ML Pathology
Newsletter

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ISSUE 1, 2022

Screening for fetal chromosomal aneuploidies using non-invasive prenatal testing (NIPT)

Dr Kym Mina, Genetic Pathologist

Non-invasive prenatal testing [NIPT] is a screening test that utilises circulating cell free DNA from maternal plasma to assess the likelihood of aneuploidy, or gains or losses of chromosomes, in the developing fetus.

NIPT outperforms traditional combined first trimester screening [cFTS] by offering an improved detection rate with fewer false positive results. In turn, this reduces the need for invasive prenatal investigations and the associated risk of procedure-related complications.

First introduced into clinical use in 2011, NIPT was initially limited to screening for common trisomies involving chromosomes 21, 18 and 13 (Down, Edwards and Patau syndromes) in pregnancies at high risk of aneuploidy due to advanced maternal age, ultrasound findings, positive serum screen or previous pregnancy with trisomy. More recently, studies have demonstrated that NIPT is suitable for use in the general pregnant population, regardless of prior risk, as a first line screen for common trisomies and sex chromosome (X and Y) aneuploidies. There is also building evidence that genome-wide NIPT, assessing for gains and losses across all chromosomes, may provide clinically important information on the chromosomal status of the fetus as well as additional insight into the health of the pregnancy.

NIPT in its various forms has been rapidly adopted in Australia and internationally. As yet, NIPT is not publicly funded in Australia, but can be accessed through private laboratories.

BASIC PRINCIPLES OF NIPT

Cell free DNA [cf-DNA] is fragmented DNA that is released into the plasma from the natural turnover of cells. During pregnancy, maternal plasma contains cf-DNA from both the mother and the placenta. NIPT uses the fraction of cf-DNA derived from the placenta, commonly referred to as fetal fraction, to assess the chromosomal status of the fetus.

In the laboratory, whole genome sequencing and bioinformatic analysis is used to sequence and count the cf-DNA fragments from each chromosome and compare the counts to those expected for a normal pregnancy of the same gestation. Deviation from the expected amount of cf-DNA for a given chromosome or chromosomal region is suggestive of fetal aneuploidy and is reported as a high-risk result.

Ensuring that there is sufficient placental cf-DNA in the tested sample is essential for the clinical accuracy of NIPT. This is achieved in two ways: 1) requiring a minimum gestational age at the time of testing (usually >10 weeks) to maximise the fetal fraction, and 2) applying quality metrics that use unique biological characteristics of placental cf-DNA to distinguish it from maternal cf-DNA. NIPT results typically include an estimate of the fetal fraction to indicate that placental cf-DNA was detected in the sample tested.

Screening using NIPT can provide information on the risk of gain or loss of whole chromosomes (autosomal and sex chromosome aneuploidies, for example trisomy 21 and monosomy X), parts of chromosomes >7Mb in size (subchromosomal aneuploidies or CNVs), and specific submicroscopic losses (microdeletions); see Figure 1. The detection of Y chromosome material can also be used to predict biological sex.

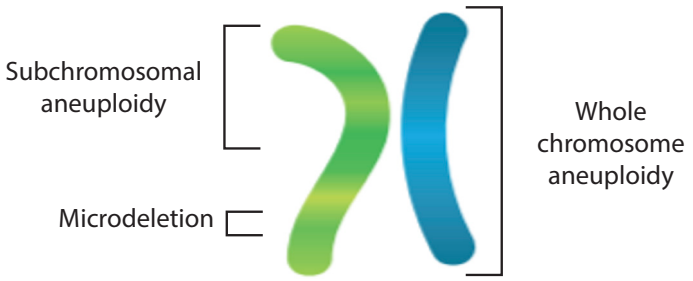

Figure 1: Types of fetal aneuploidy detected by NIPT

GENOME-WIDE NIPT

NIPT is based on sequencing of the whole genome, however risk assessment can be limited to chromosomes involved in common aneuploidies (21, 18, 13, X and Y), or expanded to provide a genome-wide risk assessment for all chromosomes (1-22, X and Y).

Aneuploidies involving chromosomes 21, 18, 13, X and Y account for approximately 80% of prenatal aneuploidies. Expanding the scope of testing to include all chromosomes enables the comprehensive detection of recurrent, well-defined conditions (such as trisomy 21 and specific microdeletion syndromes) as well as rare but clinically significant whole chromosome and subchromosomal aneuploidies, thus improving the detection rate of the screen. While it is estimated that one in four high-risk results from genome-wide NIPT would not be identified by screening limited to the common aneuploidies, it is important to be mindful that genome-wide screening can produce more false positive results (high-risk results that are not confirmed in the fetus on diagnostic testing).

SENSITIVITY AND PREDICTIVE VALUE

NIPT is a highly sensitive screen for fetal chromosomal aneuploidies. This means that if a common fetal aneuploidy is present, a high-risk result will be returned > 99% of the time. This is a significant improvement on cFTS which has a detection rate of only 85-90% for trisomy 21.

