

First Trimester Interlaboratory Comparison Program (ICP) Sponsored by Women & Infants Hospital of Rhode Island

INSTRUCTIONS

The clinical history for sample **FT-11** includes CRL and NT measurements in mm for a specific sonographer (initials **FST**). An Excel file that includes a series of NT measurements from FST (along with measurements for other sonographers) is attached. That Excel file also includes the spreadsheet for calculating a median equation. A Word document that explains how to use the spreadsheet is also attached. These files can be used to calculate a median equation for **FST** (existing members have already performed this in earlier exercises). Compute the NT MoM as part of this exercise by treating it as though it were a clinical sample. Copy the NT MoM levels given in the clinical histories onto the data form. NT MoM and clinical histories are provided for samples FT-12 to FT-15 in the original format.

You should receive by two files by email

<ICP NT analyzer-Master.xls> and <ICP NT analyzer documentation-MASTER.doc>

Note: Laboratories that use free beta hCG rather than hCG in their risk algorithm have been sent a separate set of samples (some will receive both sets). Results should be entered in the appropriate boxes on the data form. Also, be sure to select the appropriate free beta method code on page three.

Confidentiality

Although ICP program personnel may have knowledge of an individual laboratory's performance, such information will remain confidential. The de-identified data will be reported to other participants in a listing of results, along with summary information. Thus, the survey is considered confidential, but not anonymous.

Testing and submitting your results

1. Samples have been frozen before shipment and should be thoroughly mixed by several inversions before assay. Store sample in refrigerator until removed for assay.
2. Ensure that your FT-ICP Laboratory Code is present on the top of each data sheet.
3. Fax pages 3 to 8 to the number provided on the bottom.
4. In any communications, please include your laboratory code.

Special computations

Gestational ages should be reported as decimal weeks (in this distribution, just enter the provided gestational age). If you commonly use weeks and days, use the following table to convert to decimal weeks, if needed.

1 day = 0.1	3 days = 0.4	5 days = 0.7
2 days = 0.3	4 days = 0.6	6 days = 0.9

Participants are provided with a gestational age (in decimal weeks) and an NT MoM. Your software may require a NT measurement and a CRL in mm to be entered directly. If this is the case, you may need to repeatedly 'guess' NT and CRL measurements until your software produces the NT MoM and gestational age provided in the clinical histories. If you have difficulty, use the contact information provided below.

Biohazard warning

All FT-ICP samples should be treated as potentially infectious and should be handled as if they are capable of transmitting disease. Some survey samples are real patient serum pools that have been tested and found negative for infectious diseases (Hep B surface antigen, Hep C antibody and HIV Ag/AB combination). Precautions described in CDC and FDA recommendations, and OSHA blood borne pathogen rules should be followed at all times when handling FT-ICP samples.

Replacement samples: If you require a replacement sample or additional samples, call (401) 453-7650 and request to speak with either Cheryl Couture or Beth Eklund. Direct comments to George Knight, Ph.D. (gknight@ipmms.org) or Glenn Palomaki, B.S. (gpalomaki@ipmms.org). Phone (207) 894-6610, FAX (207) 642-2586.

Clinical Histories

All women are assumed to be non-Hispanic Caucasian and non-diabetic with a singleton pregnancy. Additional information relating to each specimen can be found in the following table.

Specimen	DOB	Weight (lbs)	Draw date	CRL (mm)	Sono Code	NT (mm)	NT (MoM)	GA (decimal) ¹
FT-11	05/30/87	172	10/19/09	70	FST	1.4		
FT-12	08/07/85	112	10/19/09	-	-	-	1.6	13.7
FT-13	09/29/80	152	10/19/09	-	-	-	1.8	11.4
FT-14	08/10/75	109	10/19/09	-	-	-	1.6	13.4
FT-15	12/11/78	162	10/19/09	-	-	-	1.1	11.6

¹ If needed, the approximate corresponding CRLs are 75,46,72,48 mm respectively for samples FT-12 thru FT-15. The approximate gestational ages (in weeks + days) are 13+ 5, 11+ 3, 13+ 3, 11+ 4, respectively.

Method codes for pregnancy associated plasma protein-A (PAPP-A) The following table contains method codes to describe your PAPP-A test.

Code	Description	Code	Description
Be-01	Beckman Access	Pe-02	Perkin Elmer Victor
Di-01	Beckman ELISA (formerly DSL)	Dp-02	Siemens Immulite 2000 (formerly DPC)
Pe-01	Perkin Elmer DELFIA	Ot-00	Other, specify

Method codes for human chorionic gonadotropin (hCG)

The following contains the method codes to describe your hCG test.

Code	Description	Code	Description
Ba-02	Bayer ADVIA Centaur	Di-01	Beckman ELISA (formerly DSL)
Ba-05	Bayer ADVIA CP	Dp-02	Siemens Immulite 2000 (formally DPC)
Be-01	Beckman Access / Access 2	Pe-01	Perkin Elmer DELFIA
Be-02	Beckman Dxl	Ot-00	Other, specify

Method codes for free beta hCG (hCGfb)

The following contains the method codes to describe your hCGfb test.

