



**ALL INDIA INSTITUTE OF MEDICAL SCIENCES, GORAKHPUR**  
Kunraghat, Gorakhpur, Uttar Pradesh 273008  
(An autonomous organization under the Ministry of Health & Family Welfare,  
Govt. of India).

Technical Specifications for Internal Quality Control Materials

For Clinical Biochemistry Laboratory, AIIMS Gorakhpur

**1. TRI-LEVEL CARDIAC CONTROL**

- Type: Assayed, third-party internal quality control material for cardiac markers.
- Matrix: Human serum-based.
- Formulation: Lyophilized.
- Levels: Three levels (Level 1, Level 2, and Level 3) in a single pack.
- Intended Use: For internal quality control of cardiac marker assays on automated immunoassay and clinical chemistry analyzers.
- Analyte Coverage should include:
  - CK Total
  - CK-MB Activity
  - CK-MB Mass
  - Troponin I
  - Troponin T
  - Myoglobin
  - Homocysteine
- Compatibility: Must provide instrument-specific and method-specific assigned values for major analyzers
- Reconstitution:
  - Lyophilized material should be reconstituted with distilled water.
  - Stable after reconstitution as per manufacturer instructions.
- Stability:
  - Unopened stability up to expiry date when stored at +2°C to +8°C.
  - Reconstituted material stable for minimum 5 days at +2°C to +8°C and frozen stability at -20°C.
- Certification:
  - Product should be from ISO-certified manufacturer and suitable for NABL accredited laboratories.
- Pack Size Required:
  - 3 × 1 ml or equivalent tri-level cardiac control pack.

**2. Immunoassay Speciality I Control – Level 2**

- Type: Assayed, third-party internal quality control material.
- Matrix: Human serum-based.
- Formulation: Lyophilized.
- Intended Use:
  - For internal quality control of Immunoassay analytes on automated immunoassay analyzers.
- Analyte Coverage should include:
  - Vitamin D
  - Anti-TG
  - Anti-TPO
  - C-Peptide
  - IGF-1

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- Osteocalcin
- Parathyroid Hormone (PTH)
- Additional immunoassay specialty analytes
- Compatibility:
  - Must provide assay-specific assigned values for major analysers.
- Stability:
  - Stable unopened at +2°C to +8°C till expiry.
  - Reconstituted serum stable for minimum 5 days at +2°C to +8°C and frozen stability at -20°C.
- Preparation:
  - Reconstitution with exactly 2 ml distilled water.
- Certification:
  - Product should be manufactured by an ISO-certified company and suitable for NABL accredited laboratories.
- Pack Size Required:
  - 5 × 2 ml.

**3. Immunoassay Speciality I Control – Level 3**

- Type: Assayed, third-party internal quality control material.
- Matrix: Human serum-based.
- Formulation: Lyophilized.
- Intended Use:
  - For internal quality control of Immunoassay analytes at pathological/high levels on automated immunoassay analyzers.
- Analyte Coverage should include:
  - Vitamin D
  - Anti-TG
  - Anti-TPO
  - C-Peptide
  - IGF-1
  - Insulin
  - Osteocalcin
  - Parathyroid Hormone (PTH)
  - Additional specialty immunoassay analytes
- Compatibility:
  - Must provide assay-specific assigned values for major analysers
- Stability:
  - Stable unopened at +2°C to +8°C till expiry.
  - Reconstituted material stable for minimum 5 days at +2°C to +8°C and frozen stability at -20°C.
- Preparation:
  - Reconstitution with exactly 2 ml distilled water.
- Certification:
  - Product should be manufactured by an ISO-certified company and suitable for NABL accredited laboratories.
- Pack Size Required:
  - 5 × 2 ml.

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