Sensitivity is a measure of the technical performance of the test. In clinical practice, however, a more useful test characteristic is the positive predictive value [PPV], which is a measure of the ability of NIPT to correctly identify a pregnancy as high-risk and is expressed as the percentage chance that there is a true fetal aneuploidy if a high-risk result is returned. PPVs for the general pregnant population can be estimated from large genome-wide NIPT implementation studies and range from >90% for trisomy 21 down to <10% for rare autosomal trisomies. The relative ranking of aneuploidies according to PPV is shown in Figure 2. Importantly, all forms of NIPT provide an improved PPV over cFTS for trisomy 21.

The variation in PPV with type of aneuploidy can be explained by differences in prevalence. PPV is higher when the aneuploidy is more common in the population, and so would be expected to be higher for the common trisomies than rare whole chromosome and subchromosomal aneuploidies. Variation in PPV with type of aneuploidy can also be explained by differences in the chance of a biological false positive. The comparatively low PPV for rare autosomal trisomies is consistent with the understanding that many of these are confined to the placenta and will not be detected in the fetus (referred to as confined placental mosaicism, CPM).

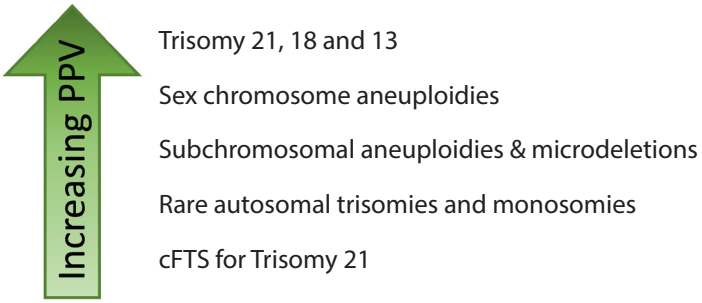

Figure 2: Relative positive predictive values for NIPT in the general pregnant population

The PPV of NIPT for an individual pregnancy can be further modified by other factors including maternal age, clinical and ultrasound findings, previous affected pregnancies and known familial chromosomal rearrangements. Advanced maternal age has an important impact on PPV because risk of some aneuploidies increases with maternal age. For example, estimated PPVs for trisomy 21 are 51% and 93% for women of ages 25 and 40 respectively.

Overall, key to the appropriate use of NIPT is the understanding that PPVs are below 100%, and therefore clinical decisions should not be made based on high-risk results alone. While false negative results can also occur due to technical and biological reasons, these are rare. Accordingly, negative predictive values, or the ability of NIPT to correctly identify a pregnancy at low risk for aneuploidy, are very high (>99%), and therefore a low-risk result is reassuring.

UTILITY OF NIPT

Clinical outcomes of fetal aneuploidy vary but include spontaneous miscarriage, abnormalities of feto-placental growth, and live birth with multiple congenital anomalies and intellectual disability. Therefore, prenatal diagnosis of fetal aneuploidy can provide important information for pregnancy management, preparation for anticipated medical care following birth, and insight into pregnancy complications and loss.

Data from thousands of pregnancies has demonstrated NIPT as a suitable screening test for fetal aneuploidy, regardless of age and risk category, for both singleton and twin pregnancies. As a screening test, NIPT provides an assessment of risk that a fetus has a chromosomal abnormality; pregnancies identified as high-risk can then be further investigated using a diagnostic test (CVS or amniocentesis) that provides a definitive answer as to whether a chromosomal abnormality is truly present in the fetus.

Compared to traditional screening methods for fetal aneuploidy, NIPT offers a significantly improved detection rate and lower number of false positive results. This enhanced test performance improves the identification of pregnancies with fetal aneuploidy, while reducing the likelihood that a patient will have to undergo an invasive procedure, therefore avoiding procedure-associated risks to the mother and the pregnancy. Supporting this, published implementation studies have demonstrated a reduction in invasive procedures following the introduction of genome-wide NIPT of greater than 50%.

Beyond the identification of pregnancies as high-risk for fetal aneuploidy, NIPT results may provide additional insights into maternal and feto-placental health.

- Repeated test failures due to persistently low fetal fraction can be indicative of an increased risk of aneuploidy.
- Rare autosomal trisomies detected on cf-DNA but not confirmed in the fetus, due to CPM, may be associated with a higher incidence of miscarriage, still birth, intrauterine growth restriction and uniparental disomy.
- Maternal chromosomal aneuploidy and maternal neoplastic processes (including malignant tumours and benign fibroids) can cause complex and non-reportable NIPT results due to interference from the maternal cf-DNA profile.

Finally, it should be noted that NIPT specifically screens for chromosomal abnormalities and does not remove the need for other screening tests in early pregnancy for other genetic and non-genetic conditions.

PRACTICAL TIPS

Choosing NIPT options

The choice of which NIPT option to use should be based on an informed discussion with the patient about the advantages and limitations of available tests, personal and family history, clinical and ultrasound findings, and other practical considerations including stage of pregnancy, turnaround time and cost.

When and how to offer NIPT

Clinical best practice guidelines from Australian and international medical societies recommend that available prenatal screening tests, including NIPT, be discussed and offered to all pregnant women.

