



The Royal College of Pathologists  
Pathology: the science behind the cure

## **OSPE EXAMPLES**

OSPE [15 stations, 9 minutes each, 135 minutes in total)

Fifteen compulsory questions, typically 9 minutes per question

Few example questions are listed below

## OSPE 1

Below are 5 different scenarios of pregnant women who have confirmed hepatitis B virus infection (HBsAg is positive at booking and confirmed with a second sample). HBV DNA and ALT were measured at 28 weeks.

All babies were set to receive HBV vaccine at birth.

Please fill in the empty boxes with a **Yes** or **No** answer regarding additional measures you would recommend to prevent vertical transmission to the babies.

[10 marks]

Question number		Pregnant 1 (2 marks)	Pregnant 2 (2 marks)	Pregnant 3 (2 marks)	Pregnant 4 (2 marks)	Pregnant 5 (2 marks)
	<b>HBsAg</b>	Positive	Positive	Positive	Positive	Positive
	<b>HB core IgM</b>	Negative	Negative	Negative	Positive [acute HBV in pregnancy]	Negative
	<b>HBeAg</b>	Positive	Negative	Negative	Positive	Negative
	<b>Hepatitis B e antibody</b>	Negative	Positive	Positive	Negative	Negative
	<b>HBV DNA in IU/mL at 28 weeks gestation</b>	1,000,000	13,000	350,000	10,000	150,000
	<b>ALT in U/l at 28 weeks of gestation</b>	17	25	39	17	62
<b>1a [5 marks]</b>	<b>Tenofovir for mother in 3rd trimester</b>					
<b>1b [5 marks]</b>	<b>Baby to have HBIG at birth</b>					

## OSPE 2

You have been asked to write a business case for setting up rapid near-patient testing [NPT] by molecular methods for respiratory viral infections in the Emergency Department and its associated Clinical Decision unit (for patients considering possible admission) in your hospital Trust.

**2a** What is a Point of Care Testing? [1.5 mark]

**2b** Which ISO regulation will Near Patient Testing fall under [since December 2022]? [1 mark]

**2c** Name 4 precise viral RNA/DNA targets that could be in a NPT limited molecular respiratory viral panel? [2 marks]

1

2

3

4

**2d** Name two commercial companies that manufacture these limited RNA panels? [1 mark]

1

2

**2e** Name 4 advantages of limited panels in an Emergency Department? [2 marks]

1

2

3

4

**2f** Name three disadvantages of limited panels in an Emergency Department? [1.5 marks]

1

2

3

**2g** Name two commercial assays that can provide rapid expanded panel for respiratory viruses in and Emergency Department setting [1 mark]

1

2

### OSPE 3

A new point of care molecular assay for RSV was evaluated against a well-established in-house molecular assay.

A total of 2,435 nasopharyngeal swab samples were part of the evaluation; these included 174 samples which were in-house assay RSV positive and 2261 samples which were in-house assay RSV negative.

A total of 165 positive samples concurred as RSV positive in both assays and 2,256 negative samples concurred as negative.

**3a** Fill the table below with figures based on the paragraph above. [6 marks]

		In house molecular RSV RNA assay		Total
		Positive	Negative	
New POCT for RSV	Positive			
	Negative			
Total		174	2,261	2,435

**3b** Calculate the specificity, sensitivity, positive predictive value and negative predictive value of the point-of-care molecular assay for detection of RSV [4 marks]

