

Prenatal Diagnostic Laboratory, Tsan Yuk Hospital

Address: 30, Hospital Road, Hong Kong Tel: (852) 2589-2218 Fax: (852) 2517-2373

Down syndrome screening tests – Instructions (PRIVATE)

1. Instructions to doctors (private) prior to making test request

1.1 Pre-test explanation

Please explain to couples that the biochemical test is a **screening test**. It is not a diagnostic test. **A screen negative result does not exclude the possibility of Down syndrome because screening does not detect all affected pregnancies.**

Please refer to the following table for the detection rate (with screen positive rate of 5%).

Comparison of the detection rates (with screen positive rate of 5%) among different Down syndrome screening tests

Down syndrome screening tests	Gestational age (weeks)	Tests	Detection rate with screen positive rate of 5% (%)
Nuchal Screening	11 - 13 ⁺⁶	NT measurement	69 ^(a) – 79 ^(b)
1 st Trimester Combined Screening Test	11 - 13 ⁺⁶	NT measurement + PAPP-A + free β -hCG	Singleton pregnancies 88 ^(b)
			Twin pregnancies ^(b) Monochorionic 90 Dichorionic 79 All 81
2 nd Trimester Quadruple Screening Test	16 - 19 ⁺⁶	AFP + free β -hCG + uE3 + Inhibin A	83 ^(c)

(a) Lam YH et al. Comparison and integration of first trimester fetal nuchal translucency and second trimester maternal serum screening for fetal Down syndrome. *Prenat Diagn.* 2002 Aug;22(8):730-5.

(b) Wald NJ, Bestwick JP, Huttly WJ, et al. Prenatal screening for Down syndrome in twin pregnancies: Estimates of screening performance based on 61 affected and 7302 unaffected twin pregnancies. *Prenat Diagn.* 2018;38:1079–1085. <https://doi.org/10.1002/pd.5381>

(c) Wald NJ et al. First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS). *J Med Screen.* 2003;10(2):56-104. Erratum in: *J Med Screen.* 2006;13(1):51-2.

1.2 A trained and qualified sonographer shall obtain an operator code from PDL, TYH in order to request for Nuchal Screening and 1st Trimester Combined Screening tests which involve nuchal measurements.

Please send a copy of the 'FMF Certificate of competence in the measurement of nuchal translucency' to Scientific Officer (Tel: 2589-2327) who will assign an operator code for each operator.

(Important note: Operators are responsible to renew their FMF Certificates yearly).

2. Instructions to doctors on sending samples

- 2.1 Complete an appropriate request form as indicated in the table in Section 2.2 with the following information:
- Patient details (patient's demographics, HKID or document ID, PDC/clinic/hospital no.)
 - Referring doctor details (name of referring doctor, contact details and address for report and billing purposes)
 - Specimen details (nature of specimen, date of sampling)
 - Test(s) requested
 - Gestational weeks and EDC (by scan or by date)
 - Clinical details (information needed for examination performance and results interpretation including patient's ancestry, family history).
 - Referring doctor's / nurse's signature (it is assumed that consent of patient has been obtained by signing the request form)
 - Important note:
 - a) For assisted reproduction with embryo transfer, please indicate whether fresh or frozen embryos were transferred, and provide the date of egg collection, date of embryo transfer, and donor's date of birth or age (if applicable).
 - b) Complete the nuchal translucency measurement section including the operator code (e.g. PR01) (please refer to Section 1.2 on how to obtain an operator code).
 - c) For pregnancies with a vanishing twin, please refer to the following table for the appropriate type of Down syndrome screening test.

Gestational age (weeks)	Ultrasound scan finding of demised twin	Down syndrome screening tests
11 - 13 ⁺⁶	with fetal pole	Nuchal Screening
	with gestation sac, no fetal pole	Either Nuchal Screening or 2 nd Trimester Quadruple test preferably after 18 wk
16 - 19 ⁺⁶	with gestation sac, no fetal pole	2 nd Trimester Quadruple test preferably after 18 wk
	with fetal pole	No biochemical screening

(Spencer K et al. First trimester aneuploidy screening in the presence of a vanishing twin: implications for maternal serum markers. Prenat Diagn 2010 Mar;30(3):235-40.)