NIPT is suitable for use from 10 weeks gestation and throughout pregnancy. It is recommended as a first line test but may also be used in a contingent model of testing, whereby NIPT is performed following a high-risk cFTS result. However, concurrent use of these two different screening tests is not recommended as it does not improve detection but does increase false positives. When using NIPT, ultrasound at 11-13 weeks remains useful for confirmation of viability and early structural assessment of the fetus.

As highlighted, NIPT is a screening test only and it is recommended that all high-risk results be confirmed by diagnostic testing (CVS or amniocentesis) prior to making definitive management decisions. Women receiving high-risk results should be offered genetic counselling for information and support, including further explanation of the potential clinical consequences of the result and non-directive advice on management options including diagnostic testing. This is of particular assistance in the setting of genome-wide NIPT with rare or complex findings.

TAKE HOME MESSAGES

NIPT is a non-invasive screen that can be used to assess the risk of chromosomal aneuploidy in the fetus to inform pregnancy management.

NIPT options include screening for common and rare whole chromosome aneuploidies, subchromosomal aneuploidies and specific microdeletions. Information on fetal sex can also be provided.

Australian guidelines recommend NIPT as a first line screening option for fetal chromosomal aneuploidies for all women with singleton and twin pregnancies

Definitive pregnancy management decisions should not be made on NIPT results alone. It is recommended that high-risk screen results be confirmed by diagnostic tests (CVS or amniocentesis).

NIPT options, results and the possibility and implication of lower positive predictive values for some types of aneuploidy should be discussed with patients to help them make the best choice for their personal circumstances.

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NIPT TESTS AVAILABLE THROUGH QML PATHOLOGY

QML Pathology, through genetic testing facility Genomic Diagnostics, offers the non-invasive prenatal test (NIPT) – Generation. Three options are available.

Generation screens for the common trisomies, T21, T18 and T13, and specific sex chromosome aneuploidies.

Generation 46 screens the whole genome for chromosomal and sub-chromosomal aneuploidy (>7Mb), including T21, T18 and T13.

Generation Plus screens for the most common trisomies, T21, T18 and T13, specific sex chromosome aneuploidies and five rare microdeletion syndromes – 22q deletion (DiGeorge syndrome), 15q deletion (Angelman/Prader-Willi), 1p36 deletion syndrome, 4p deletion (Wolf-Hirschhorn syndrome) and 5p (Cri-du-chat).

All Generation options include testing for fetal sex.

HOW TO ORDER:

1. **Consider NIPT** Discuss Generation NIPT options with your patient.
2. **Request testing** Order testing using dedicated Generation NIPT request form. Request forms are available as templates through patient software, online or as hard copy pads. Ensure the patient signs the Patient Consent section.
3. **Patient pays for the test** Patient pays online for test at genomicdiagnostics.com.au prior to having blood collected and records receipt number on test request form. Payment may be made over the phone on 1800 822 999 if online payment is not possible.
4. **Patient attends collection centre** Patient attends a collection centre where the sample is collected and sent for testing. Patient must be at least 10 weeks pregnant for collection to occur.
5. **Results return** The results will be returned using the preferred method. Genetic counselling is provided free of charge to all patients who return a high-risk result.

Please contact Genomic Diagnostics with any inquiries about Generation NIPT options.

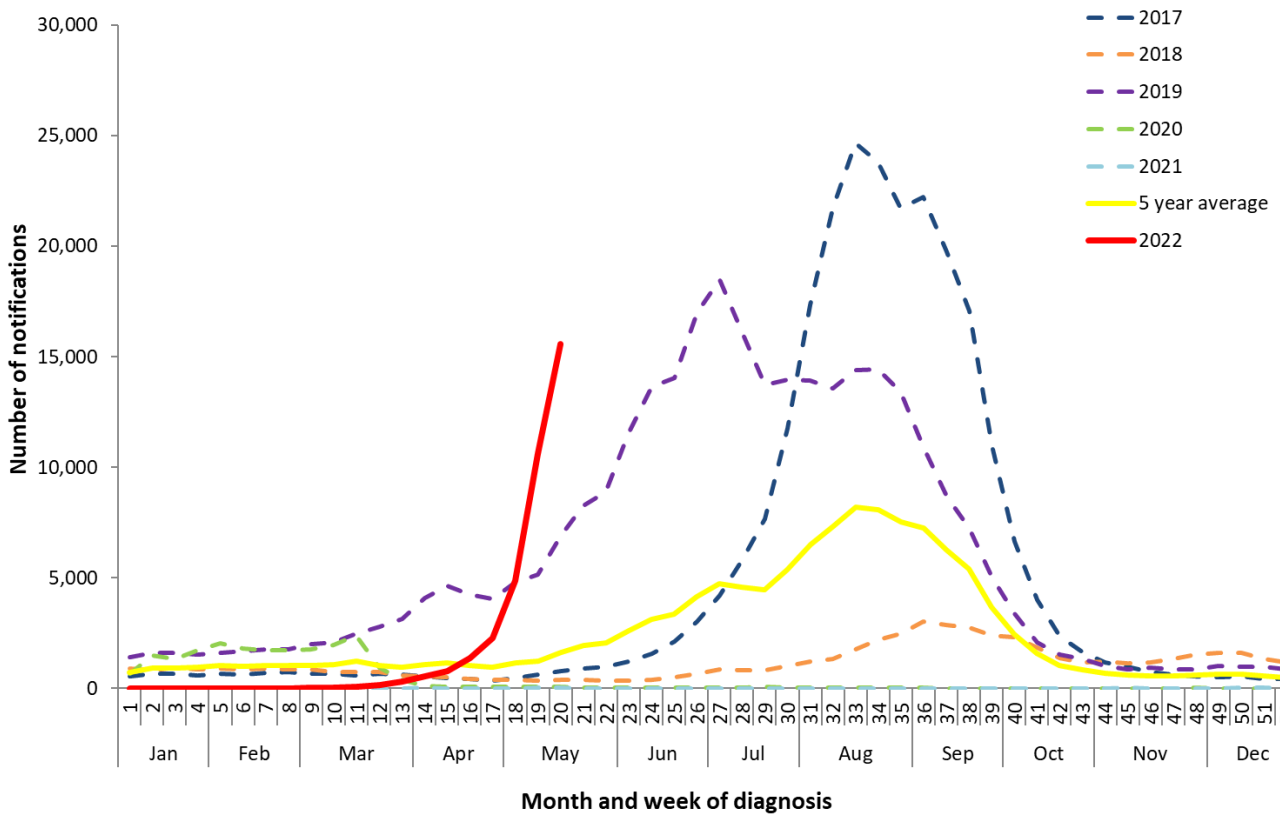
P: 1800 822 999 / E: info@genomicdiagnostics.com.au

