

11 DECEMBER 2020

**MEDIA STATEMENT ON HER2 TESTS INCIDENT AT
KHOO TECK PUAT HOSPITAL LABORATORY**

1. On 19 November, Khoo Teck Puat Hospital (KTPH) was informed by its Laboratory that its immunohistochemistry (IHC) Human Epidermal Growth Factor Receptor 2 (HER2) tests were producing higher-than-expected rates of positive results. Preliminary investigations by the Laboratory suggested that the incorrect staining process¹ for the test had produced inaccurate HER2 results. KTPH reported this incident to the National Healthcare Group (NHG) on 22 November, and to the Ministry of Health (MOH) on 24 November.
2. Since the issue was discovered, the hospital has investigated the extent of the issue and identified all the affected patients. Their samples, dating back to 2012 when HER2 testing first started in KTPH, have all been sent to various external laboratories to expedite re-testing for HER2.
3. As some of the re-test results return, the hospital has begun reaching out personally to patients and their treating oncologists to offer support. This process of contacting patients is still on-going. To ensure patient safety, the Laboratory has stopped in-house IHC HER2 testing.
4. NHG has convened an independent review committee, which includes external experts, to do a thorough review of how the incident occurred to improve the process and prevent recurrence of similar incidents.
5. Based on initial estimates, about 180 breast cancer patients may be re-classified from HER2 positive to HER2 negative. About half of these patients may have received unnecessary treatment for HER2, usually the drug Herceptin (Trastuzumab). Its common side-effects include diarrhoea, chills and fever. About 3 to 4 per cent of those who undergo Herceptin (Trastuzumab) treatment may also experience heart problems. The treatment regime of affected patients will be reviewed by their oncologists.

¹ In the IHC HER2 test, the tissue sample from the patient is “stained” with antibodies that have a coloured dye. These antibodies will attach themselves to HER2 proteins. A doctor (histopathologist) will then read the slide under a microscope to classify the sample.

HER2 gene and testing

6. HER2 is a gene that controls how a healthy cell grows, divides and repairs itself. A HER2 positive test result suggests that the HER2 gene is malfunctioning, making too many copies of itself, overproducing HER2 proteins and leading to uncontrolled growth of cells.
7. The IHC HER2 test is conducted on patients who have breast cancer, to classify the patient's HER2 status and help guide treatment. It does not diagnose whether a person has cancer.

Supporting our affected patients

8. "I would like to convey my deepest apologies to all the affected patients, their families and their treating oncologists. I am very sorry that they have to go through this. We will provide all the necessary support and assistance, and will do our best to take care of them," said Mrs Chew Kwee Tiang, CEO of KTPH.
9. "We treat this incident very seriously and will take all the necessary steps to ensure this does not happen again."
10. Patients who have any related queries may reach KTPH at this dedicated hotline: 6602-3333.

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