Sensitivity

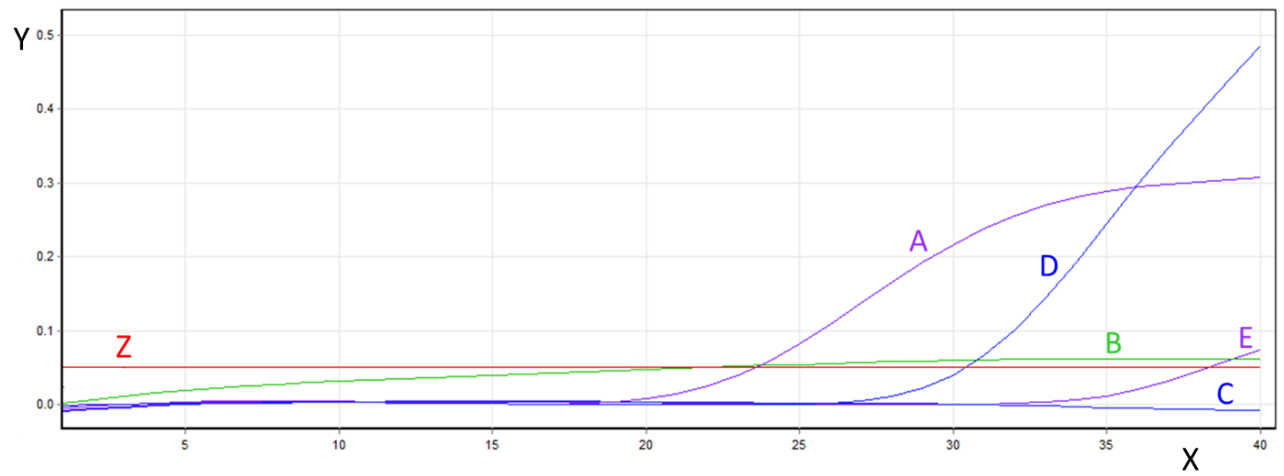
Specificity

PPV

NPV

## OSPE 4

This is the amplification plot of a real-time measles virus RNA PCR run



**4a** Label the X axis of this chart [1 mark]

**4b** Label the Y axis of this chart [1 mark]

**4c** What is the red line marked Z? [1 mark]

**4d** What is the effect of moving Line Z upward? [2 mark]

**4e** Please assess the results for samples A, B, D and E, with your reasoning [2 marks]

1. Sample A:

2. Sample B:

3. Sample D:

4. Sample E:

**4f** It was revealed that sample A was the positive control and sample E was the negative control [please do not change your answers for 4a to 4e].

Sample B, C and D were throat swab samples taken from patients with suspected measles.

What is your opinion of this run? [2 marks]

**4g** Which throat sample result can be released safely? [1 mark]

## OSPE 5

A 56-year-old man presented with progressive renal insufficiency. He had received a cadaveric renal transplant 6 months ago for chronic renal failure secondary to hypertension and diabetes mellitus.

CMV IgG status was D- / R-. He was on prednisolone, tacrolimus and mycophenolate mofetil. Progressive deterioration in allograft function was noted .

**5a** Name two most likely differential diagnoses for the possible deterioration in renal function. [2 marks]

**5b** An allograft biopsy was performed (H&E stain):

[Candidates will see H&E stained colour image](#)

Describe the features shown in the H&E stain biopsy. [2 marks]

**5c** Name the virus most likely responsible for the feature shown in the H&E stain slide and name 3 other possible virological causes [2 marks]

**5d** Further immune-histochemical staining was performed:

[Candidates will see immunohistochemical colour image](#)

In this immunostained slide, what monoclonal antibody is most commonly used to confirm the main diagnosis? What is its limitation? [1 mark]

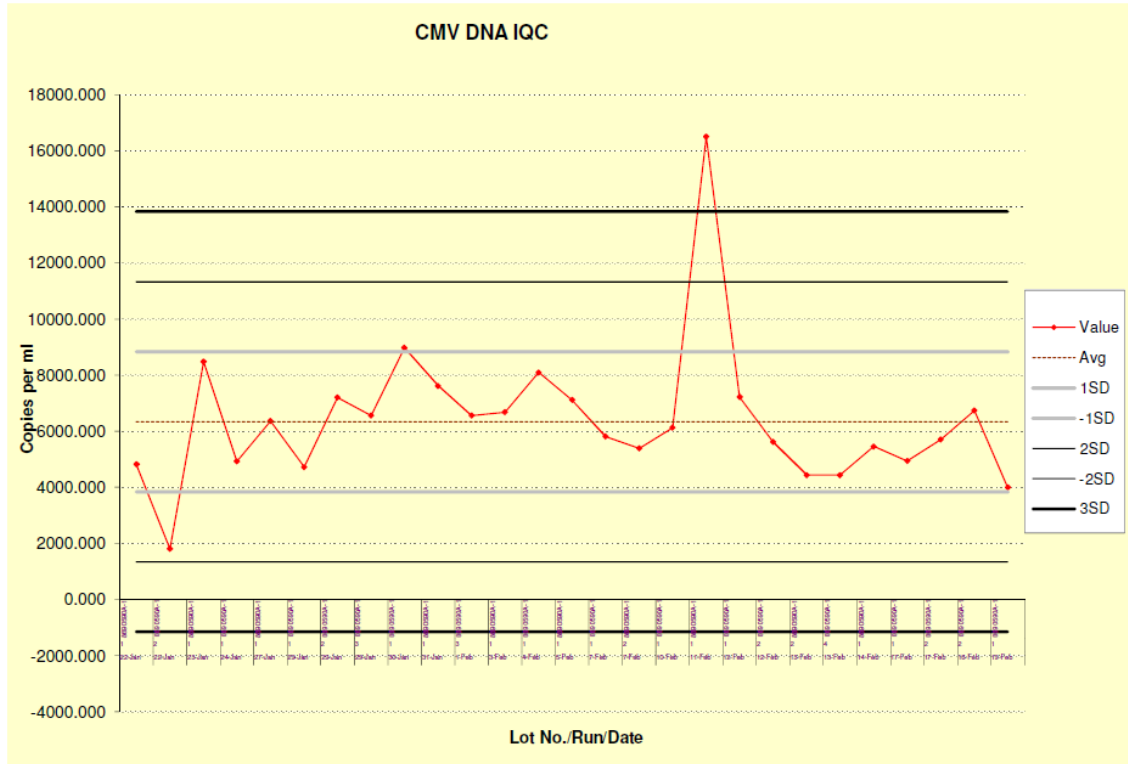
**5e** What is the most appropriate immediate management to decrease the effects of this virus? [0.5 mark]

**5f** List the key features of a post-transplant policy aimed at preventing loss of graft due to this virus infection [2.5 marks]



## OSPE 6

This is an Internal Quality Control chart for positive standard within a quantitative CMV DNA assay.



