

TECHNICAL BULLETIN #1

CE Mark Validation Study

A performance evaluation was conducted over a 3 month period at two UK NHS acute hospitals. Data was collected from a broad range of patients within the catchment area of the two hospitals. The specification for sample collection time was more than 12 hr incubation in the automated blood culture cabinet.

Results were compared with the final result at 5 days from the automated blood culture system. The study data was reviewed and verified by the Chief Clinical Investigator for the study.

A total of 1497 sample sets were evaluated. Samples that failed to provide a reportable result due to failure of either the positive control, negative control or internal positive control were removed. The 1457 remaining sample results were further analysed.

The study data provides a negative predictive value (NPV) for the Cognitor® Minus test of 99.5% versus the result after 5 days incubation in the automated blood culture incubator.

		BLOOD CULTURE	
		NEGATIVE	POSITIVE
COGNITOR® MINUS	NEGATIVE	1291	7 ²
	NOT DETERMINED ¹	131 ³	28

1. The Cognitor® Minus test has been optimised to deliver a rapid negative result with a high negative predictive value for clinically relevant organisms. It does not report a POSITIVE result. Non-negative results are reported as NOT DETERMINED.

2. Six sample sets negative by the Cognitor® Minus test, and positive by blood culture were identified as contaminants following clinical review and were reclassified as true negatives.

3. 91 of the 131 sample sets reported above as "not determined" by the Cognitor® Minus test, and negative by automated blood culture after 5 days, were identified as likely clinical positives following clinical review.

The study data provides a negative predictive value (NPV) for the Cognitor® Minus test of 99.5% versus the result after 5 days incubation in the automated blood culture incubator.