Policy Statement	The Core Laboratory evaluates the ability of suppliers of materials and services to consistently meet agreed upon requirements.
Purpose	This policy provides direction for the processes and procedures to effectively manage the quality of the test results via purchased materials and services.
Scope	This policy applies to the procurement of materials and services pertaining to the Core Laboratory.
Responsibility	The Ascension Health Supply Chain, Materials Management/Purchasing Departments are responsible for choosing vendors that meet the corporate requirements and goals. The Ascension Health Ministry Service Center is responsible for processing the order for material and services and coordinating delivery of such materials. The Core Laboratory Lead Technologists and Inventory Specialist are responsible for insuring that the inventory is maintained at a level to meet the patient care demands of the hospital. The Core Laboratory is also responsible for insuring that materials and services consistently meet current standards and regulatory requirements.
Vendor Qualification	• Saint Agnes Hospital has defined the characteristics or functional requirements for materials. • The Ascension Healthy Supply Chain, Materials Management, Purchasing Departments and the Laboratory sections assess both the ability of our vendors to meet our requirements and regularly evaluate their actual performance • See the hospital policy SYS HOS 32 for details on vendor qualifications.
Agreements	Vendors may be required to sign a contract or business agreement. All requirements are defined

	by hospital policy. 1. Contract review: • Agreements to obtain laboratory equipment, supplies and services are reviewed to insure that each party's expectations are defined and agreed to and that any changes are appropriately recorded and communicated. • The support from Materials Management, Purchasing and Legal Counsel are used as needed or indicated. See SYS CC 24 and SYS FI 41.
Incoming Receipt, Inspection, and Testing	Upon receipt of reagents or solutions the following steps are to be followed: 1. Items are inspected for damage that may have occurred during transport. A check is also made to insure that the correct volume of supplies arrive at the appropriate temperature. 2. Items are inspected to ensure that they are labeled with the following elements: a. Content b. Quantity/Concentration/Titer c. Storage Requirements d. Date prepared e. Expiration Date In the event that reagent or solution does not pass the initial inspection, the Ministry Service Center is contacted for instructions on how to proceed. 3. All reagents must be documented in the appropriate log. Documentation will include description, date received, lot number, expiration date and quantity. 4. Items are stored at the temperature specified in the package insert. 5. Prior to use a lot to lot comparison and calibration are performed, if applicable.

	In the event that the comparisons or calibrations fail, testing is repeated. If the values are still outside of the expected ranges technical support is contacted for troubleshooting instructions. <u>Chemistry</u> New lots demonstrating a greater than 1SD shift from the QC mean will require patient sample correlation, where applicable. 6. The original manufacturers label is kept on all containers. A new expiration date is recorded on the container if opening the container changes the expiration date or storage requirements. Containers are labeled with stickers to define the lot status, where applicable. • New Shipment, Same Lot • New Lot, Do Not Use • This lot is ready for use 7. If the reagents and solutions are on a purchase order, the completed paperwork is retained in a section specific binder.
Vendor Recalls	All associates must participate in any recall activities initiated by the laboratory, FDA or other governmental agency, and manufacturers of products, equipment and devices. Upon receipt of written or verbal notification, the Risk Management office will be notified and forwarded all pertinent data for file documentation. If the notification did not come from the purchasing office, the Risk Management Department will notify the Director of Purchasing in writing. A copy of the notification letter is to be provided to the Risk Management office. If a formal letter is not yet available, a memo is to be sent to the Risk Management office delineating current knowledge of the purported recall. When formal verification occurs, the documentation is to be provided to the Risk Management office.

	Additionally, the Lead Technologist for the affected department is responsible for documenting the recall by means of an ORF. All working documents are to be kept by the sections designated to follow-up on the recall process. Upon completion of the recall process, the original documents and all subsequent documents or data collected during the process are to be filed in the Risk Management office. The Laboratory will retain duplicate records of the recall process. Minimal record keeping should be inclusive of, but not limited to the following: • Date and time of receipt of recall • Recall compliance criteria (special instructions) • Internal contacts or involvements • Company or Manufacturer contacts • Final compliance date • Copy of Return Notification letter demonstrating degree of compliance .
Records	The Core Lab maintains the following records for inventory: • Business Agreements and contracts, where applicable • Inventory Log • Completed Purchase Order paperwork • Any documentation related to a vendor recall
Related Documents	• CORE 5000 F Chemistry New Lot or Shipment Comparison • CORE 0000 QP Core Lab Quality Management Plan • LADM 5000 Q Reference Lab and Critical Supplier Validation • LADM 12023 Q Device Related Adverse Event and

	Recall Notification Policy • SYSCC 24 Service Contracts • SYSHOS32 Vendor Pass • SYSFI 41 Fixed Asset Capitalization