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| **Liaison Operating Procedure** |
| **Purpose** | This procedure provides instructions for OPERATION of the DIASORIN LIAISON. |
| **Principle** | Assays that run on the LIAISON are divided into 1-step, 2-step, or 3-step assays, determined by the number of incubation sequences required. An incubation sequence is described as the amount of time a sample must enter the incubator during the run.After the last wash cycle has been completed the reaction module is transported into the measuring chamber. Starter reagent 1 is injected into the first cavity, followed by starter reagent 2 is injected into the same cavity. After a measuring delay, the signal is obtained and integrated over the measuring period of 3.0 seconds.The chemically emitted light is measured by a selected high sensitive, low-noise photo multiplier (PMT). The linear measuring range of the photo multiplier is 300-650 nm. The light peak of the chemiluminescence is emitted at a wavelength of 420 nm. The PMT is operating as an ultra-fast photon counter. A rapid electronic amplifier amplifies the pulses. A circuit, which suppresses the PMT signal-noise is also implemented in the PMT box. The Relative Light Units (RLU) are used as units of the measurement for the raw data, which is then multiplied by the RLU factor, that allows the compensation of the inevitable individual fluctuations of the cathode sensitivity of the PMT.Data reduction is performed using a master curve with 2-point recalibration. The starting point of data reduction is the master curve, stored in the analyzer. To compensate the differences between reagent lots, analyzers, and environmental conditions, assay calibration must be run and validated according to the indications reported in the assay Instructions for Use. The measuring signals of the calibrators allow the shift of all master curve points to a working curve, corresponding with the actual conditions during measurement. |
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|  | **Reagents** |
| **Materials** | * Liaison Starter Kit (319102)
* Liaison Light Check (319101)
* Liaison Wash/System Fluid (319100)
* Liaison Clean Kit (310990).
* Liaison Light Check (319101)
* Clinical Laboratory Reagent Water
* Quality Control material appropriate for the assay
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|  | **Supplies** |
|  | * Liaison Waste Bags (9450003)
* Liaison Reaction Modules (319130)
* 12 x 75 plastic tubes
* Siemens micro cuvettes
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|  | **Equipment** |
|  | * DiaSorin Liaison Chemiluminescence Analyzer System
* LIAISON Xcelerator (Cat. No. A0090)
* Sunquest Method: **LIAS**
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| **Special Safety Precautions** | Dispose of used reaction modules containing liquid in strong base hazardous waste.Dispose of Starter 2 in Base reagent Hazardous Waste container.Some reagents used in this assay contain human source material and should be treated as potentially infectious.Some reagents contain sodium azide as a preservative. Because sodium azide may form explosive lead azide or copper azide in plumbing, it is recommended that drains be thoroughly flushed with water after disposal of solutions containing sodium azide |
| **Calibration** | Data reduction is performed using a Master Curve with a 2-point recalibration. The starting point of data reduction is the master curve, stored in the analyzer.Refer to the Instructions for Use for each individual assay for calibration. See calibration instructions below. |
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| **Daily Start up Procedure** | **Step** | **Action** |
| 1 | Turn on PC monitor using button on right side of the monitor. |
| 2 | Load assay Integrals as needed1. Remove from refrigerated storage, maintaining upright orientation
2. Inspect Integral for leakage
3. Seat test integral in Xcelerator for 30 seconds
4. Gently rotate the magnetic particle vial
5. remove new integral sealing flaps slowly
6. Remove all liquid from the surfaces of the membranes to prevent cross-contamination of the reagent vials
7. Open the reagent area on the analyzer
8. 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.
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|  | **If** | **Then** |
| Insertion is successful | The barcode beeps once.The integral appears in the reagent area dialogue. |
| Insertion is not successful | The barcode beeps twice.Repeat step H. |
|  | 3 | Perform daily maintenance. See Liaison Maintenance Procedure |
| **Calibration** | 4 | Perform calibrations needed (Refer to the laminated sheet titled “Symbols Associated with Integrals”). Refer to Chapter 12 in the Liaison Operating Instructions for colored calibration status definitions.1. Tap Reagent icon on Home Screen
2. Tap integral to calibrate
3. Tap Start. Follow screen prompts. Expect Integral color icon to change.
4. Tap View when calibration is complete
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|  | **If** | **Then** |
| **Calibration (cont)** | Calibration results appear in RED  | 1. Select Reject
2. Print rejected data
3. Repeat calibration
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|  | Calibration data is acceptable | 1. Tap Calculate Curve
2. Tap Validate
3. Tap Recalc associated samples
4. Tap OK
5. Print calibration results
6. File print out in binder
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| **Quality Control** | 5 | Run Quality Control1. Insert controls into rack “C” for DiaSorin control bottles, or rack “K” for micro tube aliquots
2. Load Rack into sample lane on instrument and “empty position” is displayed. Tap “OK”
3. Repeat this step for each QC rack. The screen should now display the Sample Area. (reference the Quick Guide, 8.4.1-8.6)

