

# TDL Sexual Health 2018



Sexual Health Screening services continue to become easier to access for everyone, with testing and results becoming available more quickly through both private and NHS clinics, and online sexual health services. Patients may opt for self-sampling on site or at home, and routine STI test results are often sent electronically to patients within a few hours or days of samples being received in the laboratory, depending on the nature of the test. This allows patients who are diagnosed with an STI to be fast tracked for treatment.

Increased HIV testing is key in any HIV prevention or reduction strategy.

**November 2017: New HIV data has confirmed a reduction in the number of new HIV diagnoses in the UK with an overall decline of 18%.** Among gay and bisexual men the decline is steeper, with a decrease of 21% to 2,810 in 2016 from a high of 3,570 in 2015. The decline in new HIV diagnoses in gay and bisexual men is particularly apparent in London, where diagnoses decreased by 29%. For the first time, the overall mortality rate of people with diagnosed HIV aged 15-59 years who were diagnosed promptly was comparable to that of the general population of the same age group. These changes are dependent upon sustained prevention efforts.

## NEW HIV Rapid RNA HIV-1 QUALITATIVE – Results in 4 Hours

## NEW HIV Rapid RNA HIV-1 QUANTITATIVE – Results in 4 Hours

For some patients **earlier diagnosis of HIV infection** is important. **Xpert HIV-1 Qual** is a qualitative test that provides molecular testing for earlier diagnosis (from 10 days). (Cepheid)

### FOR PATIENTS ON TREATMENT FOR HIV

**Xpert HIV-1 Viral Load** accommodates rapid testing and measurement of blood plasma HIV-1 RNA concentration (HIV viral load/40 copies/ml). This is the established standard of care in assessing HIV-positive patient prognosis and response to antiretroviral therapy. Assessment of viral load levels is a strong predictor of the rate of disease progression either by itself or in combination with CD4 T-cell counts.

RAPID XPERT HIV-1 RNA QUALITATIVE EARLY DETECTION FROM 10 DAYS	
HIV-1 RNA	<b>NEW 2018</b>
Sample must be received in the laboratory within 24 hours of sample taking	<b>TAT 4 HOURS</b>
<b>LHIV</b>	

A

RAPID XPERT HIV-1 RNA VIRAL LOAD RAPID TESTING FOR HIV-POSITIVE PATIENT PROGNOSIS AND RESPONSE TO ANTIRETROVIRAL THERAPY	
HIV-1 RNA VIRAL LOAD (40 copies/ml)	<b>NEW 2018</b>
Sample must be received in the laboratory within 24 hours of sample taking	<b>TAT 4 HOURS</b>
<b>RHIV</b>	

A

# Sexual Health – TDL Profiles

**STD1** M/F STD QUAD (Urine and Serology)

<b>Serology</b>	<b>Urine</b>
HIV 1&2/p24 antigen	Chlamydia
Syphilis IgG/IgM	Gonorrhoea

**TAT**  
**2**  
**DAYS**

**STD1**

**B** FCRU

**STD2** M/F STI PROFILE PLUS (Urine and Serology)

<b>Serology</b>	<b>Urine</b>
HIV 1&2/p24 antigen	Chlamydia/Gonorrhoea
Hep B surface Antigen	Mycoplasma genitalium
Hep C Abs/Hep C Ag	Ureaplasma
Syphilis IgG/IgM	Trichomonas vaginalis
	Gardnerella vaginalis
	Herpes Simplex I/II

**TAT**  
**4**  
**DAYS**

**STD2**

**B** FCRU If culture swabs are needed please request separately

**STD3** FEMALE STD QUAD (PCR swab and Serology)

<b>Serology</b>	<b>Vaginal PCR Swab</b>
HIV 1&2/p24 antigen	Chlamydia
Syphilis IgG/IgM	Gonorrhoea

**TAT**  
**2**  
**DAYS**

**STD3**

**B** PCR

**STD4** FEMALE STI PROFILE PLUS (PCR swab and Serology)

<b>Serology</b>	<b>Vaginal PCR Swab</b>
HIV 1&2/p24 antigen	Chlamydia/Gonorrhoea
Hep B surface Antigen	Mycoplasma genitalium
Hep C Abs/Hep C Ag	Ureaplasma
Syphilis IgG/IgM	Trichomonas vaginalis
	Gardnerella vaginalis
	Herpes Simplex I/II