- d) The collected blood sample shall reach the laboratory within 48 hours, counting from the time of blood collection. If the sample cannot be sent to the laboratory on the day of blood collection, please keep it at the door of refrigerator (2-8°C). Samples should be delivered in a courier box/bag on ice.

2.2 Specimen specification

Collect 5 mL of peripheral blood into a serum tube (*prohibit using barrier gel tube*) labelled with at least two patient's identifiers. Cap and invert the tube well.

Request forms and specimen specification for the corresponding test as specified in the following table:

Down syndrome screening tests	Gestational age (weeks)	CRL (mm)	Specimen (volume)	Container (provided upon request)	Request form	Turn-around time
Nuchal Screening	11 - 13 ⁺⁶	42 - 83	--	--	PINK form Request form for 1 st Trimester Down Syndrome Screening PRIV (TYH-REQ-1stDS-PRIV)	2 working days
1 st Trimester Combined Screening Test	11 - 13 ⁺⁶	42 - 83	Peripheral blood (5 mL)	Serum tube*		
2 nd Trimester Quadruple Screening Test	16 - 19 ⁺⁶	--	Peripheral blood (5 mL)	Serum tube*	GREEN form Request form for 2 nd Trimester Down Syndrome Screening PRIV (TYH-REQ-2ndDS-PRIV)	3 working days

*Prohibit using barrier gel tube

2.3 Sample delivery

Courier service: Call Thunder Express Service Co. Ltd. at 2397-8781 or 2380-9122, Ms. Monica Leung on or before 11:00 am to arrange and set up specimen pick up at 12:00 noon Courier service is only available from Monday to Friday (excluding public holidays).

(Note: Please contact the laboratory to arrange specimen delivery to PDL, TYH beyond the aforementioned specimen pick up time from Monday to Friday. A special courier service fee applies).

Self drop-in: Your own personnel can bring the collected specimen to PDL, TYH within
*Specimen Reception hours: Monday to Friday: 8:45am - 4:30pm
(excluding Saturdays, Sundays and public holidays)*

3. Rejection of sample

A specimen may be rejected when the following condition is observed:

- unlabelled or incorrectly labelled specimen container
- specimen container leaks
- not suitable for analysis (e.g. frozen or grossly haemolysed, lipaemic, or icteric blood sample, using incorrect container, etc.)
- specimen cannot reach the laboratory within 48 hours after blood collection
- specimen unfit for the tests described in Section 2.1c and 2.2

In such events, you will be contacted for further actions.

4. Reporting

- Reports will be faxed and mailed to your office.
- Turn-around-time (TAT): 2 working days for Nuchal Screening and 1st Trimester Combined Screening Test
3 working days for 2nd Trimester Quadruple Screening test

(Note: After delivery of the baby or miscarriage, please complete the section of “Reply from Obstetric Units” at the bottom of the report and then return a copy of the report (by fax or by post) for auditing purpose.)

5. Payment method

- Monthly invoice will be issued from Queen Mary Hospital Finance Department, or Alternative payment method requires prior arrangement with the laboratory.

6. Address and contact information

Address: Prenatal Diagnostic Laboratory
Room 2-10, Tsan Yuk Hospital
30 Hospital Road
Sai Ying Pun, Hong Kong

Tel: 2589-2208, 2589-2288

Fax: (lab) 2857-5407, (office) 2517-2373

Website: <https://obsgyn.med.hku.hk/en/Services/Obstetrics/Maternal-Fetal-Medicine/Prenatal-Diagnosis>

Laboratory opening hours:

Monday to Friday: 8:45am - 5:30pm

(closed on Saturdays, Sundays and public holidays)

<i>Contacts:</i> Medical Technologist	Tel: 2589-2212	}	Down syndrome screening service
Senior Medical Technologist	Tel: 2589-2288		
Scientific Officer	Tel: 2589-2327 / 2589-2328		
Duty Officer / Laboratory Director	Tel: 2589-2288 / 2589-2327 Fax: 25172373	}	Other enquiry or complaint

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