Code	Description	Code	Description
Pe-01	Perkin Elmer DELFIA	Ot-00	Other, specify
Pe-02	Perkin Elmer Victor		

Method codes for dimeric inhibin A (DIA)

The following table contains method codes to describe your DIA test.

Code	Description	Code	Description
Di-01	Beckman ELISA (formerly DSL)	Be-02	Beckman Dxl
Be-01	Beckman Access / Access 2	Ot-00	Other, specify

First Trimester ICP Laboratory Profile

Instructions: This page should be completed at initial enrollment and whenever a change is made in any of the items (e.g., a method change, a new set of parameters, or different interpretive software)

1. PAPP-A method code: _____ (codes on previous page)

2a. hCG method code: _____ (codes on previous page)
 or

2b. free beta hCG (hCGfb) method code: _____ (codes on previous page)

3. Trimester of reported risk: First
 Second
 Term
 Unknown

4. NT medians are: Based on a single set (source: _____)
 Center-specific
 Sonographer-specific
 Combination of the above
 Unknown

5. Interpretative Software: LMS alpha
 Benetech *PRA*
 Maciel Prenatal Interpretive Software
 In-house
 Other (specify: _____)

6. Down syndrome cut-off: 1:

7. Maternal age-associated risk. Fill in the following table with the age-associated Down syndrome risk. We will assume the trimester of risk is the same as reported above (Q 3).

Maternal Age	DS Risk (1:n)
20.5	
25.5	
30.5	
35.5	
40.5	
45.5	

8. Age-associated risk from: Cuckle *et al.*, Br J Obstet Gynaecol. 1987;94:387-402.
 Hecht & Hook, Am J Med Genet. 1996;62:376-85.
 Morris *et al.*, Prenat Diagn. 2003;23:252-8
 Other (specify _____)
 Unknown

9. Other biochemical marker(s) you would like included in the FT survey _____

Specimen FT-11 (or FT-11fb)

Patient data

Gestational Age		Maternal Age		NT MoM
Decimal	Integer	Decimal	Integer	
<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>

Assay and interpretive results

PAPP-A (circle units)		hCG	hCGfb (circle units)	
mIU/mL or ng/mL	MoM	IU/mL	MoM	ng/mL, mIU/mL
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>

Down syndrome risk, interpretation and action

Down syndrome risk	Interpretation	Action
1: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="radio"/> screen negative	<input type="radio"/> no further action
<input type="text"/> if < than	<input type="radio"/> screen positive	<input type="radio"/> US /counsel for amnio/CVS
<input type="text"/> if > than	<input type="radio"/> uninterpretable	<input type="radio"/> collect new sample & retest
	<input type="radio"/> unknown/other	<input type="radio"/> decision made by physician
		<input type="radio"/> unknown/other

Specimen FT-12 (or FT-12fb)

Patient data

Gestational Age		Maternal Age		NT MoM
Decimal	Integer	Decimal	Integer	
<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>

Assay and interpretive results

PAPP-A (circle units)		hCG	hCGfb (circle units)	
mIU/mL or ng/mL	MoM	IU/mL	MoM	ng/mL, mIU/mL
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>

Down syndrome risk, interpretation and action

Down syndrome risk	Interpretation	Action
1: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="radio"/> screen negative	<input type="radio"/> no further action
<input type="text"/> if < than	<input type="radio"/> screen positive	<input type="radio"/> US /counsel for amnio/CVS
<input type="text"/> if > than	<input type="radio"/> uninterpretable	<input type="radio"/> collect new sample & retest
	<input type="radio"/> unknown/other	<input type="radio"/> decision made by physician
		<input type="radio"/> unknown/other

Specimen FT-13 (or FT-13fb)

Patient data

Gestational Age		Maternal Age		NT MoM
Decimal	Integer	Decimal	Integer	
<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>

Assay and interpretive results

PAPP-A (circle units)		hCG	hCGfb (circle units)	
mIU/mL or ng/mL	MoM	IU/mL	MoM	ng/mL, mIU/mL
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>

Down syndrome risk, interpretation and action

Down syndrome risk	Interpretation	Action
1: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="radio"/> screen negative	<input type="radio"/> no further action
<input type="text"/> if < than	<input type="radio"/> screen positive	<input type="radio"/> US /counsel for amnio/CVS
<input type="text"/> if > than	<input type="radio"/> uninterpretable	<input type="radio"/> collect new sample & retest
	<input type="radio"/> unknown/other	<input type="radio"/> decision made by physician
		<input type="radio"/> unknown/other

Specimen FT-14(or FT-14fb)

Patient data

Gestational Age		Maternal Age		NT MoM
Decimal	Integer	Decimal	Integer	
<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>

Assay and interpretive results

PAPP-A (circle units)		hCG	hCGfb (circle units)	
mIU/mL or ng/mL	MoM	IU/mL	MoM	ng/mL, mIU/mL
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>

Down syndrome risk, interpretation and action

Down syndrome risk	Interpretation	Action
1: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="radio"/> screen negative	<input type="radio"/> no further action
<input type="text"/> if < than	<input type="radio"/> screen positive	<input type="radio"/> US /counsel for amnio/CVS
<input type="text"/> if > than	<input type="radio"/> uninterpretable	<input type="radio"/> collect new sample & retest
	<input type="radio"/> unknown/other	<input type="radio"/> decision made by physician
		<input type="radio"/> unknown/other

Specimen FT-15 (or FT-15fb)

Patient data

Gestational Age Maternal Age NT MoM

Decimal Integer Decimal Integer

. . .