**TAT**  
**4**  
**DAYS**

**STD4**

**B** PCR If culture swabs are needed please request separately

**STD5** SEROLOGY ONLY

HIV 1&2/p24 Antigen  
Hepatitis B Surface Antigen  
Hep C Abs  
Hep C Ag (early detection)  
Syphilis IgG/IgM

**TAT**  
**4**  
**HOURS**

**STD5**

**B**

**STD6** SEROLOGY ONLY WITHOUT HIV

Hepatitis B Surface Antigen  
Hep C Abs  
Hep C Ag (early detection)  
Syphilis IgG/IgM

**TAT**  
**4**  
**HOURS**

**STD6**

**B**

**STD8** VAGINITIS/BV PROFILE USING CULTURE & PCR SWAB

Candida species  
Gardnerella vaginalis by PCR  
Trichomonas vaginalis by PCR

**TAT**  
**3**  
**DAYS**

**STD8**

PCR STM

**STD9** SYMPTOMATIC LESION SAMPLE USING PCR SWAB FROM LESION

Syphilis by PCR  
Herpes Simplex I/II by PCR (from single swab)

**TAT**  
**7**  
**DAYS**

**STD9**

PCR

**MYCOPLASMA/UREAPLASMA BY PCR** (Urine, Swab, Thin Prep, Semen)

Mycoplasma genitalium  
Ureaplasma urealyticum/parvum

**TAT**  
**2**  
**DAYS**

**MUPC**

FCRU OR PCR Swab OR TPV OR Semen

**HIV/HBV/HCV SCREEN** (HIV1/HIV2/HBV/HCV by PCR/NAAT)

HIV1 and HIV2 (RNA)  
Hepatitis B Virus (HBV DNA)  
Hepatitis C Virus (HCV RNA)

Samples must be received in the laboratory within 2 days of sample taking

**TAT**  
**3**  
**DAYS**

**STDX**

**A** 10mls or 2x4mls

**EARLY DETECTION SCREEN WITH SYPHILIS** (HIV1/HIV2/HBV/HCV by PCR/NAAT)

HIV1 and HIV2 (RNA)  
Hepatitis B Virus (HBV DNA)  
Hepatitis C Virus (HCV RNA)  
Syphilis IgG/IgM

Samples must be received in the laboratory within 2 days of sample taking

**TAT**  
**3**  
**DAYS**

**STXX**

**B** **A** 10mls or 2x4mls

**7 STI PROFILE BY PCR (7 TESTS FROM 1 SAMPLE)** (Urine, Swab, Thin Prep or Semen)

Chlamydia trachomatis  
N. gonorrhoea  
Mycoplasma genitalium  
Ureaplasma  
Trichomonas vaginalis  
Gardnerella vaginalis  
Herpes Simplex I/II

**TAT**  
**2**  
**DAYS**

**DL12**

**All tests can be requested individually.**

FCRU OR PCR Swab OR TPV OR Semen

**CT/GC/TRICHOMONAS 3 STI'S BY PCR (SWAB)** (Urine, Swab or Thin Prep)

Chlamydia  
Gonorrhoea  
Trichomonas vaginalis

**TAT**  
**2**  
**DAYS**

**CCGT**

FCRU OR PCR Swab OR TPV

## Mycoplasma genitalium (MGEN) by NAAT/PCR

*Mycoplasma genitalium* is a significant sexually transmitted pathogen that is becoming more recognised, better understood, but more complicated because of its increasing resistance to standardised treatments.

MGEN lives on and in the epithelial cells of the urinary and genital tracts of men and women. In both low and high risk populations prevalence is higher than gonorrhoea and is nearer to that of chlamydia. This in itself provides ample justification for inclusion in testing for routine STI screening. MGEN is strongly associated with non CT/GC urethritis in men and for cervicitis, pelvic inflammatory disease, preterm birth, spontaneous abortion and infertility in women, but a high proportion of cases will be asymptomatic.

