

	<b>INODAYAHospitals - Kakinada</b>		Documentation code: <b>INH/AAC.Doc.No:19</b>
	<b>Policy on Outsourced lab test and their quality assurance</b>		Prepared Date: 11/11/2025
	Reference: AAC.6.J.NABH Standards –6 <sup>th</sup> Edition		Issue date:11/11/2025
	Issue No:1	Review NO:00	Review Date:10/11/2026

## **AAC. 6J. Policy on Outsourced lab test and their quality assurance**

### **1. Purpose**

To ensure that all laboratory tests outsourced by **Inodaya Hospital** to external laboratories are performed safely, accurately, and in accordance with national and international quality standards. This policy outlines the criteria for selection, monitoring, and quality assurance of referral laboratories.

### **2. Scope**

This policy applies to:

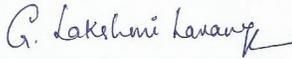
- Inodaya Hospital Laboratory Services
- All departments requesting outsourced laboratory tests
- External referral laboratories partnered with Inodaya Hospital

### **3. Definitions**

- Outsourced/Referral Laboratory: An external laboratory contracted to perform specific diagnostic tests.
- Quality Assurance (QA): Systematic actions necessary to ensure that laboratory results meet defined standards of quality.
- Service Level Agreement (SLA): A formal agreement outlining responsibilities, turnaround times, quality expectations, and reporting procedures between the institution and the referral laboratory.

### **4. Policy Statement**

**Inodaya Hospital** is committed to providing reliable diagnostic services. Outsourcing of laboratory tests will be undertaken **only with approved, accredited, and quality-compliant laboratories**. Quality, patient safety, and confidentiality shall be maintained at all times.

Prepared by: 	Verified By: 	Approved by: 
<b>Dr. Deepthy Saranya</b>	<b>Dr. Gowtham Krishna</b>	Mrs. G. Lakshmi Lavanya
Pathologist	Medical Director	Accreditation Coordinator

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### 5. Contracting and Service Level Agreement (SLA)

Inodaya Hospital will maintain an SLA/MOU with each partnered laboratory specifying:

- List of outsourced tests
- Turnaround times (TAT)

### 6. Specimen Collection and Transportation (By Inodaya Hospital)

- Samples must be collected following Inodaya Hospital's SOPs.
- Proper labeling using patient identifiers.
- Specimens must be packaged in leak-proof, temperature-controlled containers.
- Courier/transport personnel must follow biohazard and chain-of-custody protocols.
- Any deviation must be documented and corrected.

### 7. Quality Assurance and Monitoring

#### 7.1 Continuous Performance Review

The Inodaya Hospital Laboratory Quality Team shall monitor:

- Turnaround Time compliance
- Sample rejection rates
- Transport and pre-analytical errors
- Accuracy and consistency of results (repeat testing when needed)
- Complaints, errors, and corrective action reports from the referral lab

#### 7.2 External Quality Assurance (EQA/PT) Review

- **Inodaya Hospital** will review the partner lab's EQA/PT performance at least twice per year.
- Any unsatisfactory performance must result in corrective action or suspension of outsourcing.

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### 7.3 Result Verification

- Unexpected or clinically discordant results must be rechecked or discussed with the partner lab.
- Critical values must be communicated immediately by the referral lab.

### 7.4 Annual Audit

- **Inodaya Hospital** will conduct an annual audit (onsite or remote) of each referral laboratory.
- Audit findings will be documented and followed by corrective actions.

### 8. Reporting of Results

- Referral labs must send reports securely (email, LIS integration, encrypted formats).
- Inodaya Hospital must verify all results before releasing them to clinicians.
- Critical alerts must be phoned immediately as per hospital policy.

### 9. Documentation and Record Keeping

#### Inodaya Hospital will maintain:

- Accreditation certificates of partner labs
- Signed SLAs/MOUs
- Specimen dispatch registers & transport logs
- Quality monitoring records (TAT, errors, complaints)
- Audit reports and CAPA documentation
- Records retained per hospital retention policy (usually 3–5 years)

### 10. Incident Management

Any quality issue—such as delayed reports, incorrect results, lost samples, safety incidents—must be:

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1. Reported as a Non-Conformance (NC)
2. Investigated jointly with the referral lab
3. Documented with Corrective and Preventive Actions (CAPA)
4. Reviewed by the Inodaya Hospital Quality Committee

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#### Document Revision History

DOCUMENT REVISION HISTORY		
Version	Date of issue	Reason for Revision
Original version - 1		
Revised version - 2		
Revised version - 3		
Revised version - 4		
Revised version - 5		

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