Policy Statement	The Department of Pathology will select and use only reference laboratories and critical suppliers that meet required licensure, service and quality criteria. The selected vendors will be monitored to verify expected levels of service and products to meet the needs of the Laboratory.
Purpose	To provide validation criteria for the selection of reference laboratories and critical suppliers to ensure that all regulatory requirements are met.
Scope	This policy encompasses all sections of the Department of Pathology that utilize reference laboratories or critical suppliers.
Responsibility	The Laboratory Medical Director will review and provide documented approval prior to implementation of service from any new reference laboratories. In addition to the Medical Director, the Transfusion Services' Medical Director will review and provide documented approval prior to implementation of service from a new critical supplier for Transfusion Services. Section Lead Technologists will monitor the quality of services provided by reference laboratories and critical suppliers. The Quality Coordinator retains initial approval documents and requests updated documents as required. The Quality Coordinator will maintain a current list of approved reference laboratories and critical suppliers used by the Laboratory.
Definitions	Reference Laboratory – Includes any external commercial, private or public laboratory providing testing or services resulting in diagnostic patient information. Transfusion Services Critical Supplier –Includes suppliers of Blood and its components, human cell, tissue, and cellular and tissue-based product (HCT/P), and tissue derivatives used in the

	collection , preservation, storage, preparation, or testing of blood components and tissue and tissue derivatives that directly affects quality or patient safety. Transfusion Services critical suppliers excludes suppliers that provide reconstitution material for tissue and tissue derivatives.
Reference Lab and Critical Supplier Validation Criteria	The Laboratory along with Purchasing works to ensure that the selection of reference laboratories and critical suppliers are in line with Ascension Health goals. These selections may be based on pre-arranged agreements created by Ascension Health Inc. The Laboratory works to ensure that the services received are cost effective, efficient, and are of high quality. Reference labs/critical suppliers used must be duly accredited, certified and/or licensed for the level of testing or services provided, as required by regulatory or certifying agencies. • Reference laboratories must be CLIA certified and remain in good standing with Centers for Medicare and Medicaid Services throughout the contracted period of utilization. • Transfusion Services' critical suppliers must maintain a current FDA registration for applicable products. • Transfusion Services' critical suppliers must be accredited by AABB or the American Association of Tissue Banks (AATB), as applicable. • Reference labs and critical suppliers must have a valid Maryland State Laboratory Permit, as applicable. • Reference labs and critical suppliers must have the ability to provide correspondence related to recalls in a timely manner. • A signed contract with each primary reference laboratory and critical supplier is required. All critical suppliers must sign the Saint Agnes Hospital HIPAA business agreement and

	provide any other documentation as required by hospital policy. Any changes to the business agreement or any other contract must follow the hospital contract review process. This policy does not apply to suppliers that provide equipment used in the management of critical supplies. (i.e. Helmer, Sanyo, Isensix, etc.)
Validation Documents	All documentation is kept on file by the Laboratory Quality Coordinator and is reviewed annually to ensure accreditation, licensure or permit documents on file have not reached expiration.
Reference Lab and Critical Supplier Service Changes	• Reference lab/critical supplier service changes or additions are subject to the approval of the Medical Director of the Department of Pathology. • Requests from physicians for new and/or changes to existing reference laboratories must be made directly to the Laboratory in writing. The Laboratory Medical Director must approve all new and/or proposed testing changes. • Requests for new and/or changes to existing critical tissue and tissue derivative suppliers must be made directly to the Operating Room (OR) New Product Committee. The Transfusion Services' section Medical Director and Medical Director must approve all new and/or proposed critical supplier changes. • The requesting Department Chairman or requesting physician is notified of request acceptance or denial with cause.
Transfusion Services Critical Supplier Monitoring	Transfusion Services Critical Suppliers are monitored on their ability to provide products in an efficient and timely manner especially in emergent situations. If the supplier's service resulted in a delay in patient care, an Occurrence Report must be generated.

Reference Lab Turn-Around Times (TAT)	• It is the responsibility of the Lead Technologists or their designee to review reference lab logs to ensure the turn around time (TAT) is not excessive. • In the event a result is in excess of the defined TAT, the Lead Technologist or designee is responsible to make direct contact with the specific reference lab to obtain results and the written report. An Occurrence Report Form must be generated if the delay in testing altered patient care.
Reference Lab Billing	• The section Lead Technologist will review the reference laboratory fee schedule for accuracy in pricing and associated CPT codes, initially and annually thereafter. • The assigned section Lead Technologist will review all monthly invoices from reference labs to determine accuracy and reconcile any discrepancies with the reference lab's billing department. • In the event an error is found, the section Lead Technologist will take actions to ensure a correction occurs and will monitor future invoices for account credits or charges. The Lead will also review the patient's billing records to verify that credits to the Laboratory for testing not performed are also removed from the patient's account. • If problematic situations continue, the issue is referred to the Administrative Director.
Other Critical Suppliers	Educational Partners for alternate CAP External Proficiency are maintained in the same manner as a reference laboratory.
Related Documents	CAP General and Transfusion Medicine Checklist
Reference Documents	CLIA AABB

	COMAR Title 10 Subtitles 10 Laboratories SYS HOS 32-Vendor Pass SYS FI 40-Contract Review Policy SYS HIPAA 02-Business Associates