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%).

<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>69 (a)</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>85 (b) (singleton)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>84 (b) (twin monochorionic)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>70 (b) (twin dichorionic)</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 Dr. Kelvin Chan (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 demise twin</th>
<th>Down syndrome screening tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-13⁺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 2nd Trimester Quadruple test preferably after 18 wk</td>
</tr>
<tr>
<td>16-19⁺⁶</td>
<td>with gestation sac, no fetal pole</td>
<td>2nd 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>


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 (4°C).

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>Specimen (volume)</th>
<th>Container (provided upon request)</th>
<th>Request form</th>
<th>TAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nuchal Screening</td>
<td>11-13⁺⁶</td>
<td>--</td>
<td>--</td>
<td>WHITE form</td>
<td>3 working days</td>
</tr>
<tr>
<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>1st Trimester Combined Screening Test</td>
<td>11-13⁺⁶</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>Request form for 1st trimester DS (HA) (TYH-REQ-1stDS-HA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Trimester Quadruple Screening Test</td>
<td>16-19⁺⁶</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>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: 9:00am - 4:30pm
Saturday: 9:00am - 11:30am
(excluding public holidays and Sundays)

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
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: http://www.obsgyn.hku.hk/prenatal_diagnosis

Laboratory opening hours:
Monday to Friday: 9:00am - 5:30pm
Saturday: 9:00am - 12:30pm
(closed on public holidays & Sundays)

Contacts:
Ms Sario Chan (Medical Technologist)  Tel: 2589-2282  Down syndrome screening service
Mr W.K. Tam (Senior Medical Technologist)  Tel: 2589-2288
Dr Kelvin Chan (Scientific Officer i/c)  Tel: 2589-2327  Other enquiry or complaint
Duty Officer / Laboratory Director  Tel: 2589-2288 / 2589-2327
Fax: 25172373

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