Influenza vaccination and testing

Dr Renu Vohra

During the COVID-19 pandemic, public health and social measures undertaken to mitigate COVID-19 have been highly effective for preventing Influenza as well. The Australian Influenza surveillance report no 4, 2022 published by Australian Government Department of Health showed Influenza rates in 2021 were low compared to previous years (graph1). Similarly, at QML Pathology there was no Influenza A detected in years 2021 and 2020. Low case numbers along with low vaccination rates for Influenza during the COVID pandemic has left the population highly susceptible to Influenza. With the opening of international borders and relaxation of mitigation factors we are expecting to see a rise in Influenza activity this winter.

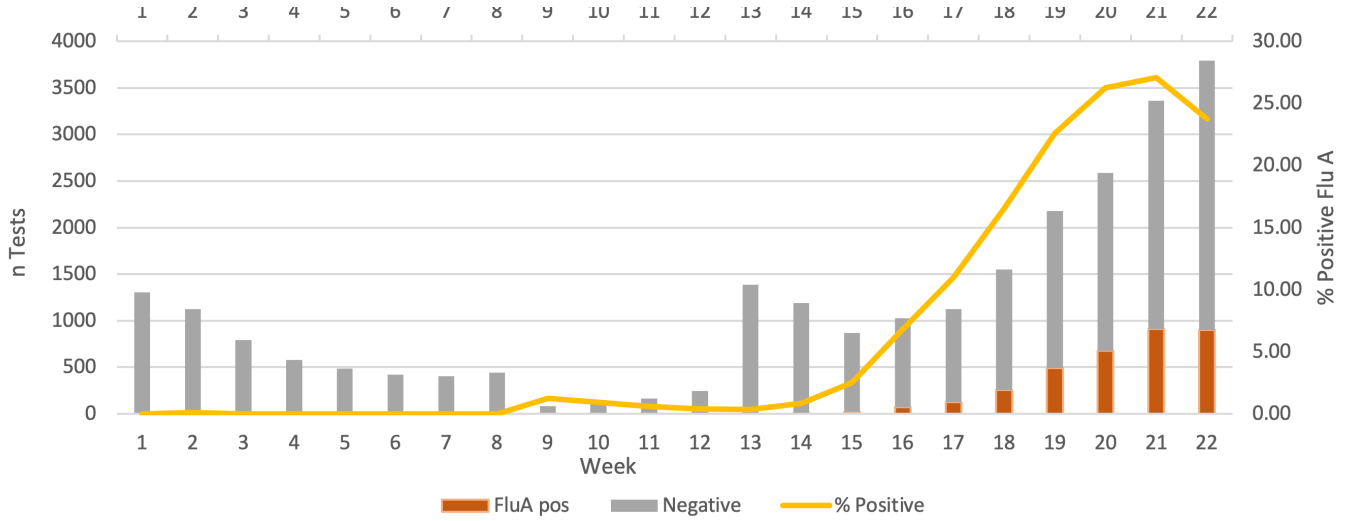
Graph 1: Notifications of laboratory-confirmed influenza, Australia, 01 January 2017 to 22 May 2022, by month and week of diagnosis.



