

National Bowel Cancer Screening Program – Questions and Answers (for participants)

Q1. Who is being invited:

The Program invites eligible 50-74 years olds. The following table provides further details:

| Phase | Start date | End date | Target ages |
|-------|----------------|--------------|---|
| 1 | 7 August 2006 | 30 June 2008 | 55 and 65 |
| 2 | 1 July 2008 | 30 June 2011 | 50, 55 and 65 |
| 2 | 1 July 2011 | 30 June 2013 | 50, 55 and 65 |
| 3 | 1 July 2013 | Ongoing | 50, 55, 60 and 65 |
| 4 | 1 January 2015 | | 50, 55, 60, 65, 70 and 74 |
| 4 | 1 January 2016 | | 50, 55, 60, 64, 65, 70, 72 and 74 |
| 4 | 1 January 2017 | | 50, 54, 55, 58, 60, 64, 68, 70, 72 and 74 |
| 4 | 1 January 2018 | | 50, 54, 58, 60, 62, 64, 66, 68, 70, 72 and 74 |
| 4 | 1 January 2019 | | 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72 and 74 |

In 2018, two new age cohorts (62 and 66 year olds) will commence receiving the new kit in addition to those already in the Program. In 2019, 52 and 56 year olds will be added. 55 year olds will stop receiving kits in 2018 as the Program will target everyone at a two yearly (rather than a five yearly) interval from 2020.

Q2. Why is a new kit being introduced into the Program?

Answer:

The current test kit is no longer available to the Program from January 2018 as it will cease to be produced. As such, a new test kit (the Eiken OC Sensor-Auto Sampling Bottle 3) and associated pathology service are being introduced into the Program following an open Request For Tender process managed by the Australian Government Department of Health.

Q3. Will the test be as good as the previous test?

Answer:

The Program requires a safe and effective kit with a good proven record of performance in detecting the early signs of bowel cancer. The Eiken OC Sensor-Auto Sampling Bottle 3, which will be used in the Program from 2 January 2018, has been extensively evaluated internationally and is a high performing kit. This test kit is in widespread usage around the world, including in bowel cancer screening programs in other countries, nationally and regionally. The Eiken test kit is already used widely in Australia (albeit not through the Program).

The Eiken OC Sensor-Auto Sampling Bottle 3 has been approved by the Therapeutic Goods Administration (TGA) for inclusion as an in vitro device on the Australian Register of Therapeutic Goods (ARTG).

It is included on the ARTG on the basis of the manufacturer's Instructions For Use for performance claims for sample stability as follows:

- haemoglobin recovery at seven (7) Days = $89\pm 20.5\%$; and
- haemoglobin recovery at 14 Days = $84\pm 23.6\%$.

The Program also requires that the associated pathology service is accredited by the National Association of Testing Authorities, Australia (NATA).

Q4. Is the new test kit more user-friendly than the previous one?

Answer:

A user-friendly test kit supports participation and a key focus in introducing the new kit has been to enhance its user-friendliness through simplified instructions. A focus on making the external packaging and the kit components as user-friendly as possible has been supported through focus group testing of the kit before its introduction from 2 January 2018.

In addition, during the first 12 months of implementation, continuous improvement of the test kit will remain a key area of focus, guided by evidence available through the Program and feedback from key stakeholders, including states and territories, and cancer councils.

Q5. Has the Program Information Line number changed? Who can I contact for assistance?

Answer:

No, the Program Information Line number remains the same: **1800 118 868**. The Program Information Line supports provision of Program relevant information, current and future participants with enquiries including about the Program Register, change of address for the Program, requesting a replacement test kit. The Program Information Line does not answer questions about completing the test kit or other specific questions about the test kit, such as the effectiveness of the test or the analysis process of the samples.

There is a new Sonic Test Kit Helpline for participants if they need help with completing the test and other similar inquiries - **1800 930 998** or email NBCSP_Helpline@sonichealthcare.com.au

The Test Kit Helpline is open from 7:30am to 10:00pm on business days and non-national public holidays; and 9:00am to 7:00pm on weekends. The Test Kit Helpline is not available on national public holidays.