Managing MGEN infection has been made more complicated by poor treatment efficacy in eradicating MGEN with doxycycline 100 mg twice a day for 7 days, or azithromycin 1g single dose, which are the current first-line treatments for non-gonococcal urethritis and cervicitis in the UK. Macrolide resistance in MGEN began in early 2000 with the increasing use of azithromycin 1g to treat STI's. Macrolide-resistant MGEN is especially recognised where azithromycin 1g is used as a first-line treatment for non-gonococcal urethritis, cervicitis, and chlamydia when testing for MGEN was either not tested or overlooked. There is a strong recommendation<sup>1</sup> that all patients with MGEN infection should be followed up regardless of the azithromycin regimen used. **Because macrolide resistance can emerge even with the use of extended azithromycin, all azithromycin-treated patients with MGEN should have a test of cure undertaken no sooner than three weeks after starting treatment, even if they're asymptomatic.**

### Testing Options for *Mycoplasma Genitalium*

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Mycoplasma genitalium	MGEN	FCRU / PCR swab / TPV / Semen	2 days
Mycoplasma genitalium/Ureaplasma	MUPC	FCRU / PCR swab / TPV / Semen	2 days
Included in the 7 STI PCR Screen	DL12	FCRU / PCR swab / TPV / Semen	2 days

<sup>1</sup> Sex Transm Infect 2017

MYCOPLASMA BY PCR (Urine, Swab, Thin Prep, Semen)	
Mycoplasma genitalium	TAT 2 DAYS
MGEN	
FCRU OR PCR Swab OR TPV OR Semen	

MYCOPLASMA/UREAPLASMA BY PCR (Urine, Swab, Thin Prep, Semen)	
Mycoplasma genitalium Ureaplasma urealyticum/parvum	TAT 2 DAYS
MUPC	
FCRU OR PCR Swab OR TPV OR Semen	

DL12 7 STI PROFILE BY PCR (7 PCR TESTS FROM 1 SAMPLE)	
Chlamydia trachomatis N. gonorrhoea Mycoplasma genitalium Ureaplasma Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	TAT 2 DAYS
MGEN	
FCRU OR PCR Swab OR TPV OR Semen	

## STI and Screening for HIV for Men who have Sex with Men (MSM) BASHH guidelines

### What STIs should MSM be tested for?

MSM should be offered testing for:

Chlamydia

Gonorrhoea

Hepatitis B

Hepatitis C\*

HIV

Syphilis

Hepatitis A may occur in local epidemics affecting MSM but routine vaccination is not currently recommended.

\*Consider if there is sex associated with trauma or injury, history of recreational drug use/chem sex, known to be HIV positive, or rectal lymphogranuloma venereum.

### How frequently should STI testing be offered to MSM?

All sexually active MSM should be tested for STIs at least annually. MSM at high risk of STIs should be tested every 3 months. High risk includes:

- any unprotected sexual contact (oral, genital or anal) with a new partner
- following the diagnosis of a new STI
- drug use may be a marker of high risk behaviour and a detailed sexual history is required in this group

### STI Profile: MSM1

HIV 1&2/p24 Ag  
Syphilis IgG/IgM  
Urine for CT/GC  
Throat Swab CT/GC  
Rectal Swab CT/GC

NEW  
2018

TAT  
2  
DAYS

MSM1

B FCRU PCR Swab Throat PCR Swab Rectal

### STI Profile: MSM2

HIV 1&2/p24 Ag  
Syphilis IgG/IgM  
7 STI by PCR Screen  
Throat Swab CT/GC  
Rectal Swab CT/GC

