

IFU 0010 Epi proColon[®] Results Form

APPLIED BIOSYSTEMS 7500 FAST DX

This form is for use with the Epi proColon test. Please refer to the *Interpretation of Results* section of the Instructions for Use (IFU 0008) 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	Ct	Acceptable Results Criteria	QC Results		Well No.	PCR Replicate	Detector	Ct	Acceptable Results Criteria	QC Results	
					Pass ✓	Fail ✓						Pass ✓	Fail ✓
	PCR1	ACTB		≤ 29.8 and NOT UD				PCR1	ACTB		≤ 37.2 and NOT UD		
		Septin 9		≤ 41.1 and NOT UD					Septin 9		Result is UD		
	PCR2	ACTB		≤ 29.8 and NOT UD				PCR2	ACTB		≤ 37.2 and NOT UD		
		Septin 9		≤ 41.1 and NOT UD					Septin 9		Result is UD		
	PCR3	ACTB		≤ 29.8 and NOT UD				PCR3	ACTB		≤ 37.2 and NOT UD		
		Septin 9		≤ 41.1 and NOT UD					Septin 9		Result is UD		

UD= No Ct 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.	PCR Replicate	Detector	Ct	Acceptable Results Criteria	Single PCR Result	Final Patient Result
	PCR1	ACTB		ACTB > 32.1 or ACTB = UD	<input type="checkbox"/> Invalid	Positive: At least 1 of 3 PCR replicates are positive Negative: All 3 PCR replicates are negative Invalid: All other cases <input type="checkbox"/> Invalid <input type="checkbox"/> Positive <input type="checkbox"/> Negative
		Septin 9		ACTB ≤ 32.1 and Septin 9 < 45	<input type="checkbox"/> Positive	
		Septin 9		ACTB ≤ 32.1 and Septin 9 = UD	<input type="checkbox"/> Negative	
	PCR2	ACTB		ACTB > 32.1 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin 9		ACTB ≤ 32.1 and Septin 9 < 45	<input type="checkbox"/> Positive	
		Septin 9		ACTB ≤ 32.1 and Septin 9 = UD	<input type="checkbox"/> Negative	
	PCR3	ACTB		ACTB > 32.1 or ACTB = UD	<input type="checkbox"/> Invalid	
		Septin 9		ACTB ≤ 32.1 and Septin 9 < 45	<input type="checkbox"/> Positive	
		Septin 9		ACTB ≤ 32.1 and Septin 9 = UD	<input type="checkbox"/> Negative	

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Detecting Cancer In Blood.

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