(refer to www1.health.gov.au/internet/main/publishing.nsf/Content/0E99E97BC6C25F4ECA25884E007E4699/$File/flu-04-2022.pdf)

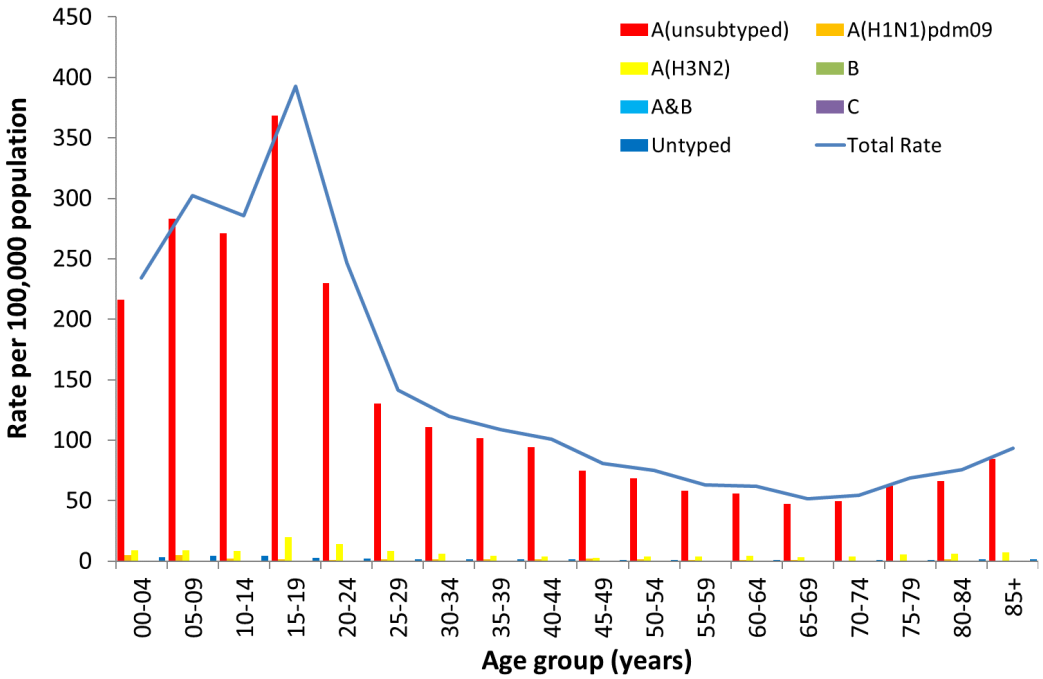
The beginning of 2022 was very quiet for Influenza activity at QML Pathology, however, the positivity rate for Influenza increased **to 22% by the end of May as seen in graph 2.** This correlates with the national increase in laboratory confirmed Influenza notifications (graph 1).

Graph 2. Influenza A detection by PCR at QML Pathology - 1st January to 28th May 2022.



Influenza A has disproportionately affected young people, with the highest notification rate seen age group 5-19 years followed by people aged 20-24 years and children younger than 5 years of age. The subtyping of the dominant strain so far has shown H3N2 to be predominant (graph 3).

Graph 3: Rate of notifications of laboratory-confirmed influenza, Australia, 01 January to 22 May 2022, by age group and subtype.



(refer to www1.health.gov.au/internet/main/publishing.nsf/Content/0E99E97BC6C25F4ECA25884E007E4699/$File/flu-04-2022.pdf)

Compared to previous years, the influenza season has started early and is showing increased positivity rate. **Any patient with symptoms of respiratory tract infection should be tested for respiratory viruses along with COVID**. At QML Pathology we have PCR assays to detect both respiratory viruses and COVID.

While we are gearing up to meet the demand in testing for Influenza, we would recommend Influenza vaccination to all those eligible. Annual Influenza vaccination is the best way to prevent influenza and its complications.

COMPOSITION OF INFLUENZA VACCINE

The strains used in seasonal influenza vaccines can change from year to year depending on which viruses are predicted to circulate in each upcoming season. Each year AIVC (Australian Influenza Vaccine Committee) determines the composition of the influenza vaccine. The recommendation made by AIVC aligns with the recommendation made by the World Health Organisation. This year the composition recommended by AIVC and endorsed by TGA is listed below.

Egg-based quadrivalent influenza vaccines:

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- an A/Darwin/9/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021-like (B/Victoria lineage) virus; and
- a B/Phuket/3073/2013-like (B/Yamagata lineage) virus.

Cell- or recombinant-based quadrivalent influenza vaccines:

- an A/Wisconsin/588/2019 (H1N1)pdm09-like virus;
- an A/Darwin/6/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

TIMING OF INFLUENZA VACCINATION

Highest protection against Influenza occurs within 3 to 4 months following vaccination, therefore best time of vaccination would be before the onset of the influenza season. The peak of Influenza is usually seen from June to September in most parts of Australia. However, Influenza epidemiology may be atypical this year due to COVID-19 and opening of international borders. In some Northern hemisphere countries report surges of both COVID-19 and Influenza concurrently. If a person had a 2021 influenza vaccine in late 2021 or early 2022, they are still recommended to receive a 2022 formulation of influenza vaccine when it becomes available.

INFLUENZA AND COVID-19 VACCINATION

The latest advice from ATAGI states that both Influenza and COVID vaccine can be co-administered on the same day. If you are eligible for a booster for COVID then you can also get the Influenza vaccine at the same time.