NEW  
2018

TAT  
4  
DAYS

MSM2

B FCRU PCR Swab Throat PCR Swab Rectal

# When to test? What to test? How to test?

BLOOD	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
Syphilis	Bacterial 9–21 days, but up to 90 days	Blood	Syphilis IgG/IgM	SERJ	<b>B</b>	4 hours
Herpes Simplex Virus I/II	Viral IgG 4–6 weeks after exposure IgM 5–35 days after exposure, after which test IgG	Blood Blood	Herpes IgG (past infection) Herpes IgM (current/recent)	HERP HERM	<b>B</b> <b>B</b>	2 days 2 days
HIV	Viral Usually 10–90 days, but up to 180 days	Blood Blood	HIV I&II /p24 antigen	HDUO	<b>B</b>	4 hours
Hep B	Viral Usually 45–180 days, average of 60–90 days	Blood Blood	Hep B surface antigen	AUAG	<b>B</b>	4 hours
Hep C Ab	Viral Usually 9–180 days, average of 45–65 days	Blood Blood	Hep C Antibodies	HEPC	<b>B</b>	4 hours
Hep C Ag	Viral Usually 9–180 days, average of 45–65 days	Blood Blood	Hep C Antigen (see lab guide page 73)	HCAG	<b>B</b>	4 hours

EARLY DETECTION PROFILES BY PCR	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
7 STIs by PCR	One sample for 7 STI Tests	Urine Cervix Vagina	Chlamydia Gonorrhoea Mycoplasma genitalium Ureaplasma genitalium Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	PP12 PP12 PP12	Thin Prep Vial or First Catch Urine or PCR Swab	2 days 2 days 2 days
HIV/HBV/HCV	Early Detection Screen by PCR Multiplex (HIV from 10 days)	Blood	HIV 1&2 RNA Hepatitis B (HBV DNA) Hepatitis C (HCV RNA)	STDx	<b>A</b> 10mls or 2x 4mls	3 days

The Self-Collection HPV test provides women with the option to self-collect a vaginal sample, that is then sent to the laboratory for testing. Results will always be sent to the requesting clinician, clinic or healthcare organisation.

HPV	HPVZ
Self-Collected HPV DNA with individual reporting of subtypes 16, and 18 and collective reporting of the other high risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).	Self-Collected HPV DNA with reporting of individual subtypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

For more information, or to order Self-Collection HPV Test Packs, please contact Annette Wilkinson on 020 7307 7343 or [annette.wilkinson@tdlpathology.com](mailto:annette.wilkinson@tdlpathology.com)

**RETESTING/TEST OF CURE**

**Chlamydia:** Allow up to 6 weeks before retesting. NAAT/PCR tests are sensitive and will pick up the DNA from a previous infection if retesting is undertaken too soon after treatment, when a positive result may be a sign of continuing or re-infection from the initial infection.

**Gonorrhoea** can usually be treated successfully with a single antibiotic injection followed by one antibiotic tablet. **Retesting two weeks after treatment will confirm clearance of gonorrhoea.** Test of cure is recommended following treatment for all gonococcal infections. This is to identify treatment failure and emerging resistance to ceftriaxone and cefixime.

**Trichomonas vaginalis:** If antibiotics are taken correctly, follow-up tests or examinations for trichomonas shouldn't be needed, but if treatment has not been completed, or there is a chance of becoming re-infected, or symptoms continue, then repeat testing and perhaps different treatment may be indicated.

**Mycoplasma genitalium:** Because macrolide resistance can emerge, even with the use of extended azithromycin, all azithromycin-treated patients with MGEN should have a test of cure carried out no sooner than 3 weeks after starting treatment even if they are asymptomatic.

# When to test? What to test? How to test?

STI's can be caused by virus, fungus, parasite or bacteria. Anyone who is sexually active may be at risk of acquiring an STI. The risk is higher for those with increased numbers of sexual partners, or who have had sex with someone who has/had many partners, or have had unprotected sex.

