# Axiom ANALYTICS

CERTIFICATE OF ANALYSIS · DX DILUENT & SOLVENT PANEL

**Axiom Analytics Laboratories**
2108 N St Ste N, Sacramento, CA 95816 US

**AX-2026-2951-GNVJ**

NU-BAC (Bacteriostatic Water for Injection, USP (0.9% benzyl alcohol added)) · Lot T-BAC-0093
Issued Oct 20, 2026 PT · v1
Verify: 1199-13CE-C82C

SCAN TO VERIFY

## PASS — ALL SPECIFICATIONS MET

7 of 7 layers complete

| L1 | L2 | L3 | L4 | L5 | L6 | L7 |
|---|---|---|---|---|---|---|
| Identity | Chromatographic & Carrier Purity | Declared Content | Sterility | Endotoxin | Heavy Metals | Physicochemical Properties |

## Sample & Vial Validation




Vial A: as received & analyzed

MORE VIEWS OF VIAL A



Vial A · right

| | | | |
|---|---|---|---|
| Brand | **NU Biotech Labs** | Product | **NU-BAC (Bacteriostatic Water for Injection, USP (0.9% benzyl alcohol added))** |
| Lot / Batch | **T-BAC-0093** | Label Claim | **10 mL** |
| Matrix | **solution** | Sample Count | **1** |
| Vial Size | **10mL** | Cap Color | **Black** |
| Crimp Color | **Silver / Aluminum** | Contents Color | **Clear/Translucent** |
| Seal Intact | **Yes** | Condition | **sealed, intact** |
| Received | **Oct 13, 2026 PT** | Sampling | **client submitted** |

Results relate only to the item or portion tested. Unless sampling was performed or witnessed by Axiom Analytics, the laboratory does not attest that the submitted sample represents the wider lot or batch. A PASS designation means only that the reported result met the specification shown. It does not establish safety, efficacy, regulatory approval, legality, or suitability for human or animal use.

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## Test Results

| Test | Specification | Result | |
|---|---|---|---|
| **Identity · GC-FID** verified compendial | retention time corresponds to the reference standard run on the same sequence | analyte 6.61 min, reference standard 6.59 min | PASS |
| **Purity · GC-FID** verified compendial | at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5% | 99.88% GC area% (largest single impurity 0.15%, total impurities 0.25%) | PASS |
| **Benzyl Alcohol Content** verified compendial | 80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required | 0.950705 % w/v · 105.6339% of the 0.9% w/v label claim | PASS |
| **Sterility · Rapid PCR** research screen | Rapid PCR screen | Target DNA not detected | PASS |
| **Endotoxin** verified compendial | < 0.5 EU/mL (USP <85>) | 0.21 EU/mL | PASS |
| **Heavy Metals** research screen | ICH Q3D(R2) Table A.2.2, parenteral route | All below limits | PASS |
| **pH** research screen | pH within 4.50 - 7.00 | pH 6.3 | PASS |
| **Visual Appearance** research screen | colorless; clear; free from visible particles | colorless; clear; no visible particles observed | PASS |

## Layer Results

### 1 Identity · GC-FID

GC-FID identity vs reference standard (USP <621>)

**analyte 6.61 min, reference standard 6.59 min** — PASS
retention time corresponds to the reference standard run on the same sequence

| | | | |
|---|---|---|---|
| Result | **analyte 6.61 min, reference standard 6.59 min** | Acceptance | **retention time corresponds to the reference standard run on the same sequence** |

### 2 Purity · GC-FID

GC-FID chromatographic purity, area% (USP <621>)

**99.88% GC area% (largest single impurity 0.15%, total impurities 0.25%)** — PASS
at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5%

| | | | |
|---|---|---|---|
| Result | **99.88% GC area% (largest single impurity 0.15%, total impurities 0.25%)** | Acceptance | **at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5%** |
| Criterion source | **Axiom Analytics SPEC-PURITY-001, Revision 1, effective 2026-08-31** | | |

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## 3 Benzyl Alcohol Content

Benzyl alcohol preservative content by GC-FID (USP <341>)

**0.950705 % w/v · 105.6339% of the 0.9% w/v label claim**
80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required

PASS

| | | | |
|---|---|---|---|
| Result | **0.950705 % w/v; 105.6339% of the 0.9% w/v label claim** | Acceptance | **80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required** |