The seasonal influenza vaccines registered for use in Australia for 2022 were listed in ATAGI (Australian Technical Advisory Group On Immunization) clinical advice "Statement on administration of seasonal influenza vaccine in 2022", that was issued in March 2022 (Table 1)

TYPES OF INFLUENZA VACCINE AVAILABLE IN 2022

- All TGA-approved influenza vaccines are inactivated or split-virion and do not transmit influenza
- Influvac Tetra® is a quadrivalent influenza vaccine that was previously registered for use in children and adults from 3 years of age. The age indication for this vaccine has now been extended to include children from 6 months of age.
- Flucelvax Quad® is a cell-based influenza vaccine that was previously registered for use in adults and children from 9 years of age. The age indication for this vaccine has now been extended to include children from 2 years of age. It is the only cell-based influenza vaccine approved for use in Australia for 2022.
- Two higher-immunogenicity vaccines are available for older people in 2022. Fluad® Quad is available and NIP funded for people aged ≥ 65 years. Fluzone High Dose Quadrivalent is available for people aged ≥ 60 years but is not NIP funded.
- Fluad® Quad is preferentially recommended over standard influenza vaccine. There is no preference for use between either Fluad® Quad or Fluzone High-Dose Quadrivalent.

The composition of trivalent influenza vaccines is recommended to include the H1N1, H3N2 and the B Victoria lineage virus.
https://www.health.gov.au/resources/publications/atagi-advice-on-seasonal-influenza-vaccines-in-2022

Table 1: Seasonal influenza vaccines registered and available for use in Australia in 2022, by age.

Vaccine / Registered age group	Vaxigrip Tetra 0.5 mL (Sanofi)	Fluarix Tetra 0.5 mL (GSK)	Afluria Quad 0.5 mL (Seqirus)	FluQuadri 0.5 mL (Sanofi)	Influvac Tetra 0.5 mL (Mylan)	Flucelvax Quad 0.5 mL (Seqirus)	Fluad Quad 0.5 mL (Seqirus)	Fluzone High-Dose Quad 0.7 mL (Sanofi)
6 to 24 months (<2 years)	✓	✓	X	✓	✓	X	X	X
≥2 to <5 years	✓	✓	X	✓	✓	✓	X	X
≥5 to <60 years	✓*	✓*	✓*	✓	✓	✓	X	X
≥60 to <65 years	✓*	✓*	✓*	✓	✓	✓	X	✓
≥65 years	✓	✓	✓	✓	✓	✓	✓	✓

Ticks indicate age at which a vaccine is registered and available. White boxes indicate availability for free under the NIP.
* NIP funding only for Aboriginal and Torres Strait Islander people, pregnant women and people who have certain medical conditions.
(refer to https://www.health.gov.au/resources/publications/atagi-advice-on-seasonal-influenza-vaccines-in-2022)

IMPORTANT NOTE

The Australian Government has mandated that all **COVID-19, influenza and National Immunisation Program (NIP)** vaccinations administered **must be reported to the Australian Immunisation Register (AIR)** commencing from:

- 19 February 2021 for COVID-19 vaccinations,
- 1 March 2021 for influenza vaccinations, and
- 1 July 2021 for all **NIP vaccinations**.

LABORATORY TESTING FOR INFLUENZA AND OTHER RESPIRATORY VIRUSES

Influenza epidemiology in Australia this year may be atypical compared to previous years due to COVID-19 circulating in the community and opening of international borders, Clinically, it is difficult to distinguish between COVID, Influenza and other respiratory viruses. **Therefore, it is important to request for both respiratory virus PCR and COVID PCR in a patient presenting with respiratory symptoms.**

IN SUMMARY

1. Low case numbers along with low vaccination rates for Influenza during the COVID pandemic has left the population highly susceptible to Influenza.
2. Both Influenza and COVID vaccine can be co-administered on the same day.
3. Two higher-immunogenicity vaccines are available for older people in 2022. Fluad® Quad is available and NIP funded for people aged ≥ 65 years. Fluzone High Dose Quadrivalent is available for people aged ≥ 60 years but is not NIP funded
4. Clinically cannot distinguish between COVID, Influenza and other respiratory viruses
5. Upper respiratory specimens should be sent to the laboratory for both COVID and respiratory virus PCR test.

REFERENCES

1. The Australian Influenza surveillance report published by Australian Government Department of Health: issue 4 week, Reporting fortnight 09 May to 22 May 2022 www1.health.gov.au/internet/main/publishing.nsf/Content/0E99E97BC6C25F4ECA25884E007E4699/$File/flu-04-2022.pdf
2. ATAGI clinical advice statement on administration of seasonal influenza vaccine https://www.health.gov.au/resources/publications/atagi-advice-on-seasonal-influenza-vaccines-in-2022

Cervical screening self-collect changes

Dr Rachel Maywald

The cervical screening guidelines are changing later this year (July 2022), to make self collection of vaginal swabs, in place of the classic clinician collected cervical sample, accessible to significantly more patients.

Until now, self collection for HPV has been restricted to women and other people with a cervix who are underscreened (and who meet other specific requirements).

WHAT IS THE EVIDENCE AND WHY IS IT CHANGING?