STD	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
<b>Chlamydia CT</b>	Bacterial	Urine Cervix/Vagina Cervix/Vagina	Chlamydia	CPCR	First Catch Urine	2 days
			Chlamydia	SPCR	PCR Swab	2 days
			Chlamydia	TPCR	Thin Prep Vial	2 days
<b>Gonorrhoea GC</b>	Bacterial	Urine Cervix/Vagina Cervix/Vagina Cervix/Vagina	Gonorrhoea by PCR	CGON	First Catch Urine	2 days
			Gonorrhoea by PCR	SGON	PCR Swab	2 days
			Gonorrhoea by PCR	TGON	Thin Prep Vial	2 days
			Gonorrhoea by CULTURE	GONN	Culture swab	2-3 days
<b>CT/GC Combined</b>	Bacterial	Urine Cervix/Vagina Cervix/Vagina Rectum Throat	CT/GC	CCG	First Catch Urine	2 days
			CT/GC	SCG	PCR Swab	2 days
			CT/GC	TCG	Thin Prep Vial	5 days
			CT/GC	RSCG	PCR Swab	2 days
			CT/GC	TSCG	PCR Swab	2 days
<b>Mycoplasma genitalium</b>	Bacterial	Urine GU Site Cervix/Vagina	Mycoplasma genitalium by PCR	MGEN	First Catch Urine	2 days
			Mycoplasma genitalium by PCR	MGEN	PCR Swab	2 days
			Mycoplasma genitalium by PCR	MGEN	Thin Prep Vial	2 days
<b>Ureaplasma urealyticum</b>	Bacterial	Urine GU Site Cervix/Vagina	Ureaplasma by PCR	UGEN	First Catch Urine	2 days
			Ureaplasma by PCR	UGEN	PCR Swab	2 days
			Ureaplasma by PCR	UGEN	Thin Prep Vial	2 days
<b>Trichomonas vaginalis</b>	Parasitic	Urine GU Site Cervix/Vagina	Trichomonas vaginalis by PCR	TVPC	First Catch Urine	2 days
			Trichomonas vaginalis by PCR	TVPC	PCR Swab	2 days
			Trichomonas vaginalis by PCR	TVPC	Thin Prep Vial	2 days
<b>Gardnerella vaginalis</b>	Bacterial	Urine GU Site Cervix/Vagina	Gardnerella vaginalis by PCR	GVPC	First Catch Urine	2 days
			Gardnerella vaginalis by PCR	GVPC	PCR Swab	2 days
			Gardnerella vaginalis by PCR	GVPC	Thin Prep Vial	2 days
<b>Bacterial Vaginosis (BV)</b>	Bacterial	Cervix/Vagina	Bacterial Vaginosis (BV) Profile by both PCR and CULTURE	STD8	Both Culture & PCR swab	3 days
			Herpes by PCR	HERS	PCR Swab	4 days
<b>Herpes Simplex Viral I/II</b>	Viral	PCR swab PCR swab	Herpes by PCR	HERD	First Catch Urine	4 days
<b>Human Papillomavirus</b>	Viral	Cervical cells Cells/papilloma from site (throat/penile/anal)	HPV DNA/mRNA	HPVT	Thin Prep Vial	5 days
			HPV Typed DNA	HP20	PCR Swab	3 days
			HPV Typed DNA	HP20	Cells/Papilloma	3 days
<b>Genital warts</b>	Viral	GU Warts	HPV Typed DNA	HPVT	Thin Prep Vial	5 days
			HPV Typed DNA	HP20	PCR Swab	3 days
			HPV Typed DNA	HP20	Cells/Papilloma	3 days
<b>Syphilis/Herpes</b>	Bacterial/ Viral	Symptomatic Lesion	Syphilis/Herpes Lesion Profile	STD9	PCR Swab	7 days



## TEST UPDATE: 5th Generation HIV

TDL has added a further two Bio-Rad analysers in the London laboratory to cover the increased activity for the 5th Gen BioPlex 2200 HIV Ag-Ab HIV. This is first commercial screening assay to be able to distinguish between HIV-1 antibodies, HIV-2 antibodies and HIV-1 p24 antigen. In addition to the early detection offered by 4th generation assays, **this 5th Generation** assay provides more information by specifically identifying HIV-1 or HIV-2 and allows results of antigen and antibody detection to be reported individually. Because antigens and antibodies are detectable at different stages of the infection, reporting of both helps to differentiate between acute and established HIV infection.