6a What is the name of this type of chart?

[1 mark]

6b Which Westgard rule was violated in the course of this chart?

[2 marks]

6c What actions need to be taken on discovery of this violation?

[2 marks]

6d Name two other mandatory Westgard rules.

[4 marks]

6e If the internal quality control is 3 SD below the mean on 4 consecutive days, what would you recommend?

[1 mark]

	<b>DONOR STATUS</b>	<b>Clinical situation</b>	<b>Question</b>	<b>Answer</b>
<b>7a</b>	Candidates will see a virus IgG Positive [2 marks]	Sperm donor	Is this donation permitted?  State any precautions.	
<b>7b</b>	Candidates will see a virus marker Positive [1 mark]	HBV cirrhosis recipient	Is liver donation permitted?	
<b>7c</b>	Candidates will see a virus RNA Positive [3 marks]	Sperm donation to wife	Is this donation permitted?  State any precautions.	
<b>7d</b>	Candidates will see a virus DNA Positive [4 marks]	Kidney donation	Is this donation permitted?  State any precautions.	

**OSPE 8**

**8a** For the following five hepatitis E virus laboratory scenarios, please state the most likely interpretation of the laboratory results: **(5 marks)**

<b>Laboratory scenarios</b>					
	<b>HEV IgM</b>	<b>HEV IgG</b>	<b>Plasma HEV RNA</b>	<b>Faeces HEV RNA</b>	<b>“What is the most likely interpretation?”</b>
Scenario 1 [1 mark]	Positive	Negative	Positive 100,000,000 IU/mL	Negative	
Scenario 2 [1 mark]	Negative	Negative	Positive 100,000,000 IU/mL	Negative	
Scenario 3 [1 mark]	Negative	Positive	Positive 100,000,000 IU/mL	Positive	
Scenario 4 [1 mark]	Negative	Negative	Positive 100,000,000 IU/mL for 4 months	Positive	
Scenario 5 [1 mark]	Negative	Positive	100 IU/mL	Negative	

**8b** For the following four clinical hepatitis E virus infection scenarios, please state your management options: **[5 marks]**

<b>Clinical scenarios (marks 8)</b>		<b>What would be your management options?</b>
Scenario 6 [1 mark]	An uncomplicated acute HEV infection in the immunocompetent	
Scenario 7 [1 mark]	First therapeutic step in management of chronic HEV infection in liver transplant recipient	
Scenario 8 [1 mark]	Specific antiviral treatment following unsuccessful Scenario 7 option	
Scenario 9 [2 marks]	What other therapeutic options are there if the treatment in scenario 8 fails?	

## OSPE 9

**9a** Name the virus family shown in 9A [1 mark]

Candidates will see a black and white electron micrograph with scale

**9b** Name 6 body organs or systems that typically could be infected with virus 9A and name one illness for that organ or system [3 marks]

1

2

3

4

5

6

**9c** Describe the morphology of the virus shown here [1 mark]

Candidates will see a black and white electron micrograph with scale

**9d** Which human virus typically shows this morphology in electron micrograph? [1 mark]

**9e** Which virus family typically shows this morphology? [1 mark]

Candidates will see a black and white electron micrograph with scale

**9f** What type of nucleic acid genome does this virus possess? [1 mark]

**9g** Which virus family typically shows this morphology? [1 mark]

Candidates will see a black and white electron micrograph with scale

**9h** Describe the morphology of virus here [1 mark]

## OSPE 10

These questions are on cytomegalovirus (CMV) infection and its management.

**10a** Name two risk factors for clinically significant congenital CMV [2 marks]

1

2

**10b** When is symptomatic congenital CMV likely to present clinically? [1 mark]

**10c** Name 6 common manifestations of symptomatic congenital CMV [6 marks]

1

2

3

4

5

6

**10d** Name antiviral options [1 mark]

1

2

## OSPE 11

You have been called by one of the infection control nurses regarding a perceived increase in incidence of diarrhoea on the paediatric primary immunodeficiency and bone marrow transplant ward. The ward consists of 8 positive pressure cubicles with airlocks. All patients are significantly immunosuppressed.

