Policy Statement	A process is required to inform caregivers, appropriate members of laboratory management and the College of American Pathologists of availability of a new laboratory service or diagnostic test.
Purpose	To provide instruction for the implementation of new services, new tests, changes in testing and discontinuation of testing.
Scope	This procedure applies to all sections within the Department of Pathology.
Responsibility	The Manager, Supervisor, or Lead of the section supporting the new technology or service is responsible for the actions required by this procedure.

The following forms need to be filled out for each type of change implemented within the laboratory.

New Services – Implementation/Changes/Discontinuation

- LADM 6002 F Implementing Pathology Service or Test Checklist
- LADM 6020 F Pilot Implementation (if applicable)
- Hospital Form – Checklist for Implementing or Discontinuing a Service or Process (If deemed appropriate by the Laboratory Director.)

New Tests – Implementation/Changes/Intermittent Testing

- LADM 6002 F Implementing Pathology Service or Test Checklist
- LADM 6020 F Pilot Implementation (if applicable)
- LADM 6025 Fa Validation Plan
- LADM 6025 Fb Validation Summary
- LADM 6025 Fc Internal Installation Checklist (if applicable)
- Hospital Form – Checklist for Implementing or Discontinuing a Service or Process (If deemed appropriate by the Laboratory Director.)

Test Discontinuation

- LADM 6002 Fe Laboratory Test Discontinuation Checklist
- LADM 6020 F Pilot Implementation (if applicable)
- Hospital Form – Checklist for Implementing or Discontinuing a Service or Process (If deemed appropriate by the Laboratory Director.)

New Reference Laboratory Tests

- LADM 6002 Fb Checklist for Implementing a New Reference Lab Test

Implementing a New Pathology Service or Test Checklist

New Service or Test to be Implemented:		
	Implementation Lead (s)	**Medical Director, Manager, Supervisor** (Responsible for oversight)
Name		
Title		
Administrative Director informed: _____ **(Date)** **Chairman informed:** _____ **(Date)** **CAP informed:** **(Date)**		

Component	**Screening Questions** **Response = Yes, No, or Not Applicable**	**Related Notes**
Regulatory **Contact: Manager**	• Has a procedure been written and signed? _____ • Are alert values required? _____ • Was verification of analytical precision and accuracy required? _____ • Analytical sensitivity assessed? _____ • Was potential of analytical interferences established? _____ • Reportable range verified? _____ • Does change in analytical method affect interpretation? _____ • Reference interval assessed? _____	

**** Mandatory = Must contact department to discuss new service.**

Implementing a New Pathology Service or Test Checklist

Component	Screening Questions Response = Yes, No, or Not Applicable	Related Notes
	• Included in CAP Proficiency Testing? If not, what is alternative? _____ • Was CAP notified of new addition to test menu? _____	
Preanalytical **Contact: Support Services Supervisor and /or Outreach Coordinator**	• Has the lab service manual been updated? _____ • Has the alpha test list been updated? ____ • Is training required of phlebotomist, unit secretary, nursing staff, or physician for order entry, collection, or transport of sample? _____ • Is a new collection device required? _____ • Are there specimen stability issues that would prevent add on request to blood in lab? _____	
Quality Management **Contact: Quality Coordinator and Manager**	• Is there an indicator associated with this new testing? _____ • Will there be resulting performance improvement? ____ • Is there a method of tracking resulting performance improvement? _____	

**** Mandatory = Must contact department to discuss new service.**

Implementing a New Pathology Service or Test Checklist

Component	Screening Questions Response = Yes, No, or Not Applicable	Related Notes
Laboratory Information Services **Contact: Laboratory** Information Services Coordinator. / Lead	• Does the computer downtime procedure require revision due to introduction of this new test, instrument, or service? ____ • Does new test, instrument, or service employ a calculation that requires verification? _____ • Have obsolete tests been removed from order entry? ____ • Are changes to reference ranges, alert values, delta checks, and duplicate request flags appropriately entered and verified? _____ • Are new or revised “canned” comments required? _____ • Has the associated patient report and Electronic Medical Record been assessed? _____ • Have components linked to billing been verified?	
Personnel **Contact: Section Supervisor or Lead**	• Is there an appropriate training checklist for the new test or service? _____ • Has competency of each individual been assessed to perform new test or elements of	

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Implementing a New Pathology Service or Test Checklist

