

**Sansure TB and RFP assay data sheet**

Test Reagent Kit	Mycobacterium Tuberculosis and Rifampicin Resistance Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)
Abbr.	TB and RFP
Catalog Number	S3363E-12-P
Instruments	iPonatic III (S-Q36 A)
Technology	Real-time PCR (One-tube fast release technology)
Targets Region	TB (IS6110,IS1081), <i>rpoB</i> gene (5 probes)
Minimum Batch Size	1
Sample Type	Sputum
Sample Extraction	Intergrated and Fully-Automated
TAT	50 min
Internal Control	RNase P

**Sansure TB assay performance**

	Experiment	Control Reagent		Total
		Positive TB	Negative TB	
Test	Positive TB	60	1	61
Reagent	Negative TB	0	35	35
Total number		60	36	96

Positive coincidence rate (sensitivity): 100.0% (95% CI: (94.04% ~ 100.00%));

Negative coincidence rate (specificity): 97.22% (95% CI: (85.47% ~ 99.93%));

Overall coincidence rate: 98.96% (95% CI: (94.33% ~ 99.97%)).

**Sansure RFP\* assay performance**

	Experiment	Control Reagent		Total
		Positive RFP	Negative RFP	
Test	Positive RFP	21	1	22
Reagent	Negative RFP	0	74	74
Total number		21	75	96

\*RFP: Rifampicin Resistance TB

Positive coincidence rate (sensitivity) for RFP: 100.0% (95% CI:83.89%~100.00%);

Negative coincidence rate (specificity) for RFP: 98.67% (95% CI: 92.79% ~ 99.97%);

Overall coincidence rate for RFP: 98.96% (95% CI: 94.33% ~ 99.97%).

For *In Vitro* Diagnostic Use.