Five of the patients and 1 staff member are currently reported to have diarrhoea. Faeces samples are received and tested using a multiplex PCR covering norovirus, sapovirus, astrovirus, rotavirus and adenovirus.

<b>Patients</b>	<b>Age</b>	<b>Duration of diarrhoea</b>	<b>Viral gastrointestinal panel results</b>
<b>Patient 1</b>	1 week	Since birth	Negative
<b>Patient 2</b>	2 months	> 4 weeks	Candidates will see a viral RNA Positive
<b>Patient 3</b>	3 months	No diarrhoea	Candidates will see a viral RNA Positive
<b>Patient 4</b>	7 months	No diarrhoea	Negative
<b>Patient 5</b>	12 months	4 weeks	Negative
<b>Patient 6</b>	2 years	3 days ago	Candidates will see a viral RNA Positive
<b>Patient 7</b>	4 years	No diarrhoea	Candidates will see a viral DNA Positive
<b>Patient 8</b>	9 years	4 weeks	Candidates will see a viral RNA Positive
<b>Staff member</b>	Adult	Diarrhoea and vomiting (recent onset)	Negative

**11a** Assess the significance of the results for Patient 3. What further diagnostic testing would you consider for this patient? (3 marks)

Assessment:

Further tests:

**11b** Assess the significance of the results for Patient 7. What further diagnostic testing would you consider for this patient? (2.5 marks)

Assessment [1 mark]

Further tests [1.5 marks]:

**11c** Comment on the likelihood that these results reflect a virus outbreak on the ward and how this might be further investigated. [4.5 marks]



## OSPE 12

The following safety signs may be found in a diagnostic laboratory. What do they indicate?

Please fill this table with your answers

[10 marks]

Safety signs	What do they indicate? (1 mark each)
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
Candidates will see a Health and Safety relevant image seen in health care setting, including laboratory.	
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## OSPE 13

As a newly appointed Consultant Virologist, you have been asked to support validation and verification of a quantitative JCV DNA assay.

**13a** How would you define the term validation? [1 mark]

**13b** How would you define verification? [1 mark]

**13c** It is anticipated that you perform some testing using the new method and compare these results against an established standard test.

Please list at least 4 controls for your validation [2 marks]

1

2

3

4

**13e** List 4 potential sources [including commercial sources] for your list in Question 13c [2 marks]

1

2

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4

**13d** List 8 assay performance characteristics you should consider during this verification and/or validation of diagnostic methods? [4 marks]

1

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5

6

7

8

## OSPE 14

Name the antigenic component or specific viral strain within these viral vaccines and the manufacturing process.

Please fill this table with your answers

Vaccine name	Antigenic component or specific viral strain [1 mark each]	Manufacturing process
<b>14a</b> Candidates will see name of a viral vaccine  [1+2 =3 marks]		
<b>14b</b> Candidates will see name of a viral vaccine  [1+1 =2 marks]		
<b>14c</b> Candidates will see name of a viral vaccine [1+2 =3 marks]		
<b>14d</b> Candidates will see name of a viral vaccine [1+1 =2 marks]		

**OSPE 15**

Name one human clinical association, if known, for these viruses. If not known, specify as “not known”. Please fill this table with your answers [10 marks]

<b>Question number</b>	<b>Virus</b>	<b>Association with human disease (1 mark each)</b>
<b>15a</b>	Candidates will see name of a virus	
<b>15b</b>	Candidates will see name of a virus	
<b>15c</b>	Candidates will see name of a virus	
<b>15d</b>	Candidates will see name of a virus	
<b>15e</b>	Candidates will see name of a virus	
<b>15f</b>	Candidates will see name of a virus	
<b>15g</b>	Candidates will see name of a virus	
<b>15h</b>	Candidates will see name of a virus	
<b>15i</b>	Candidates will see name of a virus	
<b>15j</b>	Candidates will see name of a virus	



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**Complex Case Scenarios (3 scenarios, 30 minutes each, total duration of 120 minutes)**

**CCS 1**

**15 minutes is provided for Scenarios 1 to 4 [Questions 1.1 to 1.4]**

While on clinical duty you are telephoned for advice on the management of several antenatal patients.

Please read the telephone enquiries detailed in the 4 scenarios below and document your advice in the space provided, including any clinical advice and any recommendations for further investigation.

Scenario 1

An obstetric registrar calls regarding a 32-year-old pregnant woman attending for a 36-week scan.

She reports onset of a painful genital ulcer 3 days ago. She has no previous history of genital ulceration. Her male partner also reports first episode of new multiple genital ulcers.

**1.1** Write 5 points of advice that you will give (10 marks).

1

2

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**Scenario 2**

A community midwife calls having been telephoned by a 25-week pregnant woman of Indian origin, whose 3-year-old son just developed a vesicular rash with fever, which the GP has diagnosed as likely chickenpox.