As part of an MSAC review in 2021, the body of evidence that had been collected on the topic of self collection, indicated that there was no material difference in the diagnostic accuracy of HPV testing between self collect and clinician collected samples, provided a PCR based assay was used.

The review thus indicated that giving patients the choice in screening method was both safe and effective.

Currently, about 60% of eligible patients participate in cervical screening. The expansion of self collection is being brought in in the hope that it will improve acceptability to underscreened patients and increase uptake in the screening program.

This is important, as most people diagnosed with invasive cervical cancer belong to the group of underscreened/never screened patients.

SO WHO IS ELIGIBLE FOR SELF COLLECTION?

Any individual with a cervix who is eligible for primary cervical screening or follow up testing (after an intermediate risk result 12 months previously), will be eligible to have the choice of self collect rather than clinician collect.

WHO IS NOT ELIGIBLE?

Any individual who requires a co-test as part of their testing.

- Symptomatic patients

- Patients attending for a test of cure (after histologically confirmed HSIL)

- Patients who have had previous AIS (endocervical adenocarcinoma in situ)

- DES exposed patients

These people still require a clinician collected cervical sample as they require both HPV testing and cytology co-testing.

WHAT HAPPENS IF THE SELF COLLECTED SPECIMEN IS NOT NEGATIVE?

These patients require a further appointment, either for referral or clinician collected sample.

Thus, before a patient proceeds to a self collection, they should be counselled on this possibility. On average, in Queensland, 11% of cervical HPV tests are positive for HPV, and that should be similar for patients doing a self collected sample.

Patients with positive oncogenic HPV 16/18 are referred directly to colposcopy – they do not need to have a clinician collected sample for LBC in addition to colposcopic referral, as an LBC sample will be collected at colposcopy.

Patients with positive oncogenic HPV not 16/18 (i.e. "other"), will require the patient to return for a clinician collect sample for cytology, to triage to either colposcopy or repeat in 12 months.

It should also be noted that in studies, the invalid rate for self collected is higher than clinician collected (4.7% v 0.4% respectively).

WHERE CAN THE TEST BE TAKEN/PERFORMED?

The preferred location remains (as currently), within a clinical setting.

This does not have to be in sight of the healthcare provider, however the swab should be rinsed in ThinPrep® fluid, as soon as possible (see "taking a self collect sample" below).

The updated guidelines do offer some flexibility in this however (cervical screening recommendation 6:17), – specifically, cervical screening on a self-collected vaginal sample needs to be ordered and overseen by a healthcare professional, but collection of the sample can occur in any setting that the healthcare professional ordering the test believes is appropriate, including in the context of a telehealth consultation. The healthcare professional is not required to observe the patient collecting their sample unless this is the patient's preference.

Patients attending an in-person consultation should be encouraged to collect a sample while they are still at the clinic, as sample collection is considered more likely in this context.

CAN I TEST FOR CHLAMYDIA AND GONORRHOEA ON THE SAME SAMPLE AS THE SELF COLLECTED HPV?

No – please collect a separate specimen for these.

FURTHER INFORMATION

Lubricant should not be used. If liquid of some form is needed to help collection (commonly in atrophy), saline is the preferred solution (over distilled water).

The clinician is able to help the patient take the test as needed (clinician assisted self collect).

TAKING A SELF COLLECT SAMPLE:

For the patient (Note: there is no significant change to the patient instructions):

- Use a Copan FLOQswab® swab with breakpoint (red top).
- Insert deep into the vagina, not just the entrance.
- Move around in a circular motion for about 10 rotations, then move around other areas deep in the vagina.
- Immediately place the swab back into the container, then hand the specimen to the healthcare provider.

For the clinician:

- Slowly pull the FLOQswab® cap off to remove the swab from the tube.
- Fully immerse the tip of the swab into the solution of the ThinPrep® vial.
- Swirl the swab for 20 seconds.
- Hold the tip against the inner vial wall to drain fluid from the swab.
- Place the FLOQswab® back into the tube.
- Re-cap the ThinPrep® vial.
- Send the vial to the laboratory with a form clearly indicating **SELF COLLECT CST**.

The swab may accompany the vial, but this is not required.

Note: We will also continue to accept the DRY FLOQswab® as has been the process until now, however this is a send-away test.

HOW DO I GET A SELF COLLECT KIT?

Self collect kits can be ordered from our website, visit qml.com.au/clinicians/order-consumables.

QML Pathology

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June 2022

Urgent Communication:
Global shortage of gold and blue-topped blood collection tubes

Dear Doctor,

There is currently a global shortage of blood collection tubes which is affecting pathology providers including QML Pathology. This is caused by recent events in China and Europe.

The main tubes affected are the serum tube (gold-topped serum separator tube SST) and the navy blue-topped trace metal tube supplied by Becton Dickinson (BD).

How will this affect you?

We are evaluating tubes from 2 different manufacturers as replacements for the BD tubes.

We are conserving our current tube supply as much as possible.

Additionally we ask that if you collect blood from your own patients, please collect a **single serum tube where possible** and avoid unnecessary collection of duplicates.

Thank you for your continued support during these unprecedented times.

