1. Instructions to doctors (HA) 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

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


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)
- 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 (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.

<table>
<thead>
<tr>
<th>Gestational age (weeks)</th>
<th>Ultrasound scan finding of demised twin</th>
<th>Down syndrome screening tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 - 13\textsuperscript{6}</td>
<td>with fetal pole</td>
<td>Nuchal Screening</td>
</tr>
<tr>
<td></td>
<td>with gestation sac, no fetal pole</td>
<td>Either Nuchal Screening or 2\textsuperscript{nd} Trimester Quadruple test preferably after 18 wk</td>
</tr>
<tr>
<td>16 - 19\textsuperscript{6}</td>
<td>with gestation sac, no fetal pole</td>
<td>2\textsuperscript{nd} Trimester Quadruple test preferably after 18 wk</td>
</tr>
<tr>
<td></td>
<td>with fetal pole</td>
<td>No biochemical screening</td>
</tr>
</tbody>
</table>

(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:

<table>
<thead>
<tr>
<th>Down syndrome screening tests</th>
<th>Gestational age (weeks)</th>
<th>CRL (mm)</th>
<th>Specimen (volume)</th>
<th>Container (provided upon request)</th>
<th>Request form</th>
<th>Turn-around time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nuchal Screening</td>
<td>11 - 13\textsuperscript{6}</td>
<td>42 - 83</td>
<td>--</td>
<td>--</td>
<td>WHITE form</td>
<td>3 working days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Request form for Nuchal Screening (HA) (TYH-REQ-NUCHAL-HA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1\textsuperscript{st} Trimester Combined Screening Test</td>
<td>11 - 13\textsuperscript{6}</td>
<td>42 - 83</td>
<td>Peripheral blood (5 mL)</td>
<td>Serum tube*</td>
<td>BLUE form</td>
<td>3 working days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Request form for 1st trimester DS (HA) (TYH-REQ-1stDS-HA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2\textsuperscript{nd} Trimester Quadruple Screening Test</td>
<td>16 - 19\textsuperscript{6}</td>
<td>--</td>
<td>Peripheral blood (5 mL)</td>
<td>Serum tube*</td>
<td>YELLOW form</td>
<td>3 working days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Request form for 2nd trimester DS (HA) (TYH-REQ-2ndDS-HA)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Prohibit using barrier gel tube
2.3 Sample delivery
Samples are sent to PDL via hospital portering service. Please arrange with portering service team of the referring hospital.

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

- All reports will be sent to your office by messengers. Screen positive reports will be faxed to your office. All Down syndrome screening reports can be accessed via Electronic Patient Record (ePR).
- Turn-around-time (TAT): 3 working days

(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 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)

Contacts:  
Medical Technologist  Tel: 2589-2212  
Senior Medical Technologist  Tel: 2589-2288  
Scientific Officer  Tel: 2589-2327 / 2589-2328  
Duty Officer / Laboratory Director  Tel: 2589-2288 / 2589-2327  
Fax: 2517-2373

Down syndrome screening service
Other enquiry or complaint

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