

<b>Quality Management Manual Department of Pathology</b>	<b>Document No. LADM 6002 Q Page 1 of 2</b>
<b>Implementation and Changes to Services and Testing</b>	<b>Origination: 10/2002 Version: 5</b>

<b>Policy Statement</b>	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. Significant changes in testing methods or services as well as tests performed intermittently are reviewed by the Laboratory Management Team for determination of appropriate notifications.
<b>Purpose</b>	The Department of Pathology must provide documentation of changes made to services and testing and ensure that proper notification of the changes is communicated to all affected areas within the laboratory, hospital and/or outreach locations.
<b>Scope</b>	All sections of the laboratory are responsible for adherence to this policy. This action affects all caregivers supported by the Department of Pathology.
<b>Responsibility</b>	The Manager, Supervisor, or Lead of the section supporting the new technology or service is responsible for the actions required by this policy. The Medical Director of the section of the Department of Pathology provides collaboration and guidance.

### **New Services or Tests**

Implementation of a new service or test could be the result of a process improvement project, document occurrence form, change in institutional requirements or change in regulatory guidelines. With each new service or test a series of documentation is required for internal and external review. The final internal review must be completed by the section Medical Director and Lab Council.

### **Service or Test Changes**

A service change is defined as a modification of a process that we have provided to a caregiver or external department. A testing change is defined as, but not limited to, modifications in methodology, sample type, collection container, intended patient population, interpretation, or reference ranges. Changes require review by the section Medical Director. Lab Council should review changes when applicable.

### **Intermittent Testing**

Tests taken out of production for a time, due to seasonal scheduling or vendor disruptions, require specified actions prior to being put back into production. All actions must be reviewed by Lab Council and the section Medical Director.

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### **Communication**

External communication with respect to service change or addition will be coordinated by the Laboratory Administrative Assistant. All communication regarding an approved service change or addition must be made via memorandum approved by the Administrative Director and Chairman (or Designee).

### **Related Documents**

- LADM 6002 F Implementing Pathology Service or Test Checklist
- LADM 6002 Fb Checklist for Implementing a New Reference Lab Test
- LADM 6002 Fe Laboratory Test Discontinuation Checklist
- LADM 6020 Q Pilot Implementation
- LADM 6020 R Pilot Implementation
- LADM 6020 F Pilot Implementation
- LADM 6025 Q Equipment and Process Validation
- 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