Assay and interpretive results

PAPP-A (circle units) **hCG** **hCGfb** (circle units)

mIU/mL or ng/mL MoM IU/mL MoM ng/mL, mIU/mL MoM

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Down syndrome risk, interpretation and action

Down syndrome risk Interpretation Action

1: screen negative no further action

if < than if > than screen positive US /counsel for amnio/CVS

if < than if > than uninterpretable collect new sample & retest

if < than if > than unknown/other decision made by physician

if < than if > than unknown/other unknown/other

Dimeric Inhibin-A Measurements

If your laboratory measures DIA in the first trimester, complete the following:

- Our Inhibin method code is (see page 2): _____
- Fill in the following table

Sample	Dimeric Inhibin-A (DIA)		Marker Combination ²	DS Risk
	Value ¹	MoM		
FT-11				
FT-12				
FT-13				
FT-14				
FT-15				

¹ Assumes the units are pg/mL. If this is not correct, enter units here: _____.

² If marker combination is maternal age with NT, hCG, PAPP-A and inhibin, leave column blank. Otherwise, enter the combination of markers used with DIA: _____.

Supplemental Questions: Epidemiological Monitoring for First Trimester Combined Testing

Please fill in as much information as available

Q1. Does your laboratory provide clinical results for first trimester Down syndrome screening?

- Yes (continue with Question 2)
- No (go to Question 12)

Q2. What is your first trimester risk cut-off ?

1 :

Q3. What trimester of risk is your risk cut-off?

- first
- second
- third

Q4. What percent of your women are screen positive (risk at or above the risk cut-off) ?

. %

Q5. What percent of your population is age 35 or older at EDC?

. %

Q6. Do you monitor the median MoM for each of the serum analytes used for screening?

- Yes (continue with Question 7)
- No (go to the Integrated Test Exercise below)

Q7. If yes, provide the recent median MoM for each analyte used (and time interval monitored, if available)

	Median MoM	Time interval (months)
PAPP-A	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>
hCG (1 st T)	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>
free beta hCG	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>
Inhibin A	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>

Integrated Test Exercise

The following exercise will evaluate the laboratory’s ability to report integrated risks by combining data from specimen **FT-12** (this **ICP FT-C 2009** survey) with data from specimen **FP-19** (the **CAP FP-C 2009** survey). Responses from a previous ICP survey indicated that most labs report integrated risks using second trimester quadruple test results. If your lab uses the triple test rather than the quad test report your results but note next to the risk that triple test results were used in the calculation.

Q8. Does your laboratory perform integrated risk interpretations?

- Yes, as part of a formal integrated screening program (continue with Question 7)
- Yes, but only upon request (continue with Question 7)
- No (skip to Question 10)

Q9. Please report the following quad risk for FP-19 from the CAP FP-C 2009 survey.

1 : risk based on quad markers [] second trimester risk [] term risk

To complete the integrated portion of this exercise, follow these directions:

- A. Assume that sample **FT-12** was received as the first part of an integrated test request but change the draw date of the sample to **08/04/09** (it was given as 10/19/09 in the histories on page 2).
- B. Assume that sample **FP-19** distributed in the CAP FP-C 2009 survey is the second part of the integrated test request. Use the clinical history and chemistry results that you obtained on FP-19 with no changes. Note that FP-19 is identified as coming from an Asian women. **Incorporate this information (or not) into your risk calculations exactly as you routinely do in your screening program.**

Q10. Report the following risk(s) from the integrated test using the modified information from the FT-C survey and data from the CAP FP-C 2009 survey (complete both if possible, even if that combination is not usually reported clinically).

Laboratories using PAPP-A and quadruple markers (with and without NT)

1 : full integrated risk (including NT) [] second trimester risk [] term risk

1 : serum integrated risk (excluding NT) [] second trimester risk [] term risk

Q11. Do you use the same parameters for the second trimester markers (e.g., uE3) for both the quadruple test and the integrated test (e.g., are the log mean and standard deviation for uE3 in Down syndrome pregnancies the same)?

[] Yes [] No [] Don't know

Q12. Comments (e.g., improvements, deficiencies, future supplemental topics)

Testing Personnel signature _____ Date _____

Testing Personnel signature _____ Date _____

Laboratory Director's Signature _____ Date _____