The Bio-Rad BioPlex **5th Generation HIV** test is

- One of the best performers for detecting primary HIV infection
- Useful in a confirmatory algorithm with the advantage of differentiating the individual HIV analytes
- CE marked and evaluated by PHE

TEST	CODE	SAMPLE REQUIREMENTS	TAT
<b>HIV (5th Generation) Ag-Ab Screen (Bio-Rad BioPlex 2200)</b> Results report the following: HIV-1 Antibodies, HIV-2 Antibodies, p24 Antigen, HIV 1&2 Abs/p24 Ag Summary	HIV5	<ul style="list-style-type: none"> <li><span style="border: 1px solid black; border-radius: 50%; padding: 2px;">B</span> SST/Serum or</li> <li><span style="border: 1px solid black; border-radius: 50%; padding: 2px;">B</span> TDL Tiny™</li> </ul>	24 hours

### TDL TINIES for self collection blood samples

[tinies@tdlpathology.com](mailto:tinies@tdlpathology.com)

The range of tests for Sexual Health Screening includes options for self-collection blood samples (home sample collection not home testing) and postal pathology using TDL TINIES. Orders for TDL TINIES (packs with instructions) can be made up by TDL, by arrangement, or supplied directly to doctors or healthcare companies. This is not point of care testing. All testing is undertaken in the laboratory and results for TINIES and POSTAL PATHOLOGY are always returned directly to the healthcare company or doctor, not to the patient.

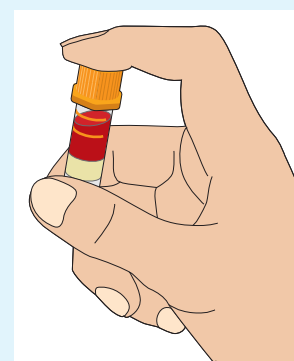
Up to 4 blood tests can be taken from one TDL TINY

- HIV 1&2/p24 Antigen
- Hep B sAg
- Hep C Abs
- Syphilis IgG/IgM

Packs can also be made up to include urine tube and swabs (e.g. MSM self-collection packs are made up for self-sample collection for:

BLOOD/TINY	URINE	PCR SWABS
HIV 1&2/p24	CT/GC	Rectal
Syphilis		Pharyngeal

**Reactive samples** must be followed up with a venous sample for confirmatory testing. For information about self collection packs, please contact Annette Wilkinson on **020 7307 7343** or email [tinies@tdlpathology.com](mailto:tinies@tdlpathology.com). All results will be sent to the healthcare practice/organisation who manage the service.



## HPV as first test for Screening Programmes Progression to Self-Collection HPV Test

Human Papillomavirus (HPV) is the primary cause of nearly all cervical cancer. In most cases, the HPV virus is harmless and causes no symptoms. Most women who acquire HPV are able to clear the infection through their own immune systems. Persistent presence of high-risk types of HPV can cause cervical lesions which over time may develop into cancer if untreated. Testing for HPV determines the presence, or absence, of HPV and will determine whether the HPV type present is high risk for CIN and cervical cancer.

The **Self Collection HPV Test** provides women with the option to self-collect a vaginal specimen that is then sent to the laboratory for testing. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens.

The **Self-Collection HPV Test** is validated, using a CE marked sample collection device for vaginal cell collection. This sample is then sent to the laboratory for processing for 14 high risk HPV DNA subtypes. A negative result means that these high-risk subtypes HPV were not detected and the patient is at extremely low risk of developing high-grade cervical disease/CIN2+ before their next routine visit.

A positive HPV result might indicate an increased risk of developing CIN/cervical cancer, and the report from the laboratory will provide a clear recommendation for follow-up/colposcopy.

The value of HPV DNA testing in cervical cancer screening and disease detection has been proven over and over again. Self-collection of specimens for HPV testing is not intended to replace existing patient management pathways but allows for:

- Those who wish to test following a change of sexual partner
- Option for identifying individual high risk DNA subtypes
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears

**The Self-Collection HPV test provides women with the option to self-collect a vaginal sample, that is then sent to the laboratory for testing. Results will always be sent to the requesting clinician, clinic or healthcare organisation.**

**HPVY** Self-Collected HPV DNA with individual reporting of **subtypes 16, and 18** and one **collective** result for the other high risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

**HPVZ** Self-Collected HPV DNA with reporting of **all subtypes individually**: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

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