The mother thinks she may have had chickenpox twice in her childhood in India.

**1.2** What immediate steps would you undertake? (4 marks).

**Scenario 3**

A GP calls for advice regarding a 14-week pregnant primary school teacher presenting with acute symmetrical arthritis affecting both hands and wrists. She reports having had a 2-day history of fine rash but this is no longer visible.

There have been reports of several children absent from school due to rash illness.

**1.3** What two viral infections would you be most concerned about, and how would you investigate for them? [6 marks]

**Scenario 4**

A biomedical scientist asks you to call the obstetrician with results of CMV serology for a pregnant woman whose fetus has been found to have polyhydramnios on a 20-week ultrasound scan.

A current blood sample

CMV IgM	Positive
CMV IgG	Positive

An antenatal booking serum at 12-weeks of gestation

CMV IgM	Positive
CMV IgG	Positive
CMV IgG avidity	Low

**1.4** What is your result interpretation, risk assessment for pregnancy outcome and immediate plan (10 marks)

**NO GOING BACK TO QUESTIONS 1.1 to 1.4**



**15 minutes is provided for Scenarios 5 to 8 [Questions 1.5 to 1.8]**

Please document your final interpretation and any further advice in the space provided for Scenarios 5 to 8 (which are extensions of scenarios 1 to 4)

**Scenario 5 [is an extension of Scenario 1]**

An obstetric registrar calls regarding a 32-year-old pregnant woman attending for a 36-week scan.

She reports onset of a painful genital ulcer 3 days ago. She has no previous history of genital ulceration. Her male partner also reports first episode of new multiple genital ulcers.

**Investigations**

Antenatal booking blood at gestation at 12-weeks' gestation:

HSV type 1 IgG	Positive
HSV type 2 IgG	Negative

Pregnant lady's genital swab at 36-weeks of gestation:

HSV type 1 DNA	Negative
HSV type 2 DNA	Positive

Current blood sample:

HSV type 1 IgG	Positive
HSV type 2 IgG	Positive

HIV 1&2 antibody/HIV-1 p24 antigen	Negative
Hepatitis B surface antigen	Negative
Treponemal total antibody	Negative

Genital ulcer swab:

C. trachomatis DNA	Negative
N. gonorrhoeae DNA	Negative

**1.5** What is your interpretation and what advice will you give regarding HSV? (12 marks)

**Scenario 6 [is an extension of Scenario 2]**

A community midwife calls having been telephoned by a 25-week pregnant woman of Indian origin, whose 3-year-old son just developed a vesicular rash with fever, which the GP has diagnosed as likely chickenpox.

The mother thinks she may have had chickenpox twice in her childhood in India.

Stored antenatal serum

Varicella zoster virus IgG

6 mIU/mL

**1.6** What is your result interpretation, risk assessment of the contact and recommendations regarding prophylaxis? [8 marks]

**Scenario 7 [is an extension of Scenario 3]**

A GP calls for advice regarding a 14-week pregnant primary school teacher presenting with acute symmetrical arthritis affecting both hands and wrists. She reports having had a 2-day history of fine rash but this is no longer visible.

There have been reports of several children absent from school due to rash illness.

Investigations on a current serum:

Parvovirus IgG	Positive
Parvovirus IgM	Positive
Rubella virus IgG	Positive
Rubella virus IgM	Negative

Investigations on an antenatal booking serum at 12 weeks' gestation:

Parvovirus IgG	Negative
Parvovirus IgM	Negative
Rubella virus IgG	Positive
Rubella virus IgM	Negative

**1.7** What is your result interpretation, and what advice would you give regarding risk to the fetus?

What should be done to mitigate any risk to the fetus?

[6 marks]

Scenario 8 [is an extension of Scenario 4]

A biomedical scientist asks you to call the obstetrician with results of CMV serology for a pregnant woman whose fetus has been found to have polyhydramnios on a 20- week ultrasound scan.

A current blood sample investigations are

CMV IgM	Positive
CMV IgG	Positive

An antenatal booking serum at 12 weeks' gestation

CMV IgM	Positive
CMV IgG	Positive
CMV IgG avidity	Low

Amniotic fluid at 21 weeks of gestation

CMV DNA	Negative (limit of detection 10 IU/mL)
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**1.8** Interpret this profile and what further advice would you give assuming the pregnancy will continue to term and live birth.

