

Example 3.



Flexicult Test

CRF 04

Today's Date

01 / 05 / 2013
d d m m y y y y

Patient ID

13001

Site ID

01

Patient's Initials

NK

Patient's Date of Birth

03 / 07 / 1985
d d m m y y y y

Please check the expiry date of the Flexicult Test
DO NOT USE IF THE TEST HAS EXPIRED

30 / 05 / 2013
d d m m y y y y

Date Inoculated

01 / 05 / 2013
d d m m y y y y

Please use 24 hour
clock eg 17:15

Time Inoculated

16 : 00
h h m m

Please read within 24
hours of this time

The following section is to be completed 24 hours after the plate has been inoculated

Date Test Read

01 / 05 / 2013
d d m m y y y y

Please use 24 hour
clock eg 17:15

Time Test Read

11 : 00
h h m m

1. Has a photo been taken? Yes No

See photography SOP in POETIC study manual

2. Is there bacterial growth (colonies) in the large control section ? (Tick One)

- No Growth - If there is no growth please go to question 5
- Pure growth (single type of bacteria) - If there is pure growth go to question 3
- Mixed Growth (multiple types of bacteria) - If there is mixed growth please answer the question below

If there is **Mixed Growth** Is there one predominant type of bacteria?
(present in a quantity 10 times higher than the other bacteria)

- Yes - please go to question 3
- No - please go to question 4



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3. Please indicate the growth, the colour, the identification and the antibiotic resistance of the (Pure or Predominant) bacteria;

Growth in control (large) compartment (tick one) <input type="checkbox"/> Less than 15 colonies <input type="checkbox"/> 15-20 colonies(= less than 10 ³ cfu/mL) <input type="checkbox"/> More than 20 colonies(= 10 ³ to less than 10 ⁵ cfu/mL) <input checked="" type="checkbox"/> Semi confluent/ confluent growth (= (greater than or equal to 10 ⁵ cfu/mL)	Colour of (pure or predominant) bacteria only Red
	Name of Predominant bacteria <input checked="" type="checkbox"/> E. coli <input type="checkbox"/> Klebsiella / Enterobacter <input type="checkbox"/> Proteus spp/ Proteus vulgaris <input type="checkbox"/> Enterococcus <input type="checkbox"/> Staphylococcus saprophyticus <input type="checkbox"/> Candida <input type="checkbox"/> Pseudomonas aeruginosa <input type="checkbox"/> Normal Flora / Contaminants <input type="checkbox"/> Not Sure

In the following table only Complete the antibiotic resistance profile if there are more than 20 colonies (10³ cfu/mL) in the large compartment.

The colonies in the antibiotic compartments should be compared to the colonies in the large control compartment.

If the number of colonies in the antibiotic compartment is much lower (or no colonies) that in the control compartment then this should be recorded as sensitive to that antibiotic.

If the number of colonies in the antibiotic compartment is similar to that in the control compartment then this should be recorded as resistant to that antibiotic

Section	Antibiotic	Sensitive	Resistant	Unsure
1	Cephalothin	✓		
2	Ciprofloxacin	✓		
3	Amoxicillin / Clavulanate	✓		
4	Nitrofurantoin	✓		
5	Trimethoprim	✓		

4 Complete only for Mixed Growth with NO Predominant Bacteria

- a. How many types of bacteria are present? 2 3 4 unable to determine
- b. Are there more than 20 colonies present in the control section in total Yes No



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Management

5. a. If the Flexicult was invalid, void or the test showed mixed growth (i.e with no predominant bacteria) did you request routine urine test Yes No N/A
- b. After reading the Flexicult Test did you contact the patient? Yes No
- c. Did you change your patients management in response to the Flexicult test Yes No

6. What advice did you give about antibiotic treatment?

No Antibiotic needed / Do not start taking antibiotics

Stop taking current antibiotic

Start taking antibiotic prescribed at baseline visit

New Antibiotic prescribed (please list below)

Name of Antibiotic	Dose	Times Per Day	Duration (Days)
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>

7. Did you give the patient any other advice following the result of the Flexicult Test?

No.