1. If “Entire” is displayed, tap this to change the display to “Edit”.
2. Select “Edit”
3. Make sure the control is backlit, then tap “Start in next Run”
4. Tap desired test(s) from the assay selection menu
5. Repeat steps D through G for each control, in each rack of QC loaded.
6. Tap “OK”
7. Tap “Start” and follow screen prompts
8. Confirm QC is running by tapping “View Status of Run”, “Results” and “Journal”
9. Note: If the bar code doesn’t read, the control(s) may be ordered manually.

(reference Quick Guide 4.7.2.5.4) 1. If the QC product is not defined, refer to Appendix C in the Quick Guide to add it.
2. Print and file daily QC results.
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| **Load Samples** | 6 | Load Patient samples1. Load patient samples into sample racks with bar-coded label facing out (right)
2. Load racks one at a time into sample lanes
3. Confirm the rack is identified, and all samples are present through the screen prompt.
4. Programming of the tests takes place by LIS query.

Missing sample ID’s |
|  | 7 | Manually program patient samples1. Select blue patient sample rack from rack station

1. Select entire rack by tapping in number area or outer grey area on rack

Tap in grey area to select entire rack1. Tap desired test, i.e. 25OHD to order Vitamin D on entire rack
2. Repeat for each rack
3. Tap “Entire” and reselect each rack to confirm order
4. Tap “OK”, and “Start”, and follow screen prompts
5. View Status of Run, tap “Results” and “Journal”. Confirm each sample states “Active”
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|  | 8 | Review and Print Results1. Check all results for Errors (Flag!)
2. Validate results: Tap “Results”, “Journal”, tag each result in the journal using the F7 key.
3. Select “Validate”, tagged, and “OK”.
4. Print results: Tap “Results”, “Valid”, “Print”
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|  | 9 | Perform Daily Shutdown1. Remove sample racks
2. Prepare Wash/System liquid for next day if < 1/3 remains in bottle. Prepare Wash/System Liquid by filling a clean Wash container with 9 L of distilled H20, then add a bottle labeled as “LIAISON® Wash/System Liquid” (1 L) taking care to minimize presence of foam. Allow to stand for a minimum of 6 hours.
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| **Interpretation/ Results** |  |
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| **Interpretation/****Results** | Refer to specific assay procedures for interpretation of results. |
| **References** | 1. LIAISON® Daily Quick Start Procedure, GOP0571, Rev. D
2. DiaSorin Liaison® Operating Instructions, User Manual 2.28, revision 03, 200/008-620,03-07/2007, DiaSorin S.p,A. 2006
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| **Alternate Methods** | If testing cannot be performed within 5 business days, refer samples to Mayo, notify the chemistry Medical Director and Technical Specialist, and notify providers of the delay in results. |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Linda Lichty | January 10, 2011 | Initial Version |
|  | Laurie Marsh | June 5, 2015 | Updated controls and sample loading |
|  | Kelsi Brown | April 28, 2017 | Biennial Review |
|  | Stephen Gripentrog | 7/13/2018 | Changed Remove sample racks and reagent integrals and store integrals according to product insert to remove sample racks. Changed Load assay Integrals for daily work to Load assay integrals as needed .  |
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