

# Epi proColon<sup>®</sup> 2.0 CE Results Form

LIGHTCYCLER<sup>®</sup> 480 INSTRUMENT II  
Not for Use in the United States

This form is for use with Epi proColon 2.0 CE. Please refer to the Interpretation of Results Section of the Instructions for Use (IFU 0009) for guidance in evaluating the Real-Time PCR results for Positive and Negative Controls and Patient Results. Control validity and patient test results interpretation are based on triplicated PCR determinations.

Test Run: _____
Run Date: _____ Operator ID: _____

Positive Control							Negative Control						
Well No.	PCR Replicate	Detector	CP	Acceptable Results Criteria	QC Results		Well No.	PCR Replicate	Detector	CP	Acceptable Results Criteria	QC Results	
					Pass	Fail						Pass	Fail
	PCR1	ACTB		≤ 30.3 and NOT UD				PCR1	ACTB		≤ 37.1 and NOT UD		
		Septin9		≤ 40.5 and NOT UD					Septin9		Result is UD		
	PCR2	ACTB		≤ 30.3 and NOT UD				PCR2	ACTB		≤ 37.1 and NOT UD		
		Septin9		≤ 40.5 and NOT UD					Septin9		Result is UD		
	PCR3	ACTB		≤ 30.3 and NOT UD				PCR3	ACTB		≤ 37.1 and NOT UD		
		Septin9		≤ 40.5 and NOT UD					Septin9		Result is UD		

UD= No CP result, Undetermined

Quality Control Run is VALID. Continue with patient test results interpretation.  Control Run is INVALID: Do not interpret or report patient test results.

PATIENT ID: \_\_\_\_\_

Well No.	Determination No.	Detector	CP	Acceptable Results Criteria	Single PCR Result	Final Patient Result
	PCR1	ACTB		ACTB > 33.7 or ACTB = UD	<input type="checkbox"/> Invalid	<b>Positive:</b> At least 2 of 3 PCR replicates are positive  <b>Negative:</b> At least 2 of 3 PCR replicates are negative  <b>Invalid:</b> All other cases
		Septin9		ACTB ≤ 33.7 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR2	ACTB		ACTB > 33.7 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.7 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR3	ACTB		ACTB > 33.7 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.7 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	

Invalid  
 Positive  
 Negative

PATIENT ID: \_\_\_\_\_


Well No.	Determination No.	Detector	CP	Acceptable Results Criteria	Single PCR Result	Final Patient Result
	PCR1	ACTB		ACTB > 33.7 or ACTB = UD	<input type="checkbox"/> Invalid	<b>Positive:</b> At least 2 of 3 PCR replicates are positive  <b>Negative:</b> At least 2 of 3 PCR replicates are negative  <b>Invalid:</b> All other cases
		Septin9		ACTB ≤ 33.7 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR2	ACTB		ACTB > 33.7 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.7 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR3	ACTB		ACTB > 33.7 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.7 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	

Invalid  
 Positive  
 Negative

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Run Date: \_\_\_\_\_ Operator ID: \_\_\_\_\_

PATIENT ID: \_\_\_\_\_

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				ACTB ≤ 33.7 and Septin9 = UD	<input type="checkbox"/> Negative	

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