Component	Screening Questions Response = Yes, No, or Not Applicable	Related Notes
	new service? _____ • Is there impact on workstation design? Is there an ergonomic issue? _____ • Will this test affect workstation assignments? Staffing on weekends, holidays, and off shifts? _____	
Post analytical **Contact: Medical Director Sponsor**	• Is result or service available to caregiver at appropriate time? ____ • Is result of service available to caregiver in appropriate format? _____ • Is Medical Director available to respond to clinicians? _____	
Environment of Care **Contact: Lab Safety Officer**	• Is reconstruction required? _____ • Are there safety issues? _____ • Have Material Safety Data sheets been logged? _____ • Are storage issues (shelving, refrigeration) considered? _____	
Materials Management/Finance **Contact: Lab Administrative Director**	• Is a contractual review required? ____ • Is a new vendor required? _____ • Does an element of new service fall under any Ascension Health Supply Chain	

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Implementing a New Pathology Service or Test Checklist

Component	Screening Questions Response = Yes, No, or Not Applicable	Related Notes
	Initiatives? _____ • Is a budget variance anticipated?_____ • Does the budget variance require generation of a new product request or a business plan? _____	
Outreach **Contact: Outreach Manager/Project Specialist**	• Are changes required to requisition? • Are changes required to Lifepoint? • Is communication to clients required? • Is this a marketing opportunity?	

Medical Director or designee	• Has the medical director reviewed prior to implementation?
	  ○ Collection Procedure? ____
	  ○ Analytical Procedure?
	  ○ Validation? _____
	  ○ Changes to lab service manual? ____
	  ○ Alpha test list? ____
	  ○ Patient report? ____
	• Has medical director prepared briefing for clinicians? _____	

HAS EXTERNAL CHECKLIST BEEN CIRCULATED AND SUBMITTED TO QUALITY DEPARTMENT? _____		

**** Mandatory = Must contact department to discuss new service.**

Implementing a New Pathology Service or Test Checklist

Component	Screening Questions Response = Yes, No, or Not Applicable	Related Notes
Medical Director, Department of Pathology _____		**Date:** _____
Administrative Director_____		**Date:** _____

**** Mandatory = Must contact department to discuss new service.**

Checklist for Implementing a New Reference Lab Test

New Test to be Implemented:		
Request received from:		
Date of Request:		
Reference Lab to be used:		
Regulatory:	• Are alert values required?	
Preanalytical:	• Has the online test search been updated?	
	• Has the desktop icon been updated?	
	• Are there specimen stability issues that would prevent add-on requests to the specimen in the lab?	
	• Will there be any new training required for the implementation of this test?	
Billing:	• Was a new billing code created or will an existing code be used?	
	• What is the billing code that will be used?	
Expense:	• What is the cost of the test?	
	• What is the charge to SAH patients?	
	• What is the charge to SLO patients?	
	• Overall?	
LIS	• Was the test created in the Meditech dictionary?	
Test activated by:		
Date of test activation:		
Manager Signature:		
Date:		

SAINT AGNES HOSPITAL

Laboratory Test Discontinuation Checklist

Service or Test to be Discontinued:	
Implementation Lead:	
Medical Director:	
Discontinued Date:	
Administrative Director Inform Date:	
CAP Inform Date:	

Circle one

Procedure

- Has the procedure been retired/updated? Y N N/A
- Has the procedure been moved to the retired folder on the P drive? Y N N/A
- Has the procedure been removed from online? Y N N/A
- Are any other procedures affected by this change? Y N N/A
- Was the assay specification sheet updated? Y N N/A
- Was the Alert Value procedure, *LADM 6005 Q Alert Value List and Notification Process,* updated to reflect the changes? Y N N/A

System

- Were all reagents removed from inventory? Y N N/A
- Were appropriate changes made to LIS dictionary to account for the changes? Y N N/A
- Were the changes reflected on the online lab test search? Y N N/A

Notification

- Was a memo created to inform the physicians and nursing staff been notified of this changes? Y N N/A
- Was there notification sent to the technical staff of the changes? Y N N/A
- Was the Quality Coordinator notified of the changes? Y N N/A
- Was the Outreach Manager notified of the changes? Y N N/A
- Was the Support Services Supervisor notified of the changes? Y N N/A

Reason for Update:_____

All items on this list have been reviewed.

Lead Signature:_____

Medical Director Signature:_____

Date of Discontinuation:_____