

CERTIFICATE OF ANALYSIS (CoA)

PROPERTY NAME: I-MYCOBACTERIA TEST

ADENOSINE DEAMINASE (ADA) DETERMINATION KIT

- Modified Giusti Method (Berthelot's Reaction-Optimized Formulation)
- DOM: 2026-07-10
- **Lot / Batch Number:** 26AT0701
- **Exp. Date:** 2028-06-20

2. COMPONENT FORMULATION & QUALITY CONTROL SPECIFICATIONS

Component	Physico-Chemical Acceptance Criteria	Status
Vial 1: Color 1	Clear, particle-free solution. Light sensitive.	PASSED
Vial 2: Color 2	Strongly alkaline solution, free of turbidity.	PASSED
Vial 3: Standard	Analytical concentration equivalent to 50 IU/L .	PASSED
Vial 4: Buffer	Controlled Clinical pH: 6.50 (KEEP @RT)	PASSED
Vial 5: Adenosine	Adenosine P.A. Buffer pH 6.50 (KEEP @RT)	Complete thermal dissolution (50°C), crystal clear. PASSED

3. ANALYTICAL PERFORMANCE VERIFICATION (Spectrophotometry at $\lambda = 560$ nm)

Functional validation runs on the spectrophotometer against distilled water yielded the following fixed analytical results:

- **Reagent Blank Absorbance (Blank): 0.039** (Safety specification: ≤ 0.100) → **COMPLIES**
- **Gross Standard Absorbance:** 0.214
- **Net Standard Absorbance (Standard - Blank): 0.175** → **COMPLIES**

Derived Calibration Parameters:

- **Batch Calibration Factor – Baseline reference (F): 285.71** (Dynamic value; subject to variation over time. Weekly verification or per-run calibration is strictly required to compensate for reagent aging).
- **Batch Linearity Limit: 250 IU/L** (Samples exceeding this value require dilution with normal saline).

4. CONCLUSION & DICTAMEN

Batch number **26AT0701** has been fully evaluated for pH accuracy, thermal dissolution, environmental ammonia control, and spectrophotometric response according to the modified Giusti method. Since it demonstrates an exceptionally clean reagent background (0.039) and an optimal linear response at the standard level (0.175), the batch is certified free of cross-contamination.

FINAL STATUS: APPROVED FOR CLINICAL USE

- **Approved by:** Jeen Tanaka
- **Signature of Conformity:** _____