Kind regards,

Dr Charles Appleton
Pathologist in Charge - Biochemistry, QML Pathology

RCPA NATA

qml.com.au

Infectious Diseases Report

GEOGRAPHIC DISTRIBUTION - DEC 2021

ORGANISM	Regions (as per key below)															TOTAL		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	DEC	NOV	OCT
Adenovirus (not typed)	5	54	10	0	0	0	17	0	8	4	48	11	2	4	1	46	54	64
Adenovirus (typing pending)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Barmah Forest virus	1	3	0	1	0	0	2	0	1	4	0	3	0	0	4	8	9	2
Bordetella pertussis	0	10	4	1	0	0	2	0	7	3	20	2	2	1	1	15	23	15
Brucella species	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Campylobacter jejuni	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Chlamydia pneumoniae	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Chlamydia trachomatis, not typed	123	258	154	58	11	0	321	3	196	70	563	200	65	136	63	654	842	725
Coxiella burnetii	3	3	8	1	0	0	3	0	0	8	3	2	2	2	3	15	10	13
Cryptococcus species	0	2	1	0	0	0	1	0	0	0	1	1	0	0	1	3	2	2
Cytomegalovirus (CMV)	2	30	8	1	0	1	24	0	18	3	41	25	3	3	3	47	66	49
Entamoeba histolytica	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Enterovirus - not typed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Epstein-Barr virus (EBV)	5	50	15	5	1	0	59	0	27	4	100	50	9	7	7	97	134	108
Flavivirus unspecified	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1
Hepatitis A virus	0	2	0	0	0	0	1	0	0	0	0	0	0	0	0	1	1	1
Hepatitis B virus	11	30	25	3	1	0	57	1	9	11	158	16	6	6	7	86	137	118
Hepatitis C virus	28	81	64	14	4	1	121	0	74	18	222	59	37	29	24	193	313	270
Hepatitis D virus	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	0
Hepatitis E virus	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Herpes simplex Type 1	33	167	56	29	3	0	163	0	109	23	297	135	40	39	34	335	418	375
Herpes simplex Type 2	17	112	28	16	0	0	72	0	47	10	123	60	5	19	12	155	185	181
Herpes simplex virus - not typed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HIV-1	1	1	5	0	1	0	11	0	5	1	9	4	0	1	0	6	12	21
HTLV-1	0	1	0	0	0	0	0	6	0	0	0	1	0	0	0	0	7	1
Human Metapneumovirus	2	72	23	1	1	0	60	1	28	17	110	51	11	12	38	130	139	158
Influenza A virus	0	1	1	0	0	1	0	0	2	1	11	2	4	0	0	7	9	7
Influenza B virus	0	2	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	2
Legionella pneumophila (all serogroups)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Legionella species	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	1	1
Leptospira species	0	0	0	0	0	2	0	0	0	0	1	1	1	4	0	4	3	2
Measles virus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mumps virus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mycoplasma pneumoniae	0	12	4	1	0	0	5	0	10	3	27	4	2	4	3	22	20	33
Neisseria gonorrhoeae	11	35	27	10	2	0	51	1	18	8	103	22	9	11	0	85	107	116
Parainfluenza virus	5	39	11	4	20	0	9	0	10	13	49	35	10	11	4	42	74	104
Parvovirus	1	2	1	0	0	0	2	0	1	2	4	3	0	1	0	2	11	4
Pneumocystis carinii	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Respiratory Syncytial virus	3	4	0	4	0	0	2	0	1	2	15	2	0	0	4	24	8	5
Rhinovirus (all types)	42	557	195	14	64	0	242	1	121	76	1074	158	85	124	57	1011	1083	716
Rickettsia - Spotted Fever Group	2	2	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	3
Ross River virus	2	6	2	1	0	0	3	0	2	5	5	16	3	1	9	22	20	13
Rubella virus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Salmonella paratyphi A	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Salmonella paratyphi B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Salmonella typhi	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Streptococcus Group A	11	17	13	2	2	2	21	237	14	6	44	14	3	18	7	106	133	172
Toxoplasma gondii	0	12	1	0	0	0	7	0	9	1	10	1	3	2	5	9	22	20
Treponema pallidum	86	62	49	9	15	0	352	8	62	17	277	33	18	97	10	337	405	353
Trichomonas vaginalis	27	5	14	4	6	0	7	2	5	5	39	3	4	29	2	39	58	55
Varicella Zoster virus	31	160	69	16	2	1	152	0	123	27	304	134	38	29	32	342	392	384
Yersinia enterocolitica	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	454	1795	788	195	133	8	1767	260	908	342	3661	1050	362	590	332	3843	4707	4095

REGIONS:
1 Cairns
2 Gold Coast/Tweed
3 Ipswich
4 Mackay
5 Mount Isa
6 New England
7 North Brisbane
8 Northern Territory
9 Redcliffe
10 Rockhampton
11 South Brisbane
12 Sunshine Coast
13 Toowoomba
14 Townsville
15 Wide Bay/Burnett

Healius Pathology Pty Ltd (ABN 84 007 190 043) t/a QML Pathology PUB/MR/001_V2_Jun22