

# QUALITY CERTIFICATE

**Product:** Cognitor® Minus Reagent Pack 1      **REF** P561  
**LOT** MBC B 138      2017-07-18

This Quality Certificate certifies that the **Cognitor® Minus** Reagent Pack shown above has been tested according to the Standard Operating Procedures of Momentum Bioscience for Quality Control and Product QC Release. The batch manufacturing record for this Lot has been reviewed and approved.

**Cognitor® Minus** Product QC Release Test results;

TEST	ACCEPTANCE CRITERIA (C <sub>t</sub> units - SmartCycler)		RESULTS
	TEST	IPC	
<i>Staphylococcus aureus</i> (ATCC® 25923) or <i>Staphylococcus epidermidis</i> (ATCC® 12228)	≤ 43.5	NA	<b>PASS</b>
<i>Escherichia coli</i> (ATCC® 25922)	≤ 43.5	NA	<b>PASS</b>
<i>Candida albicans</i> (ATCC® 10231)	≤ 43.5	NA	<b>PASS</b>
Negative Tests (unspiked)	> 43.5	≤ 44.0	<b>PASS</b>
Positive Control	≤ 40.0	NA	<b>PASS</b>
Negative Control	> 43.5	≤ 44.0	<b>PASS</b>

The Cognitor® Minus product release test was carried out on un-inoculated blood culture media supplemented with whole sheep’s blood and microbial suspensions diluted in blood culture media supplemented with whole sheep’s blood.

The product detailed in this Quality Certificate complies with all relevant requirements of European Directive 98/79/EC on in-vitro diagnostic medical devices, as transposed into UK law by Statutory Instrument 2002 No. 618

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\* Cognitor® is a trademark of Momentum Bioscience Ltd.  
 \* ATCC® is a trademark of the American Type Culture Collection.