Include CMV-specific investigation[s] at birth

[4 marks]

**CCS 2**

A number of HIV serology results are on the authorization queue for your action. Please review these results and report them with appropriate comments. Indicate if this is a final report or interim (include verbal report to requester if you are not ready to issue any report yet). Also indicate if you are waiting for further tests on the sample and the nature of these further tests **(Time allowed for 2.1 -2.5 = 15 min).**

Tests	Cut-off for Immunoassay reactivity	Sample A	Sample B	Sample C	Sample D	Sample E [tested twice in the lab including serum-on-clot]
<b>Immunoassay 1 (4<sup>th</sup> generation HIV 1/2 antibody + p24 antigen)</b>	≥ 1.00	801.75	11.04	777.01	314.05	125.43
<b>Immunoassay 2 (4<sup>th</sup> generation HIV 1/2 antibody + p24 antigen)</b>	> 0.25	24.27	0.09	28.90	25.02	0.12
<b>Immunoblot for HIV 1/2 antibodies</b>	gp36: gp140: p31: gp160: p24: gp41:  control band:	- - + + + +  +	- - - - - -  +	+ + + + + +  +	- - - - - -  +	- - - +/- - +/-  +

**2.1 Sample A (6 marks)**

Report status Final or Interim [1 mark]	
<b>HIV 1/2 antibody + p24 antigen</b> [1 mark]	
Further comments 4 marks	

**2.2 Sample B (6 marks)**

Report status Final or Interim [1 mark if justified]	
<b>HIV 1/2 antibody + p24 antigen</b> [1 mark]	
Further comments	

**2.3 Sample C (10 marks)**

Report status Final or Interim [1 mark]	
<b>HIV 1/2 antibody + p24 antigen</b> [1 mark]	
Further comments  [8 marks]	

**2.4 Sample D (7 marks)**

Report status Final or Interim [1 mark]	
<b>HIV 1/2 antibody + p24 antigen</b> [1 mark]	
Further comments  [5 marks]	

**2.5 Sample E (10 marks)**

Report status Final or Interim [1 mark]	
<b>HIV 1/2 antibody + p24 antigen</b> [1 mark]	
Further comments  [8 marks]	

**Please submit your answer before proceeding to the next section of this question**

Further tests are performed on samples B, C, D and E.

**(Time allowed for 2.6-2.10 = 15 min)**

Tests	Cut-off for Immunoassay reactivity	Sample B	Sample C	Sample D	Sample E [tested twice in the lab including serum-on-clot]
<b>Immunoassay 1 (4<sup>th</sup> generation HIV 1/2 antibody + p24 antigen)</b>	≥ 1.00	11.04	777.01	314.05	125.43
<b>Immunoassay 2 (4<sup>th</sup> generation HIV 1/2 antibody + p24 antigen)</b>	> 0.25	0.09	28.90	25.02	0.12
<b>Immunoblot for HIV 1/2 antibodies</b>	gp36: gp140: p31: gp160: p24: gp41:  control band:	- - - - - -  +	+ + + + + +  +	- - - - - -  +	- - - +/- - +/-  +
<b>HIV-1 p24 antigen</b>	≥ 1.0	0.01	Not tested	>400 [neutralised]	0.15
<b>HIV-1 RNA</b>	Detection limit 20 copies/mL	Not tested	1,008 copies/mL	6,154,746 copies/mL	< 20 copies/mL
<b>HIV-2 RNA</b>	Detection limit 400 copies/mL	Not tested	< 400 copies/mL	Not tested	< 400 copies/mL

**2.6** Provide a final report for Sample B with appropriate comments. Indicate if further investigations are required. (6 marks)

**2.7** Provide a final report for Sample C with appropriate comments. Indicate if further investigations are required. (7 marks)



**2.8** Provide a final report for Sample D with appropriate comments. Indicate if further investigations are required. (6 marks)

**2.9** Suggest 3 possible explanations for the HIV reactivity pattern of Sample E? (3 mark)

**(Time allowed for 3.1 to 3.4 = 7 minutes)**

You are provided with the following data for a quantitative CMV DNA assay run by your trainee biomedical scientist.

Standard curve for the run:

