

METHOD COMPARISON

For Serum samples

Method comparison was performed according to the Clinical and Laboratory Standards Institute (CLSI) guide: User protocol for evaluation of qualitative test performance; Approved guideline – Third edition. EP12.

MATERIALS

Components:

RPR-CARBON RA (148PA)
Positive Control (110XA)
Serology Negative Control (073XF)

Samples:

Human serum containing antibodies against antigens derived from nontreponemal sources
patient leftovers samples

METHODS

Reference method: SYPHILIS RPR TEST (Human)

Both measurement procedures, the candidate (BS) and the reference (Ref), were ran as described in their instructions for use.

Patient leftover samples were studied by both methods. Each sample has been evaluated with a single replicate.

Data analysis was carried out with the Analyse-it – Method Validation Edition software (Analyse-it software, Ltd. United Kingdom).

Acceptance criteria

Positive agreement	95	%
Negative agreement	95	%
Total agreement	95	%

RESULTS

Raw data file: MP-807 180619 Kit Validation - Laboratory in Colombia

Dataset

Sample	Run							
	1		2		3		4	
	Ref	BS	Ref	BS	Ref	BS	Ref	BS
1	+	+	+	+	-	-	-	-
2	+	+	+	+	-	-	-	-
3	+	+	+	+	-	-	-	-
4	+	+	+	+	-	-	-	-
5	+	+	+	+	-	-	-	-
6	+	+	+	+	-	-	-	-
7	+	+	+	+	-	-	-	-
8	+	+	+	+	-	-	-	-
9	+	+	+	+	-	-	-	-
10	+	+	+	+	-	-	-	-
11	+	+	+	+	-	-	-	-
12	+	+	+	+	-	-	-	-
13	+	+	+	+	-	-	-	-
14	+	+	+	+	-	-	-	-
15	+	+	+	+	-	-	-	-
16	+	+	+	+	-	-	-	-
17	+	+	+	+	-	-	-	-
18	+	+	+	+	-	-	-	-
19	+	+	+	+	-	-	-	-
20	+	+	+	+	-	-	-	-
21	+	+	+	+	-	-	-	-
22	+	+	+	+	-	-	-	-
23	+	+	+	+	-	-	-	-
24	+	+	+	+	-	-	-	-
25	+	+	+	+	-	-	-	-

N	50 positive samples
	50 negative samples

RESULTS

		Biosystems		
		+	-	Total
Reference	+	50	0	50
	-	0	50	50
Total		50	50	100

		<i>95% confidence interval</i>			
Positive agreement	100 %	93	to	100	%
Negative agreement	100 %	93	to	100	%
Total agreement	100 %	96	to	100	%

CONCLUSIONS

The obtained result for **positive** agreement is: 100%

Positive agreement %

Which meets the acceptance criteria established for positive agreement at 95%

The obtained result for **negative** agreement is: 100%

Negative agreement %

Which meets the acceptance criteria established for negative agreement at 95%

The obtained result for **total** agreement is: 100%

Total agreement %

Which meets the acceptance criteria established for total agreement at 95%