

Epi proColon[®] 2.0 CE Results Form

LIGHTCYCLER[®] 480 INSTRUMENT I
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 Pass ✓	QC Results Fail ✓	Well No.	PCR Replicate	Detector	CP	Acceptable Results Criteria	QC Results Pass ✓	QC Results Fail ✓
	PCR1	ACTB		≤ 29.5 and NOT UD				PCR1	ACTB		≤ 36.5 and NOT UD		
		Septin9		≤ 40.6 and NOT UD					Septin9		Result is UD		
	PCR2	ACTB		≤ 29.5 and NOT UD				PCR2	ACTB		≤ 36.5 and NOT UD		
		Septin9		≤ 40.6 and NOT UD					Septin9		Result is UD		
	PCR3	ACTB		≤ 29.5 and NOT UD				PCR3	ACTB		≤ 36.5 and NOT UD		
		Septin9		≤ 40.6 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 > 33.1 or ACTB = UD	<input type="checkbox"/> Invalid	Positive: At least 2 of 3 PCR replicates are positive Negative: At least 2 of 3 PCR replicates are negative Invalid: All other cases <input type="checkbox"/> Invalid <input type="checkbox"/> Positive <input type="checkbox"/> Negative
		Septin9		ACTB ≤ 33.1 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.1 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR2	ACTB		ACTB > 33.1 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.1 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.1 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR3	ACTB		ACTB > 33.1 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.1 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.1 and Septin9 = UD	<input type="checkbox"/> Negative	

PATIENT ID: _____

Well No.	PCR Replicate	Detector	CP	Acceptable Results Criteria	Single PCR Result	Final Patient Result
	PCR1	ACTB		ACTB > 33.1 or ACTB = UD	<input type="checkbox"/> Invalid	Positive: At least 2 of 3 PCR replicates are positive Negative: At least 2 of 3 PCR replicates are negative Invalid: All other cases <input type="checkbox"/> Invalid <input type="checkbox"/> Positive <input type="checkbox"/> Negative
		Septin9		ACTB ≤ 33.1 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.1 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR2	ACTB		ACTB > 33.1 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.1 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.1 and Septin9 = UD	<input type="checkbox"/> Negative	
	PCR3	ACTB		ACTB > 33.1 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin9		ACTB ≤ 33.1 and Septin9 < 50	<input type="checkbox"/> Positive	
		Septin9		ACTB ≤ 33.1 and Septin9 = UD	<input type="checkbox"/> Negative	

epigenomics

Epigenomics AG
Genestr.5
10829 Berlin, Germany
+49 30 24345 222
+49 30 24345 555
support@products.epigenomics.com
www.epigenomics.com

Epigenomics, Inc. USA
844 537 4669 (844 5 EPI NOW)
+1 240 747 7002
+1 240 747 7052
support.us@epigenomics.com
www.epigenomics.com

International Distributors
www.epiprocolon.com



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PATIENT ID: _____

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Epigenomics AG
Geneststr.5
10829 Berlin, Germany
+49 30 24345 222
+49 30 24345 555
support@products.epigenomics.com
www.epigenomics.com

Epigenomics, Inc. USA
844 537 4669 (844 5 EPI NOW)
+1 240 747 7002
+1 240 747 7052
support.us@epigenomics.com
www.epigenomics.com

 International Distributors
www.epiprocolon.com