## 4 Sterility · Rapid PCR

Rapid Microbial DNA Screen (qPCR target panel)

**Target DNA not detected**
Rapid PCR screen

PASS

| | | | |
|---|---|---|---|
| Result | **Target DNA not detected** | Acceptance | **Rapid PCR screen** |

## 5 Endotoxin

Bacterial endotoxin, USP <85> (kinetic chromogenic LAL)

**0.21 EU/mL**
< 0.5 EU/mL (USP <85>)

PASS

| | | | |
|---|---|---|---|
| Result | **0.21 EU/mL** | Acceptance | **< 0.5 EU/mL (USP <85>)** |
| Source container | **A** | | |

## 6 Heavy Metals

ICP-MS (USP 232/233)

**All below limits**
ICH Q3D(R2) Table A.2.2, parenteral route

PASS

| | | | |
|---|---|---|---|
| Result | **All below limits** | Acceptance | **ICH Q3D(R2) Table A.2.2, parenteral route** |
| Source container | **A** | | |

| Element | Specification | Result | Status |
|---|---|---|---|
| Lead (Pb) | ≤ 0.5 ppm (µg/g) | Not Detected | PASS |
| Arsenic (As) | ≤ 1.5 ppm (µg/g) | Not Detected | PASS |
| Cadmium (Cd) | ≤ 0.2 ppm (µg/g) | Not Detected | PASS |
| Mercury (Hg) | ≤ 0.3 ppm (µg/g) | Not Detected | PASS |
| Cobalt (Co) | ≤ 0.5 ppm (µg/g) | Not Detected | PASS |
| Vanadium (V) | ≤ 1 ppm (µg/g) | Not Detected | PASS |
| Nickel (Ni) | ≤ 2 ppm (µg/g) | Not Detected | PASS |

## 7 pH

pH (USP <791>) + Submitted-container visual appearance and visible-particle screen

**pH 6.3**
pH within 4.50 - 7.00

PASS

| | | | |
|---|---|---|---|
| Result | **pH 6.3** | Acceptance | **pH within 4.50 - 7.00** |
| Source container | **A** | | |

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## 7 Visual Appearance

pH (USP <791>) + Submitted-container visual appearance and visible-particle screen

**colorless; clear; no visible particles observed**
colorless; clear; free from visible particles

PASS

| | | | |
|---|---|---|---|
| Result | **colorless; clear; no visible particles observed** | Acceptance | **colorless; clear; free from visible particles** |
| Source container | **A** | | |

## Reporting Scope & Limitations

`[Sterility · Rapid PCR]` DNA-target research screen only. It detects microbial DNA from viable and non-viable organisms alike, and is neither viable-CFU enumeration under USP <61> nor a batch sterility determination under USP <71>.

## Digital Signatures

| | | | |
|---|---|---|---|
| Analyst | **Alana Reeves** | Analyst Signature | **ed25519:92d6247f1381295ceca923e0...** |
| Technical Reviewer | **Michael Niles** | Reviewer Signature | **ed25519:faf8c67c414d4a45fcddaeca...** |
| Laboratory Director | **Daniel Brennan** | Director Signature | **ed25519:8bc76185a21c101d50df33af...** |

Where physical instrument analysis is performed, it takes place within Axiom Analytics' laboratory network, allocated at Axiom's discretion based on method, capacity, and order volume. Axiom Analytics performs sample accession, chain of custody, analytical oversight, and data review, and issues and is responsible for this certificate. Where analysis is subcontracted, the method is performed within the partner laboratory's published ISO/IEC 17025 scope of accreditation for that method, not merely at a laboratory holding ISO/IEC 17025 accreditation. Axiom Analytics does not itself currently hold ISO/IEC 17025 accreditation. The method-validation status of each reported result is identified beside that result. Partner laboratory identities are not disclosed: where samples are analyzed under double-blind conditions, they are identified only by an internal lot ID.

Each signature is an ed25519 signature over the SHA-384 hash of this report. Scan the QR on the letterhead or verify independently at https://axiomanalyticslab.com/verify/AX-2026-2951-GNVJ.

**CRYPTOGRAPHICALLY SEALED (ed25519 + SHA-384)**

SHA-384: 35383ffc2eb5c8596b37ee6e15f94604e72d7606a0225401f05b3eab7f94dd22...

Seal: ed25519:b4284b0a231cbf6f99d2fc2e725e2397e6ddad5d...

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