For Dorevitch Pathology (ie enquiries regarding the 'old' kit) contact details are as follows: Ph: **1800 738 365** (Monday to Friday 9:00am to 5:00pm, Sydney time).

Q6. Will there be two pathology providers supporting the Program in 2018?

Answer:

Yes there will be two providers supporting the Program during calendar year 2018. This is because the current provider, Specialist Diagnostic Services (operating as Dorevitch Pathology), will remain in service to support the testing of any returned samples from kits that were sent out in 2017. The new provider, Sonic Healthcare, started supplying the new Eiken OC Sensor-Auto Sampling Bottle 3 test kit from 2 January 2018 and will also test completed samples returned using the new Eiken test kits.

Q7. Why does the new arrangement with Sonic require three laboratories rather than the previous one laboratory arrangement?

Answer:

- The Australian heat and distances pose unique challenges for a Program kit given that the Program uses a mail-out model.
- The new (Eiken OC Sensor-Auto Sampling Bottle 3) test kit is included on the Australian Register of Therapeutic Goods and is already used widely in Australia (albeit not through the Program).
- Multiple laboratories have been chosen to allow for timely return of samples and to minimise the distance travelled by completed samples. All correctly completed samples received will be analysed on the same day they arrive in the laboratory.
- The arrangement with Sonic includes three laboratories – in Sydney, Brisbane and Perth.
 - The Sydney and Brisbane laboratories will go live from 2 January 2018, and the Perth laboratory will go live from 12 February 2018. Any relevant samples prior to 12 February 2018 will be couriered by Sonic to its Sydney laboratory for analysis.
 - The Sydney laboratory will be the main laboratory for the Program; in addition to testing returned samples, it will also manage functions that require centralised management – for example, Program reporting, kit testing helpline and stock management.
 - A fourth laboratory is available as an option and Health and Sonic will await monitoring data post implementation to see if this is needed.

- Importantly, the three laboratories will operate virtually as one laboratory because all Sonic laboratories supporting the Program will work under a single inter-connected Laboratory Information System and Quality Management System.
- In addition to sample stability reasons, it makes good program management sense to have a viable working alternative to the main Program laboratory, given that the Program continues to grow and will be inviting 4 million people annually from 2020 with at least 2 million expected to return test kits every year.

Q8. Which of the three Sonic labs will returned samples go to?

Answer:

- Completed samples from participants in New South Wales, Australian Capital Territory, Victoria, South Australia and Tasmania will go to the Sydney lab located at: 14 Giffnock Avenue, Macquarie Park.
- Queensland and Northern Territory completed samples will go the Brisbane lab located at: 24 Hurworth Street, Bowen Hills.
- Western Australia completed samples will go to the Perth lab located at: 310 Selby Street North, Osborne Park.

Q9. I live in Sydney/Brisbane/Perth close to the Sonic laboratory – can I drop in my samples?

Answer:

Yes. While the Program pays for a reply paid sample return, if you wish to drop in your samples to the Sonic laboratory, then you can do so. Please ensure, however, that the samples are still returned in their reply paid envelope so that the laboratory can easily identify these as being from a Program participant. Also, please don't remove the samples from your fridge until just before you commence your journey, and please try and keep them cool in your car/mode of transport during the trip to the laboratory. Once at the laboratory, drop off your samples in the reply paid envelope at the reception area.

Q10. Do I need to stop taking my medication/aspirin or change my diet for the purposes of taking the test?

Answer (regardless of which test kit received):

No, you do not have to stop taking any of your usual medication before taking this test. If you have questions about your medication and completing the test please speak with your doctor.

Diet will not affect the test due to the type of testing used.

Q11. What do I do if I make a mistake when using the kit?

Answer (if Sonic test kit received):

If you need help completing the Sonic test kit, or are having trouble understanding the instructions, you can call this Sonic Test Kit Helpline on **1800 930 998**. An operator can talk you through it step by step. If you prefer to email you can do so at: NBCSP_Helpline@sonichealthcare.com.au

If you require a replacement kit this can be arranged when you call the Sonic Test Kit Helpline. You can also directly request a replacement kit by calling the Program Information Line on **1800 118 868**.

If you need help to complete the Dorevitch kit, the test kit helpline number is **1800 738 365**.