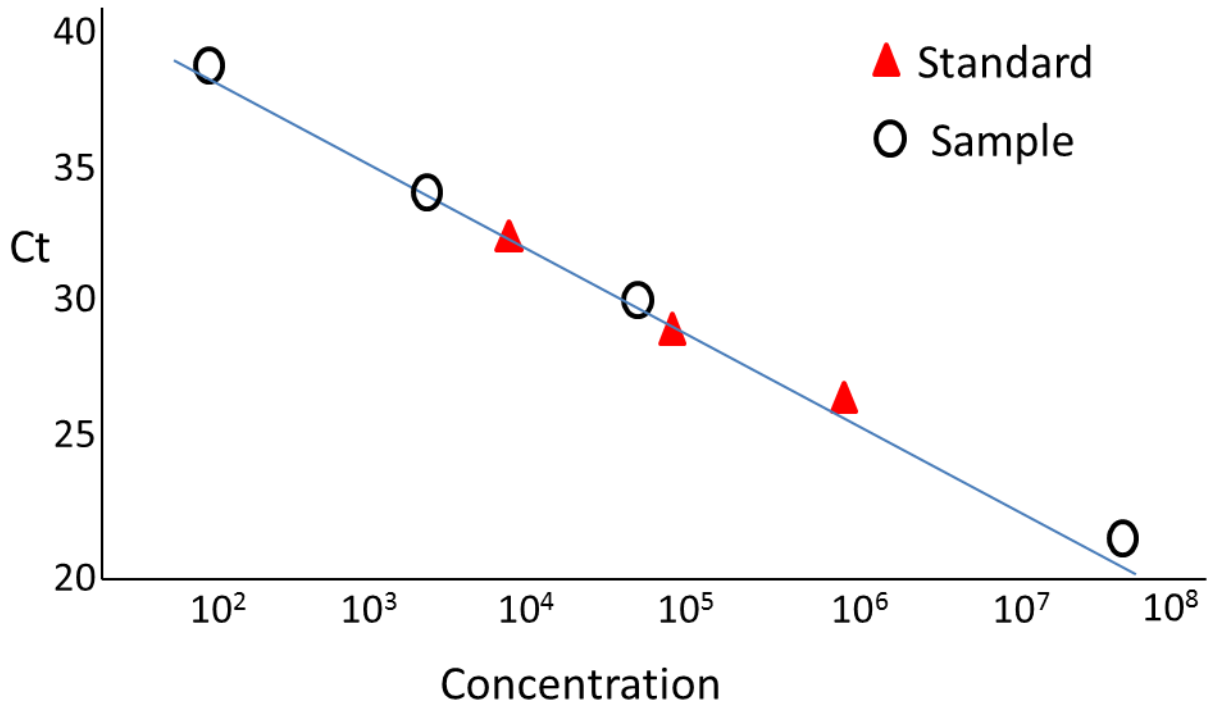


Table showing the Ct values of the standards and samples and the calculated CMV DNA (No Ct value means no amplification):

Standard / sample	Ct value	Expected CMV DNA concentration (IU/mL)	Calculated CMV DNA concentration (IU /mL) based on standard curve
$10^6$ standard	26.5	1000000	987000
$10^5$ standard	29.3	100000	97500
$10^4$ standard	33.0	10000	10400
$10^3$ standard		1000	0
Sample 1	21.4		86000000
Sample 2			0
Sample 3	39.0		101
Sample 4	34.0		5045
Sample 5	29.8		84300
Sample 6			0

**3.1** What are the problems with this PCR run? Specify missing items (6 marks)

**3.2** Would you accept this standard curve? Please explain why? (3 marks)

**3.3** Can any of the results be reported? Please explain. (2 marks)

**3.4** What do you recommend your lab staff to do next? (3 marks)

**Please submit your answers before you proceed to the next question**

**(Time allowed for 3.4 to 3.11 = 14 min)**

The whole PCR run was repeated with a new set of standard and appropriate controls.  
Standard curve for the repeat run:

