

SCLTest, Standard for Verification of
Test Legipid® Legionella Fast
Detection curve

Catalogue reference:

311-30-SC

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I. INTRODUCTION

SCLTest, Standard for Verification of Test Legipid® Legionella Fast Detection curve (Ref. No. 311-10-SC) is a simple and fast system for the laboratory to verify the calibration curve of the test **Legipid® Legionella Fast Detection**. This curve, provided by the manufacturer, predicts the concentration of equivalent CFUs (CFU_{eq}) in a sample as a function of relative absorbance (**Abs_r**) at 429 nm. On a Log₁₀-Log₁₀ scale, it is a linear calibration curve, characterized by its slope and its intercept:

$$\text{Log}_{10} \text{CFU}_{\text{eq}} = 2.3061 \times \text{Log}_{10} \text{Abs}_r + 4.9815 \quad (1)$$

With the validation data of the **Legipid® test**, the confidence intervals (CI) with a confidence level of 95% are provided, both for the slope and for the intercept of said curve:

- for the slope [1.83, 2.78]
- for the intercept [4.53, 5.43]

SCLTest allows to prepare a series of standard samples of 9 mL, at three different levels of **Log₁₀ UFC_{eq}**, with n-replicas for each level. The laboratory records the **relative absorbances** obtained for each concentration when applying the **Legipid®** test to the samples.

The data is entered into a spreadsheet that contrasts the hypothesis that the experimental values of slope and intercept are within their CIs. In that case, the verification is suitable, and the linear calibration curve of the test is accepted.

II. KIT REAGENTS AND COMPONENTS

Reference **311-10-SC** contains 5 vials per level (high, medium, low) with a volume of 0.6 mL/vial of a non-culturable frozen suspension of a known concentration of **Log₁₀ CFU_{eq}** and one L0 bottle with 300ml.

III. EXPIRY AND STORAGE

Once received, vials should be immediately stored at $-20 \pm 5^{\circ}\text{C}$. The expiration of the material, properly stored, is **3 months** from the date of supply. Each set of vials per level is labeled with its batch number and storage conditions. In addition, the protocol includes code, batch number and expiration, so the traceability of all vials is guaranteed.

IV. MATERIAL REQUIRED BUT NOT PROVIDED

- ◆ Pipettes 100-1000µl.

V. CAUTIONS AND RECOMMENDATIONS

- ◆ The vial should be immediately frozen upon receipt.
- ◆ Thaw and temper the vial to be used. Once thawed and tempered, use the contents as described in VI. Protocol, and do not save any remnants.

VI. PROTOCOL

Before you start:

Remove from the freezer the exact number of vials you need, for each level. As many as replicas per level you will use. Allow to thaw and temper at room temperature, before preparing the standard samples and analyzing them with the Legipid® *Legionella* Fast Detection kit.

Procedure:

1. Defrost and temper n-vials per level, as many as replicas you will use (for example, n=3).
2. For each level and n-vials, **take 0.5 mL** of each vial and add it in each of the Legipid® n-cuvettes.
3. Bring all cuvettes to a final volume of 9 mL with L0 (that is, add 8.5 mL of L0).
4. Perform the Legipid test® on all samples (use a negative control per batch)
5. Record the **absolute absorbance value of the negative control**
6. Record the **relative absorbance values (with respect to the negative control) of the samples**

Interpretation:

Enter in the worksheet:

- the **recorded absolute absorbance of the negative control**.
- the **certified Values of Log₁₀CFU_{eq}** provided by the manufacturer for each level (suspension volume 0.5 mL, brought to 9 mL with L0).
- the **relative absorbance values obtained for the samples for each level**.

The worksheet will return as a result the expression “APTA”, only in the case where both the slope and the intercept of the experimental curve are within the corresponding CIs.

Analyst:				Confidence interval, 95%		[1.83, 2.78]			
Date:				Confidence interval, 95%		[4.53, 5.43]			
Abs negative control:		0,095							
CFUeq, log10	Replicate	Absr	Log ₁₀ Absr	Mean Log ₁₀ Absr	Slope		Intercept		Curve/Decision
					Value	Status	Value	Status	
	1		-	-					
	2		-						
	3		-						
	4		-						
	5		-						
	1		-	-	NO APTA		NO APTA	NO APTA	
	2		-						
	3		-						
	4		-						
	5		-						
	1		-	-					
	2		-						
	3		-						
	4		-						
	5		-						

Number of lot: <input type="text"/> Concentration (Log₁₀ CFU_{eq}): <input type="radio"/> Nivel 1: <input type="text"/> <input type="radio"/> Nivel 2: <input type="text"/> <input type="radio"/> Nivel 3: <input type="text"/> Expiration from date of supply: __/__/__	For technical assistance please contact: Biótica, Bioquímica Analítica, S.L. Parque Científico y Tecnológico, Universidad Jaume I Edificio Espaitec 2, planta baja, lab 2 E12071 – Castellón, Spain www.biotica.es info@biotica.es Tel.: +34 964108131 Fax: +34 964737790	 FAST DETECTION FOR LIFE
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Note to user: Use this product only for internal testing