by wearing appropriate PPE  * All samples and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents. The waste must be handled with care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country. | | |
| **Calibration** | Assay of calibrators contained in the reagent integral allows the analyzer to recalibrate the stored master curve, as indicated by Radio Frequency Identification transponder (RFID Tag) on the reagent integral label. Refer to the Operator's Manual or LIAISON XL® Quick Guide for calibration instructions.  Recalibration is required:   * With each new lot of reagents (reagent integral or Starter reagents). * Every 14 days. * After servicing the LIAISON XL® Analyzer. * If quality controls are out of your acceptable range.   Verify new reagent lots before use by testing LIAISON® Control Mumps IgG ([REF] 318841). Comparable results verify the new reagent lot. Discrepant results must be resolved before the reagent can be used for patient testing. | | |
| **Analytical Measuring Range (AMR)** | Mumps IgG is an FDA-cleared/approved in vitro diagnostic assay that reports the qualitative result based on a predefined cut-off value. Verification of AMR or the cut-off value is not required by CAP or CLIA. The AMR of Mumps IgG per DiaSorin is 5.00-300.00 AU/mL (arbitrary units). | | | |
| **Quality Control** | **LIAISON® Control Mumps IgG ([REF] 318841)**   * Negative control (0.7 mL x 2 vials) containing a barcode label * Positive control (0.7 mL x 2 vials) containing a barcode label * Allow controls to reach room temperature prior to use. Return controls to the refrigerator immediately after each use.   **Frequency:** Run 2 levels every day of use. Load the bar-coded control vials into the “T” rack on the Liaison XL.  **Stability:**  Unopened: When controls are stored sealed and kept upright, they are stable at 2-8°C up to the expiry date.  Opened: Once opened controls are stable for eight weeks when properly stored at 2-8°C  **Acceptable ranges:**   * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules. * New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot. * Refer to the [Westgard Rules in Chemistry procedure](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.18-westgard-rules-in-chemistry.pdf) for current Westgard rules in place for each analyte. * **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface. * In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section. * Do not load or release patients until QC is acceptable in Unity Real Time. | | |
| **Procedure** | Refer to the instrument Operating procedure.Strict adherence to the relevant Analyzer Operator’s Manual ensures proper assay performance. **LIAISON**® **XL Analyzer**. Each test parameter is identified via information encoded in the reagent integral Radio Frequency IDentification transponder (RFID Tag). In the event that the RFID Tag cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral; contact your local DiaSorin technical support for instruction.  The analyzer operations are as follows:  1. Dispense calibrators, controls or specimens into the reaction module.  2. Dispense specimen diluent  3. Dispense magnetic particles.  4. Incubate.  5. Wash with Wash/System liquid.  6. Dispense conjugate into the reaction module.  7. Incubate.  8. Wash with Wash/System liquid.  9. Add the Starter Kit and measure the light emitted. | | |

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| **Dilutions** | Do not dilute. See result Reporting. | | | |
| **Reference Intervals** | < 9.0 AU/mL: Absence of detectable mumps virus IgG antibodies. A negative result generally indicates that the patient has not been infected and is susceptible to mumps. If the subject has no history of mumps, has not been previously vaccinated and exposure to mumps virus is suspected despite a negative finding, a second sample should be collected and tested no less than one to two weeks later.  ≥ 9.0 AU/Ml and< 11.0 AU/mL: Equivocal samples should be retested. If the result remains equivocal after repeat testing, a second sample should be collected no less than one to two weeks later.  ≥ 11.0 AU/mL: Presence of detectable mumps virus IgG antibodies. A positive result generally indicates past exposure to mumps virus or previous vaccination.  Diagnosis of infectious diseases should not be established on the basis of a single test result, but should be determined in conjunction with previous infection history, clinical findings and other diagnostic procedures as well as in association with medical judgment.  **Warning -** If the sample result displays “Invalid RLU” and an exclamation mark (!) flag, the result obtained lies below the assay signal range. The sample must be retested. If the sample result upon retest still displays “Invalid RLU”, call DiaSorin Technical Support. | | | |
| Limitations | Specimens from patients receiving preparations of mouse monoclonal antibodies for therapy or diagnosis may contain human anti-mouse antibodies (HAMA). Such specimens may interfere in a monoclonal antibody-based immunoassay and their results should be evaluated with care. | | | |
| **Result Reporting** | Release results in Sunquest following LIS procedures for OEM. Comments are automatically appended when resulting in OEM or MEM using the LIAS worksheet.  Results <9 AU/mL without error messages are reported with the numerical result, and interpreted as Negative.  Results between 9 and 10.9 AU/mL must be repeated prior to reporting and are reported with the numerical result and interpreted as Equivocal.  Results ≥11 AU/mL without error messages are reported with the numerical result, and interpreted as Positive. | | | |
| **Alternate Methods** | * When test performance does not meet quality standards, consult the technical specialist or Medical Director, and refer testing to Mayo Medical Laboratory. * MUMG: MUMPS IgG ANTIBODY 0.5 ML Serum to LabCorp. | | | |
| **References** | 1. LIAISON® Mumps IgG ([REF] 318840) Directions for Use, DiaSorin, Inc., Stillwater, MN 55082, May 2019 2. LIAISON® Control Mumps IgG ([REF] 318841)Directions for Use, DiaSorin, Inc., Stillwater, MN 55082 | | | |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Stephen Gripentrog/Erin Bartos | August 13, 219 | Initial Procedure |
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