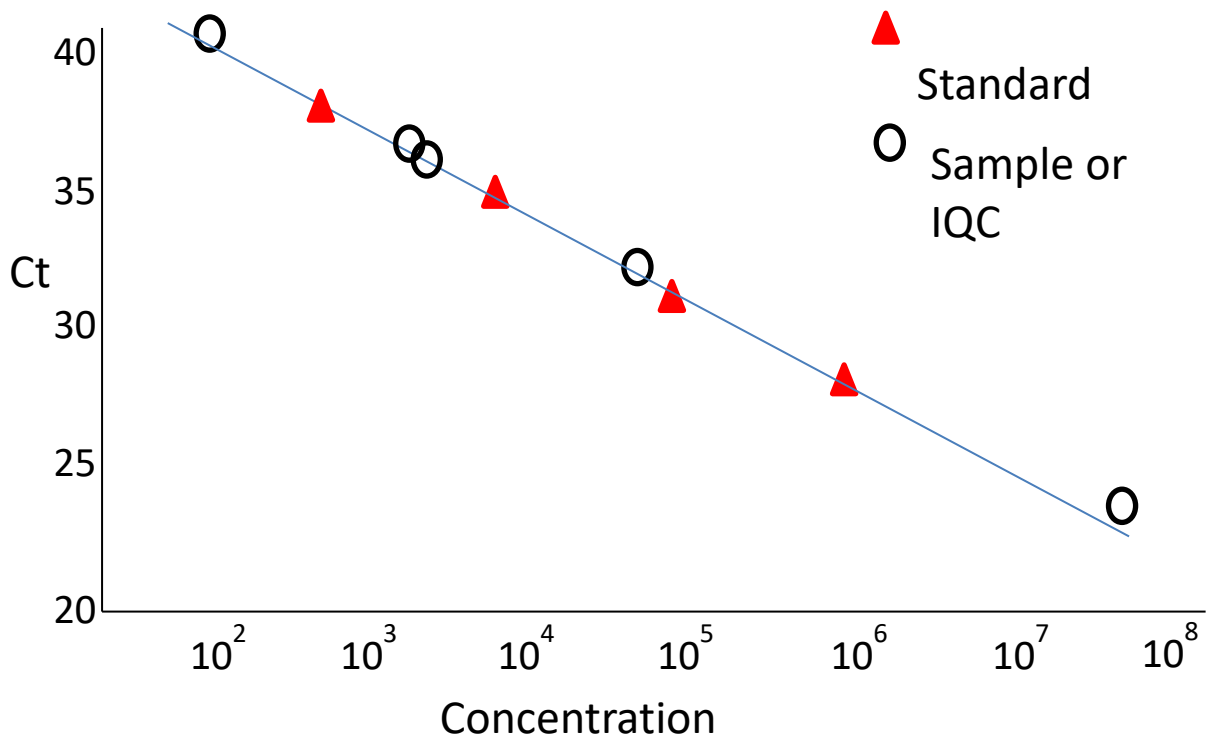


Table showing the Ct values of the standards and samples and the calculated CMV DNA (No Ct value means no amplification):

<b>Standard/sample</b>	<b>Ct value</b>	<b>Expected CMV DNA concentration (IU/mL)</b>	<b>Calculated CMV DNA concentration (IU/mL) based on standard curve</b>	<b>Ct values of internal control (spiked phocine herpes virus)</b>
10 <sup>6</sup> standard	26.3	1000000	1015000	
10 <sup>5</sup> standard	29.2	100000	99860	
10 <sup>4</sup> standard	32.9	10000	10500	
10 <sup>3</sup> standard	36.0	1000	985	
Negative control			0	29.3
Sample 1	21.1		91000000	31.8
Sample 2			0	29.6
Sample 3	38.7		136	29.2
Sample 4	34.1		4987	29.5
Negative control			0	29.0
Sample 5	29.9		86400	29.4
Sample 6			0	28.9
Positive IQC	34.8	3000	3280	29.5
Negative control			0	29.3
Water control			0	29.2

**3.5** Is this run valid and is the standard curve acceptable? Please explain. (7 marks)

**3.6** The lower limit of detection of this assay was previously determined to be 100 IU/mL, whereas the lower limit of quantification was 400 IU/mL.

Define these two concepts and clarify how these are usually determined. Explain how can a sample be positive but below the limit of quantification. [10 marks]

**3.7** How would you report the result of each of the samples? (8 marks)

Sample 1 [2 marks]:

Sample 2 [1 mark]:

Sample 3 [2 marks]:

Sample 4 [1 mark]:

Sample 5 [1 mark]:

Sample 6 [1 mark]:

**3.8** Sample 5 is vitreous humour fluid that has increased by 1.0 log, 1 week after intravitreal ganciclovir administration.  
Name 3 laboratory tests for CMV susceptibility testing [3 marks]

Please submit your answer before proceeding to the next section of this question

(Time allowed for 3.9 to 3.12 = 9 min)

**3.9** State the relative sensitivities of genotypic assays by Sanger sequencing and NGS [2 marks]

**3.10** What do you understand by false positive, false negative and discordant results in genotypic assays? (3 marks)

**3.11** How do you prove that a mutation detected by genotypic assay conveys drug resistance or not? [5 marks]



**3.12** Add values to each grade of CMV resistance by filling the three gaps in this table [3 marks]

Grades of resistance	Value for each grade of resistance with reference to control strains (3 marks)
High-grade	
Moderate	
Low-grade	
Insignificant	<2x

**3.13** How would you treat a patient with drug resistant CMV infection? (5 marks)



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**Oral Stations [4 stations, 15 minutes each including change over, total duration of 60 minutes)**

Four compulsory verbal questions

(One minute to consider the case before examination, 10 minutes of verbal communication, 4 minutes to move to the next question)

Few examples given below:

**Verbal Question 1:**

A midwife calls you to say that a follow-up blood sample from a pregnant lady is clearly HIV negative, whereas the first blood sample taken a week before is HIV-1 positive.

Discuss.

**Verbal Question 2:**

A terrorist bomb victim sustained a penetrative injury from a sharp piece of bone, which originated from a deceased terrorist.

The Emergency Department team is calling you for advice.

**Verbal Question 3:**

A 32-year-old male sewerage engineer presents with a 1-day history of fever, abdominal pain, headache, myalgia and drowsiness. He had just completed a 3-month assignment in rural Nigeria and returned to UK two days prior to his onset of illness. The Emergency Department registrar has called you to discuss.

**Verbal Question 4:**

The intensive care unit consultant calls you regarding a 40-year-old female with jaundice, dark urine, encephalopathy and multi-organ failure. The only unusual history is a new sexual partner. Discuss.