

# Certificate of Analysis for RPR Kit

## 1- Product Identification:

<b>Lot No</b>	22100515
<b>Product Name</b>	RPR Syphilis kit
<b>QC Method No</b>	F30D
<b>Batch Size</b>	3
<b>EXP. Date</b>	10.2024
<b>Mfg. Date</b> (if applicable)	N.A

## 2- Physical Inspection:

Inspection level	AQL	Sample size code letter	Inspected quantity	Accepted	Rejected
S-1	1.0	A	2	0	1

Applicable test type	Inspected item / criteria	Inspection results
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status:	RPR carbon Ag/reagent: Black – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control: Colorless /Yellowish – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control: Colorless /Yellowish – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	RPR carbon Ag/reagent :2 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control : 0.5 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control : 0.5 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Stirring Sticks:	No breaking sticks and clean	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Paper Card:	No scratch in test circles or edges and clean	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label. • Record the QTY/Kit: 6/1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify: .....	

Done by (Signature): .....*Foga*.....  
QC Officer/Supervisor

Date: 12.10.2022

Time: 14:40

### 3- Biochemical Inspection:

	RN No./Lot No.	Agglutination time	Agglutination Intensity	Result (Agg./No Agg.)	Result (Pass / Fail)
RPR Antigen (if requested)	22100515	8 min	+3/-ve	Agg./No Agg.	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Control Check	22100515	8 min	+3	Agg.	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Negative Control Check	22100515	8 min	-ve	No Agg.	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify: .....			
Done by (Signature): ... <i>Toga</i> .....		Date: 12.10.2022		Time: 14:50	
QC Officer/Supervisor					

Final Conclusion: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
Final QC Manager Approval (Signature): <i>Tasneem</i>	Date: 12.10.2022

QC Release Stamp:

